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As filed with the Securities and Exchange Commission on May 31, 2007

Registration No. 333 -141164

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 5
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

JAZZ PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**05-0563787**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

3180 Porter Drive
Palo Alto, CA 94304
(650) 496-3777
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Samuel R. Saks, M.D.
Chief Executive Officer
3180 Porter Drive
Palo Alto, CA 94304
(650) 496-3777
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Suzanne Sawochka Hooper, Esq. **John M. Geschke, Esq.** **Cooley Godward Kronish LLP** **Five Palo Alto Square** **3000 El Camino Real** **Palo Alto, CA 94306-2155** **(650) 843-5000**	**Carol A. Gamble, Esq.** **Philip J. Honerkamp, Esq.** **Jazz Pharmaceuticals, Inc.** **3180 Porter Drive** **Palo Alto, CA 94304** **(650) 496-3777**	**Bruce K. Dallas, Esq.** **Davis Polk & Wardwell** **1600 El Camino Real** **Menlo Park, CA 94025** **(650) 752-2000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)
Issued May 31, 2007

6,000,000 Shares

COMMON STOCK

Jazz Pharmaceuticals, Inc. is offering 6,000,000 shares of its common stock. This is our initial public offering and no public market exists for our shares. We anticipate that the initial public offering price will be between $20.00 and $21.00 per share.

We have applied to have our common stock listed on the NASDAQ Global Market under the symbol "JAZZ".

Investing in the common stock involves risks. See " Risk Factors" beginning on page 9.

PRICE $ A SHARE

	Price to Public	*Underwriting Discounts and Commissions*	*Proceeds to Jazz Pharmaceuticals*
Per Share	*$*	*$*	*$*
Total	*$*	*$*	*$*

We have granted the underwriters the right to purchase up to an additional 900,000 shares of common stock to cover over-allotments.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on , 2007.

MORGAN STANLEY *LEHMAN BROTHERS*

CREDIT SUISSE

NATEXIS BLEICHROEDER INC.

, 2007

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You should rely only on the information contained in this prospectus or any related free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any related free writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any related free writing prospectus is accurate only as of its date, regardless of its time of delivery, or of any sale of the common stock. Our business, financial conditions, results of operations and prospects may have changed since that date.

Through and including , 2007 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside of the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere in this prospectus. This summary highlights what we believe is the most important information about us and this offering. Before you decide to invest in our common stock, you should read the entire prospectus carefully, including the "Risk Factors" section and the financial statements and related notes included in this prospectus.

JAZZ PHARMACEUTICALS, INC.

Corporate Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development and acquisition and in-licensing activities and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies available from third parties, we also explore potential new indications for known drug compounds. Since our inception in 2003, our experienced executive management team has built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of $41.9 million in 2006, one product candidate for which an approvable letter has been issued by the U.S. Food and Drug Administration, or FDA, and five product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our marketed products and late-stage product candidates are:

- *Xyrem (sodium oxybate) oral solution*. Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain's inability to regulate sleep-wake cycles normally. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. Cataplexy, the sudden loss of muscle tone, is the most well-recognized symptom of narcolepsy. Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our 55 person specialty sales force. We have significantly increased domestic net product sales of Xyrem since our acquisition of Orphan Medical, Inc. in June 2005. Our net product sales of Xyrem were $29.0 million in 2006 and $8.6 million in the first quarter of 2007. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB has commercially launched Xyrem in 12 countries.
- *Antizol (fomepizole)*. Antizol is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. Our net product sales of Antizol were $12.5 million in 2006 and $2.6 million in the first quarter of 2007. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected

or confirmed ethylene glycol poisonings in dogs. Net product sales of Antizol-Vet were $313,000 in 2006 and $65,000 in the first quarter of 2007.

- *Luvox CR (fluvoxamine maleate extended release capsules).* Our most advanced product candidate is Luvox CR, an extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, which has been developed for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are a class of antidepressants used in the treatment of depression, anxiety disorders and some personality disorders. According to the National Institute of Mental Health, obsessive compulsive disorder and social anxiety disorder affect approximately 2.2 million and 15 million adults in the United States, respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. In addition, Solvay has assigned to us its rights and obligations under its license and supply agreement with Elan. Under this agreement, Elan has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. Under the terms of our license agreement with Solvay, we made an initial payment to Solvay, and we are required to make additional payments to Solvay if various development and commercial milestones are achieved. We have also agreed to pay royalties to Solvay at specified rates based on net product sales and to pay to Elan development and commercial milestone payments, royalties on net product sales and supply price payments for the supply of Luvox CR.

  Solvay submitted a new drug application, or NDA, to the FDA for Luvox CR in April 2006, and, in February 2007, the FDA issued an approvable letter to Solvay. The requirements set forth in the approvable letter include the completion of certain toxicology studies on the impurities that are generated by fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR, the submission of additional information relating to the chemistry, manufacturing and controls section of the NDA and the re-analysis by Solvay of certain data set forth in the NDA. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA for Luvox CR. Subject to the satisfaction of the requirements set forth in the approvable letter and receipt of FDA approval, we expect to commence promotion of Luvox CR in the United States in the first quarter of 2008 through a significantly expanded specialty sales force. During 2007, we expect to make significant expenditures relating to the planned commercial launch of Luvox CR.
- *JZP-6 (sodium oxybate).* We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia syndrome. Fibromyalgia syndrome is a chronic pain condition that affects between two and four percent of the U.S. population, according to the American College of Rheumatology. There are currently no products approved by the FDA for the treatment of fibromyalgia syndrome. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia syndrome. We are currently conducting two Phase III pivotal clinical trials, and we expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

In addition to our product candidates in late-stage development, our clinical development pipeline consists of the following product candidates:

- *JZP-4 (type IIa sodium channel antagonist).* JZP-4, a controlled release formulation of an anticonvulsant that is in the same chemical class as Lamictal (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline, is being developed for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy and, according to the National Institute of Mental Health, approximately 5.7 million

people in the United States are affected by bipolar disorder. We have planned two proof of concept clinical trials designed to provide evidence of therapeutic activity of JZP-4. A proof of concept study is performed in a small group of subjects to test whether a product candidate is likely to have the desired therapeutic effect. The results from the first proof of concept clinical trial indicate potential central nervous system activity of JZP-4, and the second proof of concept clinical trial is expected to commence in the third quarter of 2007. Subject to satisfactory results from the second proof of concept clinical trial, long-term toxicology studies, formulation studies and certain drug-drug interaction studies, we plan to commence a Phase II clinical trial of JZP-4 for the treatment of epilepsy beginning in the fourth quarter of 2007.

- *JZP-8 (benzodiazepine).* JZP-8, a novel formulation incorporating a benzodiazepine, is being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who have been unresponsive to previous treatments. Recurrent acute repetitive seizures are bouts of multiple seizures occurring over a short period of time. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are unresponsive, or refractory, to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures. We have completed development activities to select the active pharmaceutical ingredient for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We plan to commence a Phase II clinical trial of JZP-8 for the treatment of recurrent acute repetitive seizures in refractory epilepsy patients in the fourth quarter of 2007.
- *JZP-7 (dopamine agonist).* JZP-7, a novel formulation incorporating a dopamine agonist, is being developed for the treatment of restless legs syndrome. Dopamine is naturally produced by the human body, and in the brain, dopamine functions to help nerve cells communicate. A dopamine agonist is a drug compound that mimics the effects of dopamine. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome. We have completed development activities to select the active pharmaceutical ingredient for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We intend to conduct an additional pharmacokinetic study, or a study designed to assess how the body processes a drug once the drug is delivered to the body, in 2007 prior to commencing Phase II clinical trials for the treatment of restless legs syndrome.
- *JZP-2 (benzodiazepine).* JZP-2, a formulation of a benzodiazepine that is designed to enter the bloodstream faster than a dose from a conventional tablet form, is being developed for the acute, or short-term, treatment of panic attacks associated with panic disorder. Benzodiazepines are a class of psychoactive drugs with varying hypnotic, sedative, anti-anxiety, anticonvulsant, muscle relaxant and amnesic properties. According to the National Institute of Mental Health, approximately six million people in the United States suffer from panic disorder in any given year. We have developed a target formulation for JZP-2 and plan to commence one or more clinical trials of JZP-2 with this formulation in 2007.

We have an ongoing program for generating, identifying and conducting feasibility studies for new product candidates. Our JZP-2, JZP-7 and JZP-8 product candidates resulted from this program. Several other product candidates identified through this program are in various stages of early development, including the use of sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of movement disorders. We are working on ways to expand our Xyrem franchise by developing improvements to Xyrem, such as new dosage forms that could be more convenient for patients. These activities are in the early stages of development.

Our executive management team has substantial experience in developing and commercializing novel therapeutic products. During their time working together as part of the executive management team at ALZA Corporation, a pharmaceutical company acquired by Johnson & Johnson in 2001, our executive management team participated in the successful development and commercialization of a broad portfolio of products and product candidates to address specialized markets.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry and, over the longer term, in additional specialty therapeutic areas. Key elements of our strategy to achieve this goal include:

- focusing on specialty markets, particularly neurology and psychiatry, in which a relatively small number of healthcare providers write a large percentage of prescriptions for the indications we target;
- expanding and leveraging our U.S. specialty sales force to promote our growing portfolio of commercial products;
- mitigating risks and reducing the costs and time associated with the development and commercialization of our products by focusing on known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, and structuring our development and commercial relationships to minimize financial risk;
- expanding our portfolio to include additional products and product candidates that we believe have significant commercial potential through our internal research and development efforts and our acquisition and in-licensing activities; and
- leveraging the expertise of our experienced executive management team in developing and commercializing novel therapeutic products.

Risks Associated with Our Business

We are a specialty pharmaceutical company with historical net operating losses, and our operations to date have generated substantial and increasing needs for cash. Our business and our ability to execute on our business strategy are subject to many risks that you should be aware of before you decide to buy our common stock. These risks are discussed more fully in “Risk Factors” beginning on page 9. For example:

- Our clinical trials may fail to adequately demonstrate the safety and effectiveness of our product candidates. If a product candidate fails at any stage of development, we will not have the anticipated revenues from that product candidate to fund our operations, and we will not receive any return on our investment in that product candidate.
- The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining regulatory approvals for the commercialization of some or all of our product candidates. If we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.
- Even if approved for sale by the appropriate regulatory authorities, our products may not achieve market acceptance. Market acceptance is dependent upon, among other things, the availability of adequate reimbursement by third parties and acceptance by physicians and patients of each of our products as a safe and effective treatment.
- We face competition from both generic and branded pharmaceutical products and if we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to other therapies, we may not generate meaningful revenues from sales of our products.
- Our ability to grow our business is dependent on our ability to successfully develop, acquire or in-license new products and product candidates.

- From our inception in 2003 through March 31, 2007, we incurred net losses of $191.5 million, and we expect to continue to incur net losses for the next several years. We are unable to predict with certainty the extent of any future losses or when we will become profitable. We will also need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, if at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations.

Corporate Information

We were incorporated in California in March 2003, and we reincorporated in Delaware in January 2004. Our principal executive office is located at 3180 Porter Drive, Palo Alto, California 94304. Our telephone number is (650) 496-3777. Our website address is www.jazzpharmaceuticals.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

Unless the context indicates otherwise, as used in this prospectus, the terms “Jazz Pharmaceuticals,” “we,” “us” and “our” refer to Jazz Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries. We use Jazz Pharmaceuticals™, Xyrem®, Antizol®, Luvox® and the Jazz Pharmaceuticals logo as trademarks in the United States and other countries. We have licensed the right to use the registered trademarks Antizol® from Mericon Investment Group, Inc. and Luvox® from Solvay Pharmaceuticals, Inc. All other trademarks or trade names referred to in this prospectus are the property of their respective owners.

Market Data

This prospectus contains market data and industry forecasts that were obtained from industry publications. We have not independently verified any of this information.

THE OFFERING

Common stock offered by us	6,000,000 shares
Common stock outstanding after this offering	24,550,554 shares
Over-allotment option	900,000 shares
Use of proceeds	We expect to use the net proceeds from this offering (1) to fund activities and make milestone payments related to the planned U.S. launch and commercialization of Luvox CR and (2) to continue to fund our Phase III pivotal clinical trials of JZP-6. See “Use of Proceeds.”
Proposed NASDAQ Global Market symbol	JAZZ

The number of shares of common stock outstanding immediately after this offering is based on 18,550,554 shares of common stock outstanding as of March 31, 2007. This number excludes:

- 1,862,530 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2007, having a weighted average exercise price of $21.34 per share;
- 215,792 shares of common stock reserved for future issuance under our 2003 Equity Incentive Plan as of March 31, 2007; provided, however, that immediately upon the signing of the underwriting agreement for this offering, our 2003 Equity Incentive Plan will terminate so that no further awards may be granted under our 2003 Equity Incentive Plan;
- an aggregate of up to 5,175,042 shares of common stock reserved for future issuance under our 2007 Equity Incentive Plan, 2007 Non-Employee Directors Stock Option Plan and 2007 Employee Stock Purchase Plan, each of which will become effective immediately upon the signing of the underwriting agreement for this offering; and
- 785,728 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2007, having an exercise price of $20.36 per share.

Except as otherwise indicated, all information in this prospectus assumes:

- the conversion of all our outstanding shares of preferred stock into 17,921,551 shares of common stock immediately prior to the closing of this offering;
- the filing of our fourth amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering; and
- no exercise of the underwriters’ over-allotment option.

We completed a 1-for-11.06701 reverse stock split of our common stock and preferred stock on May 15, 2007. All share and per share amounts have been retroactively adjusted to give effect to this stock split.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our financial data. We have derived the following summary of our consolidated statements of operations data for the years ended December 31, 2004, 2005 and 2006 from our audited consolidated financial statements appearing elsewhere in this prospectus. The summary of our consolidated statements of operations data for the three months ended March 31, 2006 and 2007, and the consolidated balance sheet data as of March 31, 2007, have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus, which in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly our financial position and results of operations. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary of our financial data set forth below should be read together with our consolidated financial statements and the related notes to those statements, as well as "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," appearing elsewhere in this prospectus. The pro forma balance sheet data give effect to the conversion of all outstanding shares of convertible preferred stock into common stock immediately prior to the closing of this offering. The pro forma as adjusted balance sheet data give effect to the conversion of all outstanding shares of convertible preferred stock into common stock immediately prior to the closing of this offering, and to reflect the sale of shares of our common stock in this offering at an assumed initial public offering price of $20.50 per share, the mid-point of the range reflected on the cover page on this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005(1)	2006	2006	2007
				(Unaudited)	
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net	$ —	$ 18,796	$ 43,299	$ 9,771	$ 11,625
Royalties, net	—	146	594	66	211
Contract revenue	—	2,500	963	—	2,252
Total revenues	—	21,442	44,856	9,837	14,088
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technology)	—	4,292	6,968	1,569	2,003
Research and development	17,988	45,783	54,956	12,894	14,867
Selling, general and administrative	7,459	23,551	51,384	12,219	14,339
Amortization of intangible assets	—	4,960	9,600	2,400	2,362
Purchased in-process research and development	—	21,300	—	—	—
Total operating expenses	25,447	99,886	122,908	29,082	33,571
Loss from operations	(25,447)	(78,444)	(78,052)	(19,245)	(19,483)
Interest income	643	1,318	2,307	581	1,091
Interest expense (including $4,595 and $9,024 for the years ended December 31, 2005 and 2006, respectively, and $2,185 and $2,254 for the three months ended March 31, 2006 and 2007, respectively, pertaining to related parties)	—	(7,129)	(14,129)	(3,777)	(3,268)
Other income (expense)	—	(901)	(1,109)	62	(3,069)
Gain on extinguishment of development financing obligation	—	—	31,592	—	—
Gain on sale of product rights	—	—	—	—	5,145
Net loss	(24,804)	(85,156)	(59,391)	(22,379)	(19,584)
Beneficial conversion feature	—	—	(21,920)	(3,501)	—
Loss attributable to common stockholders	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$ (19,584)
Loss per share attributable to common stockholders, basic and diluted	$(1,550.25)	$(14,192.67)	$(6,254.69)	$ (2,875.56)	$ (851.48)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	16	6	13	9	23
Pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted(2)			$ (6.04)		$ (1.11)
Weighted-average common shares used in computing pro forma loss per share attributable to common stockholders (unaudited), basic and diluted(2)			13,466		17,666

	As of March 31, 2007		
	Actual	Pro Forma (Unaudited)	Pro Forma As Adjusted(3)
	(In thousands, except per share data)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 67,667	$ 67,667	$ 179,757
Working capital	46,673	58,261	170,351
Total assets	197,910	197,910	310,000
Senior secured notes (including $52,100 as of March 31, 2007 (unaudited), held by related parties)	74,429	74,429	74,429
Convertible preferred stock	263,852	—	—
Common stock subject to repurchase	8,749	12,954	12,954
Accumulated deficit	(197,227)	(197,227)	(197,227)
Total stockholders' equity (deficit)	(195,420)	75,815	187,905

(1) We acquired Orphan Medical on June 24, 2005, and the results of Orphan Medical are included in the consolidated financial statements from that date.
(2) Assumes the conversion of all outstanding shares of convertible preferred stock outstanding as of December 31, 2006 and March 31, 2007, as applicable, into common stock.
(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $20.50 per share, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $5.6 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of one million shares in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately $19.1 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

RISK FACTORS

You should carefully consider the risks described below, which we believe are the material risks of our business and this offering, before making an investment decision. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this prospectus, including our financial statements and related notes.

Risks Related to Our Business

The FDA may not approve Luvox CR for marketing in the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR and Luvox in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox CR was developed by Solvay in collaboration with Elan Pharma International Limited. In December 2000, Solvay submitted an NDA to the FDA for Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder. In June 2001, as a result of challenges related to Elan's scale-up of the process to manufacture commercial quantities of Luvox CR, Solvay and Elan mutually agreed to withdraw the NDA for Luvox CR. In April 2006, Solvay resubmitted the Luvox CR NDA to the FDA, requesting approval to market the product for the treatment of obsessive compulsive disorder and social anxiety disorder. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA. In February 2007, the FDA issued an approvable letter to Solvay. The requirements set forth in the approvable letter include the completion of certain toxicology studies on the impurities that are generated by fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR, the submission of additional information relating to the chemistry, manufacturing and controls section of the NDA and the re-analysis by Solvay of certain data set forth in the NDA. Solvay must satisfy the conditions set forth in the letter in order to obtain FDA approval. If Solvay is unable to meet these conditions, or for other reasons, the FDA may not approve Luvox CR for marketing in the United States or the approval could be delayed.

Under the terms of our license agreement with Solvay, we made an initial payment of $2.0 million to Solvay. Although it is still uncertain when, or if, Luvox CR will be approved by the FDA, we intend to significantly expand our sales force, marketing and commercial operations departments and administrative staff in 2007 in anticipation of the commercial launch of Luvox CR. In addition, we have engaged numerous third party vendors, such as contract manufacturers, advertising agencies, market research firms and other service providers, to assist in the anticipated launch of Luvox CR, including Elan, who will manufacture quantities of Luvox CR sufficient for commercial launch. These expenses are significant and must be incurred prior to the approval of Luvox CR in order for us to be prepared to launch the product as soon as possible following approval. The costs cannot be recouped or applied to other products if the FDA does not approve Luvox CR. In addition, the failure to obtain FDA approval for Luvox CR would result in the loss of a major source of potential near-term revenue for us and postpone the time at which we could become profitable.

Our only product candidate currently in Phase III clinical trials is JZP-6 for the treatment of fibromyalgia syndrome. The Phase III clinical trials may not show JZP-6 to be safe and effective for the treatment of fibromyalgia syndrome or the FDA may not otherwise approve JZP-6 for marketing, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are currently conducting two Phase III pivotal clinical trials for the use of JZP-6 to treat fibromyalgia syndrome, both of which must have statistically significant positive results before we can submit an NDA to the FDA seeking approval of JZP-6 for the treatment of fibromyalgia syndrome. Our Phase III clinical program for

JZP-6 is costly, and we do not expect to complete the program until early 2009. We do not know if our ongoing Phase III pivotal clinical trials will show JZP-6 to be safe and effective for the treatment of fibromyalgia syndrome, or if the FDA or other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia syndrome. Favorable results from our prior Phase II clinical trials with JZP-6 for the treatment of fibromyalgia syndrome may not be indicative of the clinical results from our Phase III pivotal clinical trials. Further, although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy, this does not assure approval by the FDA, or any other regulatory authorities, of this active pharmaceutical ingredient for the treatment of fibromyalgia syndrome. Unsuccessful Phase III pivotal clinical trials or a failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia syndrome could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Even if the FDA approves JZP-6 for the treatment of fibromyalgia syndrome, the FDA is likely to require us to have a risk management program similar to the one we use for Xyrem. Under the Xyrem risk management program, Xyrem must be distributed through a single central pharmacy. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy must verify the prescription and obtain additional information by contacting the physician's office and the patient's insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign for the package. The initial shipment may only be for a one-month supply, and patients may not receive more than a three-month supply at any time.

The Xyrem risk management program is labor intensive, complex and expensive to operate. Since Xyrem is currently prescribed for a relatively small number of patients, the risk management program does not prevent us from effectively supplying Xyrem to narcolepsy patients. However, significantly more patients are diagnosed with fibromyalgia syndrome, and if the same or a similar risk management program is required for JZP-6, scale-up of the risk management program could make it difficult for us to timely supply all of the patients who may be prescribed JZP-6 for the treatment of fibromyalgia syndrome. This could make JZP-6 less attractive to physicians and patients than other products that may be approved for the treatment of fibromyalgia syndrome, which could limit potential sales of JZP-6.

Many of our product candidates are in preclinical or early-stage clinical development. A failure to prove that our product candidates are safe and effective in clinical trials would require us to discontinue their development, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Significant additional research and development, financial resources and additional personnel will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. As a condition to regulatory approval, each product candidate must undergo extensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The clinical trials for a product candidate can cost between $40.0 million and $100.0 million, and potentially even more. If a product candidate fails at any stage of development, we will not have the anticipated revenues from that product candidate to fund our operations, and we will not receive any return on our investment in that product candidate. For example, our Phase III clinical trial of JZP-3, a product candidate for the treatment of general anxiety disorder, was not successful after we incurred significant development costs, and we ceased further development of JZP-3.

Clinical testing can take many years to complete, and failure can occur any time during the clinical trial process. In addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced

clinical trials after showing positive results in earlier clinical trials. The completion of clinical trials for our product candidates may be delayed or halted for many reasons, including:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- regulators or institutional review boards may not authorize us to commence or continue a clinical trial;
- our inability, or the inability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials;
- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;
- difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, including adverse events associated with product candidates;
- the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;
- governmental or regulatory delays or changes in regulatory requirements, policy and guidelines; and
- varying interpretation of data by the FDA or foreign regulatory agencies.

In addition, our product candidates are subject to competition for clinical study sites and patients from other therapies under development that may delay the enrollment in or initiation of our clinical trials. For example, other companies have stated publicly that they are testing product candidates for the treatment of fibromyalgia syndrome. Some of these companies have more significant financial and human resources than we do.

The FDA or foreign regulatory authorities may require us to conduct unanticipated additional clinical trials, which could result in additional expense and delays in bringing our product candidates to market. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We rely on third parties to conduct clinical trials for our product candidates, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We design the clinical trials for our product candidates, but rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays.

Although we rely on third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. The FDA enforces good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our contract research organizations or our study sites fail to comply with applicable good clinical practices, the clinical data

generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's current Good Manufacturing Practices, or cGMP, regulations. Our failure, or the failure of our contract manufacturers, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates.

The commercial success of our products will depend upon attaining market acceptance by physicians, patients, third party payors and the medical community.

Even if our product candidates are approved for sale by the appropriate regulatory authorities, physicians may not prescribe our products, in which case we would not generate the revenues we anticipate. Market acceptance of any our products by physicians, patients, third party payors and the medical community will depend on:

- the clinical indications for which a product is approved;
- prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and
- the availability of adequate reimbursement by third parties.

We depend upon UCB to market and promote Xyrem outside of the United States, and we are dependent upon our collaboration with UCB for the development and potential commercialization of JZP-6 for the treatment of fibromyalgia syndrome in major markets outside of the United States.

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the United States. If UCB does not obtain regulatory approvals for and launch Xyrem in its licensed countries in the time frames that we expect, or at all, our revenues would be adversely affected. If UCB terminates its relationship with us, we would need to find another party or parties to commercialize Xyrem in UCB's licensed territories. We may be unable to find another party or parties on acceptable terms, or at all, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, under the terms of our collaboration with UCB, we granted UCB the exclusive right to commercialize JZP-6 for the treatment of fibromyalgia syndrome in the same territories that UCB has the right to market and promote Xyrem for patients with narcolepsy. We have relied and will continue to rely in part on milestone payments from UCB to reduce our development costs of JZP-6. UCB has the right to terminate our collaboration on 18 months' notice (or less in certain circumstances). If UCB terminates our collaboration, we would need to find another party or parties to commercialize JZP-6 in UCB's territories and may need to execute alternative

financing plans to help fund our development of JZP-6. We may be unable to do either of these on acceptable terms, or at all.

We depend on one central pharmacy distributor for Xyrem sales in the United States and the loss of that distributor or its failure to distribute Xyrem effectively would adversely affect sales of Xyrem.

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the United States must be shipped directly to patients through a central pharmacy. The process under which patients receive Xyrem under our risk management program is cumbersome. While we have entered into an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, Inc., if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem, and our sales, would be adversely affected. Changing central pharmacy distributors could take a significant amount of time and require FDA approval of the new central pharmacy distributor. In addition, sodium oxybate, the active pharmaceutical ingredient in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. The new distributor would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute Xyrem, including the risk management program approved by the FDA. If we change distributors, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new distributor could result in product shortages, which would adversely affect sales of Xyrem in the United States.

Our supplier of the active pharmaceutical ingredient and our product manufacturer must obtain DEA quotas in order to supply us with Xyrem, JZP-6 and sodium oxybate, and these quotas may not be sufficient to satisfy our clinical and commercial needs.

The DEA limits the quantity of certain Schedule I and II controlled substances that may be produced in the United States in any given calendar year through a quota system. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient and our product manufacturer must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our supplier's and contract manufacturer's DEA quotas, our supplier and contract manufacturer would need quota increases from the DEA, which would be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. In cooperation with our manufacturing partners, we are seeking to significantly increase their 2007 quotas from the DEA for sodium oxybate, Xyrem and JZP-6 to satisfy the forecasted demand for Xyrem and to conduct our clinical studies of JZP-6. In the future, we intend to seek further increased quotas to supply and manufacture JZP-6 as necessary to complete our clinical trials and, if approved, to commercialize the product. However, our manufacturing partners may not be successful in obtaining increased quotas from the DEA, and without sufficient DEA quotas, there could be shortages of Xyrem for the marketplace or JZP-6 for use in our clinical studies, or both.

We depend on single source suppliers and manufacturers for each of our products and product candidates. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We do not have, and do not intend to establish in the near term, our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. Accordingly, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. Our suppliers and contract manufacturers may not be able to

manufacture our products or product candidates without interruption, or may not comply with their obligations to us under our supply and manufacturing arrangements. We may not have adequate remedies for any breach and their failure to supply us could result in a shortage of our products or product candidates.

The availability of our products for commercial sale is dependent upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a "prior approval supplement" and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer. For Xyrem, JZP-6 or sodium oxybate, the new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. If there are delays in qualifying the new manufacturer or the new manufacturer is unable to obtain a sufficient quota from the DEA, there could be a shortage of Xyrem for the marketplace. For example, we entered into an agreement with Patheon Pharmaceuticals, Inc., or Patheon, in March 2007 for the supply of Xyrem in connection with the planned termination, effective January 1, 2008, of our supply agreement with our current supplier. Patheon has not yet been qualified by the FDA to manufacture Xyrem, and we cannot assure you that Patheon will be qualified by the FDA to manufacture Xyrem on a timely basis, or at all, nor can we assure you that Patheon will obtain a quota from the DEA, or a quota that is sufficient to satisfy our commercial requirements of Xyrem. Furthermore, we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers on acceptable terms and at reasonable prices, or at all.

Due to FDA-mandated dating requirements, DEA quotas relating to Xyrem and JZP-6, and the limited market size for our approved products, we are subject to complex manufacturing logistics and minimum order quantities that could result in excess inventory as determined under our accounting policy, unsalable inventory as a result of product expiring prior to use, and competition with others for manufacturing services when needed or expected. We have adopted a production planning program to assess and manage manufacturing logistics among the vendors supplying our requirements of active pharmaceutical ingredient, drug product and packaging; however, unexpected market requirements or problems with vendors' facilities, among other things, could result in shortages of one or more of our products for the marketplace or product candidates for use in our clinical studies, or both.

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with cGMP requirements. In complying with cGMP requirements, our suppliers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. DEA regulations also govern facilities where controlled substances such as sodium oxybate are manufactured. Manufacturing facilities are subject to periodic unannounced inspection by the FDA, the DEA and other regulatory authorities, including state authorities. Failure to comply with applicable legal requirements subjects the suppliers to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need.

Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects. For example, under our agreement with Solvay, Solvay is responsible for providing fluvoxamine, the active pharmaceutical ingredient in Luvox CR, to us for use in the manufacture of Luvox CR by Elan. If Solvay fails to provide fluvoxamine in the quantities we need, our launch of Luvox CR could be delayed or there could be an interruption in the supply of Luvox CR to the market. In addition, under our agreements with UCB and Valeant, we are responsible for the supply of Xyrem and JZP-6 to UCB and Xyrem, and potentially JZP-6, to Valeant. Our failure to meet our contractual obligations to supply UCB and Valeant with adequate quantities of Xyrem and JZP-6 would result in lost revenues to us and, if material, could result in termination of our agreements by UCB or Valeant.

Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale.

Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. For example, if Luvox CR, for which we have obtained the exclusive rights to market and distribute in the United States from Solvay, is approved for commercial sale, Elan will manufacture Luvox CR for us in exchange for royalty and milestone payments and supply price payments. Luvox CR has never been produced on a commercial scale, and the NDA for Luvox CR was withdrawn in June 2001 by Solvay and Elan as a result of difficulties encountered during the scale-up of manufacturing of Luvox CR. Although the FDA has issued an approvable letter to Solvay, there is no assurance that Elan will be able to manufacture Luvox CR to specifications acceptable to the FDA, or if Luvox CR is approved, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of our products for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We could be materially adversely affected if we or our products are subject to negative publicity. For example, sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a derivative of gamma hydroxybutyrate, or GHB, which has been a drug of abuse and may not be sold legally in the United States. If physicians and patients perceive Xyrem and JZP-6 to be the same as or similar to GHB, sales of Xyrem and JZP-6 could be adversely affected.

From time to time, there is negative publicity about GHB and its effects, including with respect to illegal use, overdoses, serious injury and death and because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Because sodium oxybate is a derivative of GHB, patients, physicians and regulators may view Xyrem as the same as or similar to GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally. Xyrem's label includes information about adverse events from GHB, and we anticipate that if JZP-6 is approved, its label will include similar information. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects.

An investigation by the U.S. Attorney's Office for the Eastern District of New York concerning the sales and marketing of Xyrem is likely to result in fines, penalties or other adverse consequences that could result in adverse publicity and could harm our business.

In April 2006, we and our subsidiary Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. In April 2006, a physician who was a speaker for Orphan Medical, and for a short time for us, was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for us, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce. This investigation has resulted in adverse publicity for Xyrem and for us.

We and Orphan Medical are discussing a possible settlement with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services, relating to this matter. If we complete a settlement on the terms that we are currently discussing, Orphan Medical would plead guilty to one felony count of introducing a misbranded drug into interstate commerce and would pay a total of approximately $20.5 million in civil and criminal payments over the next several years in connection with this matter. We would guarantee payment of these amounts by Orphan Medical.

If we complete a settlement on the terms that we are currently discussing, the U.S. Attorney has indicated that we would not be prosecuted. As part of the settlement, we would enter into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which would require us to maintain a comprehensive compliance program. We would have additional ongoing compliance-related operating costs related to this compliance program.

The settlement terms described above are subject to the negotiation and execution of definitive agreements. These agreements, if executed, could result in additional negative publicity for us and for Xyrem. Even if we execute the definitive agreements, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states' attorneys general with respect to the activities covered by the settlement. We cannot assure you that the definitive agreements will be executed. If we do not execute them, we would be required to spend significant amounts defending ourselves and Orphan Medical. This could involve criminal charges and civil and criminal fines and penalties against Orphan Medical or us, or both. If we are unable to complete the settlement described above, we cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome, and such an outcome could have a material adverse effect on our financial position, liquidity and results of operations.

Whether or not we resolve the ongoing investigation of Xyrem off-label promotion satisfactorily, there is no assurance that we will not be subject to future investigations. Many pharmaceutical companies have announced government investigations of their sales and marketing practices for many of their products. Even with compliance training and a company culture of compliance, our current or future practices may nonetheless become the subject of an investigation. A number of laws, often referred to as "whistleblower" statutes, provide for financial rewards to employees and others for bringing to the attention of the government sales and marketing practices that the government views as illegal or fraudulent. The costs of investigating any claims, responding to subpoenas of investigators, and any resulting fines, can be significant and could divert the attention of our management from operating our business.

Xyrem cannot be advertised directly to consumers, which could limit sales.

Because Xyrem is a derivative of GHB, a known drug of abuse, the FDA has required that Xyrem's label include a box warning regarding the risk of abuse. A box warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A box warning also means, among other things, that the product cannot be advertised directly to consumers. Provigil (modafinil), the only other product approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, does not have a box warning and can be advertised directly to consumers. In addition, Xyrem's type of FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. Unlike Xyrem, Provigil was not approved under the FDA's Subpart H regulations and is not subject to the pre-review requirements. Accordingly, promotional materials for Provigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

Since JZP-6 contains the same active pharmaceutical ingredient as Xyrem, we anticipate that the label for JZP-6, if approved by the FDA, will also include a box warning. Although there are no current FDA-approved treatments for fibromyalgia syndrome, future competing products may not be subject to this restriction, and the box warning may negatively affect potential JZP-6 sales if competing products can be advertised directly to consumers.

We face substantial competition from companies with greater resources than we have.

With respect to all of our existing and future products, we may compete with companies selling or working to develop products that may be more effective, safer or less costly than our products. The markets for which we are developing products are competitive and include generic and branded products, some of which are marketed by major pharmaceutical companies that have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing and marketing and selling approved products than we do. While Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, although none of these compounds has been approved by the FDA for the treatment of cataplexy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil (modafinil), the only other FDA-approved product for the treatment of excessive daytime sleepiness in patients with narcolepsy.

We intend to market Luvox CR in the United States for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Four branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including three selective serotonin reuptake inhibitors: Paxil (paroxetine HCl), which is marketed by GlaxoSmithKline, Zoloft (sertraline HCl), which is marketed by Pfizer, and Prozac (fluoxetine hydrochloride), which is marketed by Eli Lilly. Anafranil (clomipramine hydrochloride), the other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the United States. Each of these products currently has generic equivalents. Generic products are generally sold at significantly lower prices than branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Fluvoxamine, the generic equivalent of Luvox and a selective serotonin reuptake inhibitor, is the only other drug currently approved for the treatment of obsessive compulsive disorder. Four products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR (venlafaxine HCl). Paxil CR and Effexor XR, developed and sold by GlaxoSmithKline and Wyeth, respectively, do not have generic competitors, whereas Paxil and Zoloft have generic competitors.

We are developing JZP-6 for the treatment of fibromyalgia syndrome. There are currently no products approved by the FDA for the treatment of fibromyalgia syndrome. In clinical practice, a variety of drugs is often prescribed to address individual symptoms of fibromyalgia syndrome, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants. In addition to JZP-6, there are currently four programs that have completed or are in Phase III clinical development for the treatment of fibromyalgia syndrome, including programs being conducted by large pharmaceutical companies with far greater resources than we have. In particular, Lyrica (pregabalin), an anticonvulsant being developed by Pfizer, has previously been approved by the FDA for the treatment of partial seizures, post herpetic neuralgia and diabetic peripheral neuropathy. In December 2006, Pfizer submitted a supplemental NDA seeking FDA approval of Lyrica for the treatment of fibromyalgia syndrome, or certain symptoms associated with fibromyalgia syndrome.

Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with other large, established companies. Our commercial opportunities may be reduced or eliminated if our competitors develop and commercialize generic or branded products that are safer or more effective, have fewer side effects or are less expensive than our products.

Our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may. For example, four major pharmaceutical companies are conducting, or have computed, Phase III clinical trials of product candidates for the treatment of fibromyalgia syndrome and Pfizer has submitted a supplemental NDA to the FDA with respect to one of these products, Lyrica. These product candidates may reach the market before JZP-6, or may be better accepted by physicians and patients. Thus, even if we successfully complete our Phase III clinical trials for JZP-6 for the treatment of fibromyalgia syndrome and achieve FDA approval, JZP-6 may not result in significant commercial revenues for us.

Our competitors may market their products more effectively than we do. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to other therapies, we may not generate meaningful revenues from the sales of our products.

If generic products that compete with any of our products are approved, sales of our products may be adversely affected.

Our products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of our products or because our protection has expired or is not sufficiently broad. The FDA has granted orphan drug exclusivity for Xyrem until July 2009 for cataplexy in patients with narcolepsy, and until November 2012 for excessive daytime sleepiness in patients with narcolepsy. Once our orphan drug exclusivity periods for Xyrem expire, other companies could introduce generic equivalents of Xyrem if the generic equivalents do not infringe our existing patents covering Xyrem. Once our orphan drug exclusivity period for Xyrem for the treatment of cataplexy expires in July 2009, prescriptions for Xyrem, or if approved by the FDA, JZP-6, could possibly be filled with generic equivalents that have been approved for the treatment of cataplexy in patients with narcolepsy, even if the patient is diagnosed with excessive daytime sleepiness or fibromyalgia syndrome. Orphan exclusivity for Antizol for ethylene glycol poisoning expired in 2004 and the orphan exclusivity for Antizol for methanol poisoning will expire in December 2007. Patent protection is not available for the active pharmaceutical ingredient in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Although Xyrem is covered by patents expiring in 2019 with claims covering the formula and process for manufacturing our commercial formulation of Xyrem, it is possible that other companies could manufacture generic equivalents of Xyrem in ways that are not covered by the claims of these patents.

Part of our business strategy includes the ongoing development of proprietary product improvements to Xyrem, including new and enhanced dosage forms. However, we may not be successful in developing or obtaining FDA and other regulatory approvals of these improvements. Although the active pharmaceutical ingredient in Xyrem and JZP-6 is a DEA scheduled compound for which a quota is required and the FDA has required a risk management program for its distribution, and therefore generic competition may be more difficult and expensive than it might be for other products not requiring a risk management program for distribution, our

competitors will not be prevented from introducing a generic equivalent. We have filed a patent application with claims covering the method for distributing sodium oxybate using a centralized distribution system, but we cannot assure you that this patent will issue or, if issued, whether it will provide any significant protection of Xyrem from generic competition.

Luvox CR is covered by a patent application filed by Elan with claims covering the orally administered extended release formulation of fluvoxamine. This patent may not issue, and even if this patent issues, it is possible that other companies could manufacture similar or therapeutically equivalent products in ways that are not covered by the claims of the patent. Further, there may be other patents that we are not aware of that cover some aspect of the Luvox CR formulation and that would prevent launch of the product or require us to pay royalties or other forms of consideration.

After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product generally may be filled with the generic version at the pharmacy, resulting in a loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Generic competition often results in decreases in the prices at which branded products can be sold. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the use of generic products rather than branded products where a generic equivalent is available. Generic competition for our products earlier than expected could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be able to enter into acceptable agreements to commercialize our products in international markets.

If appropriate regulatory approvals are obtained, we generally intend to commercialize our products in most markets outside of the United States through arrangements with third parties. If we decide to sell our products in markets outside of the United States, we may not be able to enter into any arrangements on acceptable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we promoted our products directly in international markets. If we choose to market our products directly in markets outside of the United States, we may not be able to develop an effective international sales force. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenues outside of the United States would be limited. In either case, our marketing efforts (and those of our partners) outside of the United States may be subject to regulatory requirements and politico-economic climates that are dissimilar to those in the United States and which could impose unforeseen costs or restrictions on us or our partners.

We may not be able to successfully acquire or in-license additional products or product candidates as part of growing our business.

In order to grow our business, we intend to acquire or in-license additional products and product candidates that we believe have significant commercial potential. Any growth through acquisitions or in-licensing will be dependent upon the continued availability of suitable acquisition or in-license products and product candidates at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify products or product candidates suitable for potential acquisition or in-licensing. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for the right to acquire and in-license such products or product candidates.

We currently have a small sales organization. If we are unable to appropriately expand our specialty sales force and sales organization in the United States to promote additional products, the commercial opportunity for our products may be diminished.

Our sales force is currently comprised of 55 sales professionals. Our potential future commercial products, including Luvox CR and JZP-6, will require an expanded sales force and a significant sales support organization,

and we will need to commit significant additional management and other resources to the growth of our sales organization before the commercial launch of those product candidates. We may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel. If we elect to rely on third parties to sell our products in the United States, we may receive less revenues or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately expand our sales force or collaborate with third parties to sell our products, our ability to generate revenues would be adversely affected.

If we fail to attract and retain key personnel, or to retain our executive management team, we may be unable to successfully develop or commercialize our products.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team. The loss of services of any one or more of our members of executive management team or other key personnel could delay or prevent the successful completion of some of our key activities.

Competition for qualified personnel in the life sciences industry is intense. We will need to hire additional personnel as we expand our development, clinical and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms. We do not carry “key person” insurance. Although the members of our executive management team have employment contracts with us through February 2009, each member of our executive management team and each of our other key employees may terminate his or her employment at any time without notice and without cause or good reason.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 203 full-time employees as of March 31, 2007, approximately 36% of whom joined us in the last 12 months. To continue our commercialization and development activities, we will need to expand our employee base for managerial, operations, development, regulatory, sales, marketing, financial and other functions. It is particularly difficult to recruit new employees to the San Francisco Bay Area, where our offices are located, in large part due to high housing costs. If we cannot recruit qualified employees when we need them, our key activities could be delayed. Growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, particularly with respect to the expansion of our sales and marketing organization and related functions for the potential commercialization of Luvox CR and JZP-6. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any growth effectively, and our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

Our offices are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could damage our facilities, which could adversely affect our operations.

Our offices are located in the San Francisco Bay Area, near known earthquake fault zones and are therefore vulnerable to damage from earthquake. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. We are also vulnerable to damage from other disasters such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, their use and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership

or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our research and development collaborators over the ownership of rights to jointly developed intellectual property. Such disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or commercialize, our products.

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and foreign counterparts, and may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, in part because of prior research performed and patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents or in or our licensed patents or those of our partners, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Patent infringement lawsuits are costly and could affect our results of operations and divert the attention of management and development personnel. There is a risk that a court could decide that we or our partners are infringing third party patent rights. In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

- pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;
- cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;
- expend significant resources to redesign our products so that they do not infringe others' patent rights, which may not be possible;

- discontinue manufacturing or other processes incorporating infringing technology; or
- obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

The pharmaceutical and life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the United States.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors' or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Related to Our Industry

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, selling and marketing of pharmaceutical products are subject to extensive regulation by FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our products. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, generally of an NDA. The NDA must contain, among other things, data to demonstrate that the drug is safe and effective for its intended uses and that it will be manufactured to appropriate quality standards. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process, and the FDA has substantial discretion in the approval process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, untitled letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the marketability of the product or otherwise reduce the size of the potential market for that product. Following any regulatory approval of our products, we will be subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, if the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with any of our products in the United States or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers' facilities, or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products and our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits, including class action suits. The FDA and other governmental authorities also actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

We are also subject to regulation by regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we commercialize our products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. These statutes and regulations include antikickback statutes and false claims statutes.

The federal health care program antikickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting identified common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from antikickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority

of states also have statutes or regulations similar to the federal antikickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and the reporting of gifts to individual physicians in the states. Other states require the posting of information relating to clinical studies. In addition, California requires pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for or payments to individual prescribers. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we or any of our partners fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our or our partners' ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. The minimum amount of the rebate for each unit of product is set by law at 15.1% of the average manufacturing price of that product, or if it is greater, the difference between the average manufacturing price and the best price we make available to any customer. The rebate amount also includes an inflation adjustment, if necessary.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to the Centers for Medicare & Medicaid Services at the U.S. Department of Health and Human Services of our current average manufacturing price and best prices for the quarter. If we become aware that our reporting for prior quarters was incorrect, or changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected average manufacturing price or best price for that quarter. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. In addition to retroactive rebates (and interest, if any), if we are found to have knowingly submitted false information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Services' pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The Public Health Services pricing program extends discounts comparable to the Medicaid rebates to a variety of community health clinics and other entities that receive health services grants from the Public Health Services, as well as hospitals that serve a disproportionate share of poor patients and children.

Reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract strategic partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because Luvox CR will compete in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to effectively commercialize our products.

There have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides a new Medicare prescription drug benefit, that became effective in January 2006, and mandates other reforms. Although we cannot predict the full effect on our business of the implementation of this new legislation, it is possible that the new benefit, which is managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues. Currently, there are legislative proposals that would permit the U.S. Secretary of Health and Human Services to negotiate directly with pharmaceutical companies to obtain lower prices for drugs covered under Medicare Part D.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

Sales of our products in the United States may be adversely affected by consolidation among wholesale drug distributors and the growth of large retail drug store chains.

The market participants to whom we sell Antizol, which accounted for $12.5 million and $2.6 million in net product sales in 2006 and the first quarter of 2007, respectively, and the market participants to whom we expect to sell most of our future products, including Luvox CR, have undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drugstore chains has decreased. In addition, excess inventory levels held by large distributors can lead to periodic and unanticipated reductions in our revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

Prescription drug importation from Canada and other countries could increase pricing pressure on our products and could decrease our revenues and profit margins.

Under current U.S. law, there is a general prohibition on imports of unapproved products. The FDA has published internal guidance that sets forth the agency's enforcement priorities for imported drugs. Under this policy, the FDA allows its personnel to use their discretion in permitting entry into the United States of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the United States from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and will permit pharmacists and wholesalers to import prescription drugs into the United States from Canada under specified circumstances. These additional import provisions will not take effect until the Secretary of Health and Human Services makes a required certification regarding the safety and cost savings of imported drugs and the FDA has promulgated regulations setting forth parameters for importation. These conditions have not been met to date and the law has therefore not taken effect. However, legislative proposals have been introduced to remove these conditions and implement changes to the current import laws, or to create other changes that would allow foreign versions of our products priced at lower levels than in the United States to be imported or reimported to the United States from Canada, Europe and other countries. If these provisions take effect, the volume of prescription drug imports from Canada and elsewhere could increase significantly and our products could face competition from lower priced imports.

Even if these provisions do not take effect and alter current law, the volume of prescription drug imports from Canada and elsewhere could increase due to a variety of factors, including the further spread of internet pharmacies and actions by a number of state and local governments to facilitate Canadian and other imports. These imports may harm our business.

We recently licensed Xyrem to Valeant to distribute in Canada. Due to government price regulation in Canada, products are generally sold in Canada for lower prices than in the United States. Due to the risk management program for Xyrem and our agreement with Valeant, we believe that it is unlikely that Xyrem will be imported from Canada to the United States.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products entail significant risk of product liability claims or recalls. Our products and product candidates are designed to affect important bodily functions and processes. Side effects of, or manufacturing defects in, the products sold by us could result in exacerbation of a patient's condition, further deterioration of a patient's condition or even death. This could result in product liability claims and/or recalls of one or more of our products. For example, studies and publications suggest that selective serotonin reuptake inhibitors, including the active pharmaceutical ingredient in Luvox CR and its immediate release formulation Luvox, may increase the risk of suicidal behavior in adults and adolescents. In addition, the current selective serotonin reuptake inhibitor products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Side effects associated with selective serotonin reuptake inhibitors include sexual dysfunction, adverse drug interaction and risk of hypertension. Claims may be brought by individuals seeking relief for themselves or by groups seeking to represent a class. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe that it is likely product liability claims will be made against us. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. Partly as a result of product liability lawsuits related to pharmaceutical products, product liability and other types of insurance have become more difficult and costly for pharmaceutical

companies to obtain. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.

Product recalls may be issued at our discretion or at the discretion of our suppliers, the FDA, other government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation.

Risks Relating to Our Financial Condition

We have a history of net losses, which we expect to continue for at least several years and, as a result, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

We have a limited operating history and have incurred significant net losses since our inception in 2003, and we expect to continue to incur net losses for the next several years. Our net losses for the year ended December 31, 2006 and the quarter ended March 31, 2007 were $59.4 million and $19.6 million, respectively, and we had an accumulated deficit of $197.2 million at March 31, 2007. We expect our operating expenses to increase over the next several years as we develop additional products, acquire or in-license additional products, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We will need to expand our commercial organization to launch additional products. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Our operations have generated negative cash flows, and if we are unable to secure additional funding, we may be required to reduce operations.

As of March 31, 2007, we had approximately $67.7 million in cash, cash equivalents and marketable securities. Our cash flows used in operations were approximately $57.4 million and $20.9 million during 2006 and the first quarter of 2007, respectively. Substantially all of our $43.3 million and $11.6 million in net product sales during 2006 and the first quarter of 2007, respectively, resulted from sales of Xyrem and Antizol. Sales of either or both products could decrease due to adverse market conditions, introduction of generic products, negative publicity or other events outside our control. We must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials of our product candidates and significant funds to our commercial operations. While we believe that our current cash, cash equivalents and marketable securities and the anticipated net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations for the next 12 to 15 months, we expect to raise additional funds within this period of time through development financings, collaborations or public or private debt or equity financings. We have based this estimate on assumptions that may prove to be wrong, and we could

utilize our available financial resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the amount of sales and other revenues from our commercial products, including selling prices for products that we may begin selling and price increases for our current products;
- market acceptance of and the number of prescriptions written for our products;
- selling and marketing costs associated with Luvox CR and Xyrem in the United States, including the cost and timing of expanding our marketing and sales capabilities;
- revenues from current and potential future development and/or commercial collaboration partners;
- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the number and characteristics of product candidates that we pursue;
- the cost and timing of establishing clinical and commercial supplies of our product candidates;
- the cost and timing of obtaining regulatory approval;
- payments of milestones to third parties;
- increased expenses associated with new employees hired to support our continued growth;
- the cost of investigations, litigation and/or settlements related to regulatory activities, in particular the ongoing investigation by the U.S. Attorney for the Eastern District of New York;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the extent to which we acquire, in-license or invest in new businesses, products or product candidates.

Although we generate product revenues, since our inception in 2003 we have financed our operations primarily through the sale of convertible preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates and our collaboration with UCB related to Xyrem and JZP-6. In addition, our audit report in our 2006 consolidated financial statements contains an explanatory paragraph stating that our recurring losses from operations and cash used in operating activities raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern; however, if we are unable to successfully complete this offering, we will need to execute alternative financing or operational plans to continue as a going concern.

Even if the offering is successful, we will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations. We may also be required to license to third parties products and product candidates that we would prefer to develop and commercialize ourselves. We may seek to raise additional funds through development financings, collaborations, or public or private debt or equity financings. If we raise funds through collaborations, we may be required to relinquish, on terms that are not favorable to us, rights to some of our products or product candidates that we would otherwise seek to develop or commercialize ourselves. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization or our products. Our failure to raise capital when needed may harm our business and operating results.

We have a substantial amount of debt, which may adversely affect our cash flows and our ability to operate our business.

As of March 31, 2007, we had secured indebtedness of $83.1 million at face value, substantially all of which we incurred in connection with our acquisition of Orphan Medical. Our substantial debt combined with our other financial obligations and contractual commitments could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, capital expenditures, acquisitions and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a competitive disadvantage compared to our competitors that have less debt; and
- limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, under specified circumstances, our lenders could demand repayment of all of our debt, which would have a material adverse effect on our business, financial condition and results of operations. If we do not have sufficient earnings to service our debt, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner or at all.

The terms of our debt could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.

Our existing senior secured debt contains, and any future indebtedness would likely contain, a number of restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests. Our existing debt includes covenants, including requirements that we:

- generally not borrow additional amounts without the approval of our lenders;
- dispose of assets acquired in the Orphan Medical acquisition only in accordance with the terms of our existing senior secured debt;
- not impair our lenders' security interests in our assets; and
- maintain minimum cash balances.

Risks Relating to this Offering and Ownership of Our Common Stock

The market price of our common stock may be volatile, and the value of your investment could decline significantly.

Investors who purchase our common stock in this offering may not be able to sell their shares at or above the initial public offering price. Security prices for companies similar to us experience significant price and volume fluctuations. The following factors, in addition to other risks described in this prospectus, may have a significant effect on our common stock market price:

- the success of our development efforts and clinical trials;
- announcement of FDA approval or non-approval of our product candidates, or specific label indications for their use, or delays in the FDA review process;

- actual or expected fluctuations in our operating results, including as a result of fluctuating demand for our commercial products as a result of purchases by wholesalers in connection with product launches, stockpiling or inventory drawdowns by our customers, or otherwise;
- changes in the market prices for our products;
- the success of our efforts to acquire or in-license additional products or product candidates;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- announcements of product innovations by us, our partners or our competitors;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements;
- actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- conditions or trends in the pharmaceutical industry, the financial markets or the economy in general;
- the outcome of, and any expenses related to, the U.S. government investigation of the promotion of Xyrem;
- actual or expected changes in our growth rates or our competitors' growth rates;
- changes in the market valuation of similar companies;
- trading volume of our common stock; and
- sales of our common stock by us or our stockholders.

In addition, the stock market in general and the market for life sciences companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market after this offering, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Based on the number of shares of common stock outstanding as of March 31, 2007, upon completion of this offering, we will have 24,550,554

shares of common stock outstanding, or 25,450,554 shares if the underwriters exercise their over-allotment option in full, assuming no exercise of outstanding options or warrants.

All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, except for any shares purchased by our affiliates as defined in Rule 144 under the Securities Act of 1933, as amended. The remaining 18,550,554 shares of common stock outstanding after this offering, based on shares outstanding as of March 31, 2007, will be restricted as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

- no restricted shares will be eligible for immediate sale upon the closing of this offering;
- approximately 14,219,877 shares, less shares subject to a repurchase option in our favor tied to the holders' continued service to us (which will be eligible for sale upon lapse of the repurchase option), will be eligible for sale upon expiration of lock-up agreements 180 days after the date of this prospectus; and
- the remainder of the restricted shares will be eligible for sale from time to time thereafter upon expiration of their respective one-year holding periods, but could be sold earlier if the holders exercise any available registration rights.

Morgan Stanley & Co. Incorporated and Lehman Brothers Inc., may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements prior to expiration of the lock-up period. See "Shares Eligible for Future Sale."

After this offering, the holders of approximately 19,306,128 shares of common stock, based on shares outstanding as of March 31, 2007, including 785,728 shares underlying outstanding warrants, will be entitled to rights with respect to registration of such shares under the Securities Act of 1933, as amended. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights with respect to registration of the shares of common stock acquired on exercise. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights, these sales may impair our ability to raise capital. In addition, prior to the consummation of this offering, we intend to file a registration statement on Form S-8 under Securities Act to register up to 5,175,042 shares of our common stock for issuance under our stock option and employee stock purchase plans.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned approximately 83.5% of our capital stock as of March 31, 2007, and we expect that upon completion of this offering, that same group will beneficially own at least 64.0% of our capital stock, of which 7.1% will be beneficially owned by our executive officers. Accordingly, after this offering, our executive officers, directors and principal stockholders will be able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our common stock, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, and rules of the Securities and Exchange Commission and the NASDAQ Stock Market, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our annual report on Form 10-K for the fiscal year ended December 31, 2008. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

We have broad discretion to use the net proceeds from this offering and our investment of these proceeds may not yield a favorable return. We may invest the proceeds of this offering in ways you disagree with.

Our management has broad discretion as to how to spend and invest the proceeds from this offering and we may spend or invest these proceeds in a way with which our stockholders may disagree. Accordingly, you will need to rely on our judgment with respect to the use of these proceeds. We plan to invest the net proceeds of this offering in short-term, investment-grade, interest bearing securities. These investments may not yield a favorable return to our stockholders.

If we acquire or in-license products or product candidates, or acquire companies that we believe are complementary to our business, the process of integrating the acquired or in-licensed products or product candidates, or acquired companies may result in unforeseen difficulties and expenditures, and may require significant management attention that would otherwise be devoted to our existing business and products. We could fail to realize the anticipated benefits of any acquisition or in-licensing arrangement. Future acquisitions could reduce your percentage of ownership of us or the value of your common stock and could cause us to incur debt and expose us to liabilities.

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. Although we expect that our common stock will be approved for listing on the NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. This initial public offering price may vary from the market price of our common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, or for a change in the composition of our board of directors or management to occur, even if doing so would benefit our stockholders. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- dividing our board of directors into three classes;
- limiting the removal of directors by the stockholders;
- eliminating cumulative voting rights and therefore allowing the holders of a majority of the shares of our common stock to elect all of the directors standing for election, if they should so choose;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

We have never declared or paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

Our business requires significant funding, and we currently invest more in product development than we earn from sales of our products. In addition, the agreements governing our debt restrict our ability to pay dividends on our common stock. Therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently plan to invest all available funds and future earnings in the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements under "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Many important factors affect our ability to achieve our objectives, including:

- the success and timing of our product development activities and clinical trials;
- our ability to obtain and maintain regulatory approval of our product candidates;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- our ability to successfully commercialize our products;
- the successful development and expansion of our specialty sales force and commercial organization;
- the rate and degree of market acceptance of our current products;
- the performance of our single source suppliers and manufacturers;
- the success of competing branded and generic drugs;
- our ability to identify, develop, acquire and in-license new products and product candidates and to attract appropriate collaboration partners;
- the loss of key personnel;
- regulatory developments in the United States and foreign countries;
- our use of the proceeds from this offering;
- the accuracy of our estimates regarding revenues, expenses, capital requirements and needs for additional financing, and our ability to obtain additional financing; and
- our ability to obtain and maintain intellectual property protection for our products.

In addition, you should refer to the "Risk Factors" section of this prospectus for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933 do not protect any forward-looking statements that we make in connection with this offering.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the shares of our common stock in this offering will be approximately $112.1 million, or approximately $129.2 million if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of $20.50 per share, the mid-point of the range reflected on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses. Each $1.00 increase (decrease) in the assumed initial public offering price of $20.50 per share would increase (decrease) the net proceeds to us from this offering by approximately $5.6 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of one million shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $19.1 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We currently expect to use the net proceeds from this offering as follows:

- between $80.0 and $90.0 million to fund the planned U.S. launch and commercialization of Luvox CR, including $41.0 million for development and commercial milestone payments to Solvay in connection with the acquisition of our U.S. rights to Luvox CR, between $30.0 and $40.0 million for activities related to our preparation for marketing, promotion and expansion of our specialty sales force and approximately $10.0 million for production of initial commercial quantities of Luvox CR; and
- the remainder to continue to fund our Phase III pivotal clinical trials of JZP-6.

We will need an estimated $25.0 million to fund our Phase III pivotal clinical trials of JZP-6 through the completion of the first Phase III clinical trial. We expect to fund all or a portion of this amount from the net proceeds of this offering. If the trial is successful, we would need an estimated additional $50.0 million to complete the remaining JZP-6 clinical and other development activities and to commercially launch JZP-6.

We may also use a portion of the net proceeds to fund continued development of and feasibility activities for our portfolio of clinical and early-stage product candidates during the next 12 to 15 months, as well as working capital, capital expenditures and other general corporate purposes. The completion of development activities and commercial launch of each of our early stage product candidates would require substantial additional funds.

We may also seek to obtain debt or other non-equity financing for a portion of the costs to launch and commercialize Luvox CR, to complete the development and planned commercial launch of JZP-6, to fund continued development and commercialization of our portfolio of clinical and early-stage product candidates and/or for the acquisition or in-licensing of, or investment in, products, product candidates, or companies that complement our business. We have no current understandings, commitments or agreements with respect to any such potential financing.

The expected use of net proceeds of this offering represents our current intentions based upon our present plans and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

The amount and timing of our expenditures will depend on several factors, including whether and when Solvay obtains regulatory approval of Luvox CR, the success of our research and development programs and clinical trials, expenditures to acquire or in-license additional products or product candidates, our ability to

establish and maintain collaborative arrangements that reduce our expenses, any settlement of the U.S. Attorney's Office investigation of Orphan Medical's promotion of Xyrem, future sales growth, cash generated from future operations and actual expenses to operate our business. Pending their uses, we plan to invest the net proceeds of this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

While we believe that our current cash, cash equivalents and marketable securities and the net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations for the next 12 to 15 months, we expect to raise additional funds within this period of time through development financings, collaborations, or public or private debt or equity financings. In addition, we do not expect that our existing capital resources and the net proceeds from this offering will be sufficient to enable us to fund the completion of the development of our current product candidates, and we will need to raise substantial additional capital to fund our operations and to continue to develop our product portfolio, acquire or in-license additional products and product candidates, and launch and market our products.

DIVIDEND POLICY

We have never declared or paid any dividends on our common stock or any other securities. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, the agreements covering our debt restrict our ability to pay dividends on our common stock. Any future determination relating to our dividend policy will be made at the discretion of our board of directors, based on our financial condition, results of operation, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and capitalization as of March 31, 2007:

- on an actual basis;
- on a pro forma basis to reflect the conversion of all of our outstanding shares of preferred stock into 17,921,551 shares of common stock immediately prior to the closing of this offering, the transfer of common stock subject to repurchase from stockholders' equity to temporary equity and the reclassification of preferred stock warrant liability to additional paid-in capital upon conversion of the preferred stock underlying the warrants into common stock; and
- on a pro forma as adjusted basis to reflect the sale of 6,000,000 shares of common stock in this offering at an assumed initial public offering price of $20.50 per share, the mid-point of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses.

You should read the information in this table together with "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of March 31, 2007		
	Actual	Pro Forma (Unaudited)	Pro Forma As Adjusted(1)
	(In thousands, except per share data)		
Cash and cash equivalents	$ 67,667	$ 67,667	$ 179,757
Senior secured notes (including $52,100 as of March 31, 2007 held by related parties)	$ 74,429	$ 74,429	$ 74,429
Preferred stock warrant liability (including $8,469 as of March 31, 2007 held by related parties)	11,588	—	—
Convertible preferred stock, $.0001 par value; issuable in series, 27,851,839 authorized, 17,921,551 shares issued and outstanding, actual; 27,851,839 authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	263,852	—	—
Common stock subject to repurchase	8,749	12,954	12,954
Stockholders' equity (deficit):			
Preferred stock, $.0001 par value, no shares authorized, issued and outstanding, actual and pro forma; 20,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	—	—	—
Common stock, $.0001 par value, 22,835,080 shares authorized, 629,003 shares issued and outstanding, actual; 22,835,080 shares authorized, 18,550,554 shares issued and outstanding, pro forma (unaudited); 150,000,000 shares authorized, 24,550,554 shares issued and outstanding, pro forma as adjusted	—	2	2
Additional paid-in capital	1,807	273,040	385,130
Accumulated other comprehensive income	—	—	—
Accumulated deficit	(197,227)	(197,227)	(197,227)
Total stockholders' equity (deficit)	(195,420)	75,815	187,905
Total capitalization	$ 163,198	$ 163,198	$ 275,288

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $20.50 per share, the mid-point of the range reflected on the cover page of this prospectus, would increase (decrease) each of additional paid-in capital, total stockholders' equity and total

capitalization by approximately $5.6 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of one million shares in the number of shares offered by us would increase (decrease) each of additional paid-in capital, total stockholders' equity and total capitalization by approximately $19.1 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

The outstanding share information in the table above excludes as of March 31, 2007:

- 1,862,530 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of $21.34 per share;
- 215,792 shares of common stock reserved for future issuance under our 2003 Equity Incentive Plan as of March 31, 2007; provided, however, that immediately upon the signing of the underwriting agreement for this offering, our 2003 Equity Incentive Plan will terminate so that no further awards may be granted under our 2003 Equity Incentive Plan;
- an aggregate of up to 5,175,042 shares of common stock reserved for future issuance under our 2007 Equity Incentive Plan, 2007 Non-Employee Directors Stock Option Plan and 2007 Employee Stock Purchase Plan, each of which will become effective immediately upon the signing of the underwriting agreement for this offering; and
- 785,728 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of $20.36 per share.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share and the pro forma net tangible book value per share of our common stock after this offering. Historical net tangible book value per share is determined by dividing our total tangible assets (total assets less intangible assets), less total liabilities, convertible preferred stock and common stock subject to repurchase, by the number of outstanding shares of our common stock. As of March 31, 2007, we had a historical net tangible book value (deficit) of our common stock of $(296.9) million, or approximately $(471.97) per share. The pro forma net tangible book value (deficit) of our common stock as of March 31, 2007 was approximately $(25.6) million, or approximately $(1.38) per share, based on the number of shares of common stock outstanding as of March 31, 2007, after giving effect to the conversion of all outstanding convertible preferred stock into shares of common stock and the reclassification of the preferred stock warranty liability to equity immediately prior to the closing of this offering.

Investors participating in this offering will incur immediate, substantial dilution. After giving effect to the sale of common stock offered in this offering at an assumed initial public offering price of $20.50 per share, the mid-point of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2007 would have been approximately $86.5 million, or approximately $3.52 per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $4.90 per share to existing stockholders, and an immediate dilution of $16.98 per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$20.50
Historical net tangible book value (deficit) per share as of March 31, 2007	$(471.97)	
Pro forma increase in net tangible book value per share attributable to conversion of convertible preferred stock	470.59	
Pro forma net tangible book value (deficit) per share before this offering	$ (1.38)	
Pro forma increase in net tangible book value per share attributable to investors participating in this offering	4.90	
Pro forma as adjusted net tangible book value per share after this offering		3.52
Pro forma dilution per share to investors participating in this offering		$16.98

Each $1.00 increase (decrease) in the assumed initial public offering price of $20.50 per share would increase (decrease) our pro forma as adjusted net tangible book value by approximately $5.6 million, or approximately $.23 per share, and the pro forma dilution per share to investors in this offering by approximately $.77 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase of one million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value by approximately $19.1 million, or $.61 per share, and the pro forma dilution per share to investors in this offering would be $16.37 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a decrease of one million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value by approximately $19.1 million, or $.66 per share, and the pro forma dilution per share to investors in this offering would be $17.64 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option in full to purchase 900,000 additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be $4.07 per share, the increase in the pro forma net tangible book value per share to existing stockholders would be $5.45 per share and the pro forma dilution to new investors purchasing common stock in this offering would be $16.43 per share.

The following table summarizes, on a pro forma basis as of March 31, 2007, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted average price per share paid by existing stockholders and by investors participating in this offering at an assumed initial public offering price of $20.50 per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Weighted Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	18,550,554	76%	$266,807,000	68%	$ 14.38
Investors participating in this offering	6,000,000	24	123,000,000	32	20.50
Total	24,550,554	100%	$389,807,000	100%	

The above discussion and tables are based on 18,550,554 shares of common stock outstanding as of March 31, 2007. This number excludes, as of March 31, 2007:

- 1,862,530 shares of common stock issuable upon the exercise of outstanding options with a weighted average exercise price of $21.34 per share;
- 215,792 shares of common stock reserved for future issuance under our 2003 Equity Incentive Plan; provided, however, that immediately upon the signing of the underwriting agreement for this offering, our 2003 Equity Incentive Plan will terminate so that no further awards may be granted under our 2003 Equity Incentive Plan;
- an aggregate of up to 5,175,042 shares of common stock reserved for future issuance under our 2007 Equity Incentive Plan, 2007 Non-Employee Directors Stock Option Plan and 2007 Employee Stock Purchase Plan, each of which will become effective immediately upon the signing of the underwriting agreement for this offering; and
- 785,728 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of $20.36 per share.

The following table summarizes, on a pro forma basis as of March 31, 2007, after giving effect to the exercise of all stock options and warrants outstanding as of March 31, 2007, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted average price per share paid by existing stockholders and by investors participating in this offering at an assumed initial public offering price of $20.50 per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Weighted Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	21,198,812	78%	$322,550,000	72%	$15.22
Investors participating in this offering	6,000,000	22	123,000,000	28	20.50
Total	27,198,812	100%	$445,550,000	100%	

The number of shares of common stock outstanding in the table above is based on the pro forma number of shares outstanding as of March 31, 2007 and assumes no exercise of the underwriters' option to purchase

additional shares. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of common stock held by existing stockholders will be reduced to 75% of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be increased to 6,900,000 shares or 25% of the total number of shares of common stock to be outstanding after this offering.

Effective upon the closing of this offering, an aggregate of up to 5,175,042 shares of our common stock will be reserved for future issuance under our equity benefit plans, and these share reserves will also be subject to automatic annual increases in accordance with the terms of the plans. To the extent that new options are issued under our equity benefit plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read together with our consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

The selected consolidated statements of operations data for the period from March 20, 2003 (date of inception) through December 31, 2003 and the selected consolidated balance sheet data as of December 31, 2003 and 2004 are derived from our audited consolidated financial statements not included in this prospectus. We derived the consolidated statements of operations data for the years ended December 31, 2004, 2005 and 2006 and the consolidated balance sheet data as of December 31, 2005 and 2006 from our audited consolidated financial statements appearing elsewhere in this prospectus. The selected consolidated statements of operations data for the three month periods ended March 31, 2006 and 2007, and the selected consolidated balance sheet data as of March 31, 2007, have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus, which, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly our financial position and results of operations.

	Period from March 20, 2003 (Inception) to December 31, 2003	Year Ended December 31,			Three Months Ended March 31,	
		2004	2005(1)	2006(2)	2006	2007
					(Unaudited)	
	(In thousands, except per share amounts)					
Consolidated Statements of Operations Data:						
Revenues:						
Product sales, net	$ —	$ —	$ 18,796	$ 43,299	$ 9,771	$ 11,625
Royalties, net	—	—	146	594	66	211
Contract revenue	—	—	2,500	963	—	2,252
Total revenues	—	—	21,442	44,856	9,837	14,088
Operating expenses:						
Cost of product sales (excluding amortization of acquired developed technology)	—	—	4,292	6,968	1,569	2,003
Research and development	—	17,988	45,783	54,956	12,894	14,867
Selling, general and administrative	2,538	7,459	23,551	51,384	12,219	14,339
Amortization of intangible assets	—	—	4,960	9,600	2,400	2,362
Purchased in-process research and development	—	—	21,300	—	—	—
Total operating expenses	2,538	25,447	99,886	122,908	29,082	33,571
Loss from operations	(2,538)	(25,447)	(78,444)	(78,052)	(19,245)	(19,483)
Interest income	10	643	1,318	2,307	581	1,091
Interest expense (including $4,595 and $9,024 for the years ended December 31, 2005 and 2006, respectively, and $2,185 and $2,254 for the three months ended March 31, 2006 and 2007 (unaudited), respectively, pertaining to related parties)	—	—	(7,129)	(14,129)	(3,777)	(3,268)
Other income (expense)	—	—	(901)	(1,109)	62	(3,069)
Gain on extinguishment of development financing obligation	—	—	—	31,592	—	—
Gain on sale of product rights	—	—	—	—	—	5,145
Net loss	(2,528)	(24,804)	(85,156)	(59,391)	(22,379)	(19,584)
Beneficial conversion feature	—	—	—	(21,920)	(3,501)	—
Loss attributable to common stockholders	$ (2,528)	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$(19,584)
Loss per share attributable to common stockholders, basic and diluted	$ (81.55)	$(1,550.25)	$(14,192.67)	$(6,524.69)	$(2,875.56)	$(851.48)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	31	16	6	13	9	23
Pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted(3)				$ (6.04)		$ (1.11)
Weighted-average common shares used in computing pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted				13,466		17,666

(1) We acquired Orphan Medical, Inc. on June 24, 2005, and the results of Orphan Medical are included in the consolidated financial statements from that date.
(2) Operating expenses include stock-based compensation expense of $3.5 million of which $8,000, $661,000 and $2.8 million were charged to cost of product sales, research and development and selling, general and administrative expense, respectively.
(3) Assumes the conversion of all outstanding shares of convertible preferred stock outstanding as of December 31, 2006 and March 31, 2007, as applicable, into common stock.

	As of December 31,				As of March 31, 2007
	2003	2004	2005	2006	(Unaudited)
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 4,460	$ 33,678	$ 20,614	$ 78,948	$ 67,667
Working capital	4,488	36,663	8,048	61,043	46,673
Total assets	4,900	42,850	164,781	214,571	197,910
Senior secured notes (including $50,620 and $51,998 as of December 31, 2005 and 2006, respectively, and $52,100 as of March 31, 2007 (unaudited), held by related parties)	—	—	73,629	74,283	74,429
Convertible preferred stock	7,076	64,009	163,862	263,852	263,852
Common stock subject to repurchase	—	3,665	5,924	8,183	8,749
Accumulated deficit	(2,528)	(27,332)	(118,252)	(177,643)	(197,227)
Total stockholders' (deficit)	(2,512)	(30,923)	(118,248)	(176,296)	(195,420)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with our consolidated financial statements and the notes to those statements included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development and acquisition and in-licensing activities and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies available from third parties, we also explore potential new indications for known drug compounds. Since our inception in 2003, our experienced executive management team has built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of $41.9 million in 2006, one product candidate for which an approvable letter has been issued by the U.S. Food and Drug Administration, or FDA, and five product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development. In March 2007, we sold our rights to a third marketed product that generated net product sales of $1.4 million in 2006 for cash consideration of $9.0 million.

In March 2003, we were incorporated in the State of California and began operations. In April 2003, we entered into agreements with investors for a $15.0 million Series A preferred stock financing, the funds from which were received in 2003 and early 2004. In January 2004, we reincorporated in the State of Delaware. In February 2004, we entered into agreements with investors for a $250.0 million Series B preferred stock and Series B Prime preferred stock financing led by an affiliate of Kohlberg Kravis Roberts & Co., the funds from which were received in 2004, 2005 and 2006. All of our outstanding preferred stock will convert into common stock in connection with this offering. On June 24, 2005, we acquired Orphan Medical, Inc., including its three marketed products, Xyrem, Antizol and Cystadane, in order to complement our development portfolio with marketed products and to build our commercial organization.

Our marketed products in 2006 were:

- *Xyrem (sodium oxybate) oral solution*. Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Net product sales of Xyrem were $29.0 million in 2006 and $8.6 million in the first quarter of 2007. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our 55 person specialty sales force. Xyrem is distributed in the United States by Express Scripts Specialty Distribution Services, or Express Scripts, a specialty pharmaceutical distribution company, which is our only customer for Xyrem. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. In October 2005, the European Agency for the Evaluation of Medical Products approved Xyrem for the treatment of cataplexy associated with narcolepsy and in March 2007, the European Agency for the Evaluation of Medical Products approved the product for the treatment of narcolepsy with cataplexy in adult patients. UCB has commercially launched Xyrem in 12 countries.

- *Antizol (fomepizole).* Antizol is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Net product sales of Antizol were $12.5 million in 2006 and $2.6 million in the first quarter of 2007. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisoning in dogs. Net product sales of Antizol-Vet in 2006 were $313,000.
- *Cystadane (betaine anhydrous).* Cystadane is approved by the FDA for the treatment of homocystinuria, an inherited metabolic disease. Net product sales of Cystadane in 2006 were $1.4 million. In March 2007, we sold our rights to Cystadane to an unrelated third party for cash consideration of $9.0 million.

Our late-stage product candidates are:

- *Luvox CR (fluvoxamine maleate extended release capsules).* Our most advanced product candidate is Luvox CR, an extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, which has been developed for the treatment of obsessive compulsive disorder and social anxiety disorder. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay Pharmaceuticals, Inc., or Solvay, in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Solvay submitted a new drug application, or NDA, to the FDA for Luvox CR in April 2006, and, in February 2007, the FDA issued an approvable letter. Under our agreement with Solvay, Solvay has primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA for Luvox CR. Subject to the satisfaction of the requirements set forth in an approvable letter issued by the FDA to Solvay and FDA approval, we expect to commence promotion of Luvox CR in the United States in the first quarter of 2008 through an expanded specialty sales force. During 2007, we expect to make significant expenditures relating to the planned launch and commercialization of Luvox CR, including milestone payments to Solvay, activities related to our preparation for marketing and promotion, expansion of our specialty sales force and production of commercial quantities of Luvox CR.
- *JZP-6 (sodium oxybate).* We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia syndrome. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia syndrome. We are currently conducting two pivotal Phase III clinical trials, and we expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. We have granted to UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

In addition to our product candidates in late-stage development, our clinical development pipeline consists of the following product candidates:

- *JZP-4 (Type IIa sodium channel antagonist).* Subject to the results of a proof of concept clinical trial, formulation studies and long-term toxicology studies, we plan to commence a Phase II clinical trial of JZP-4 for the treatment of epilepsy in the fourth quarter of 2007. We are also developing JZP-4 for the treatment of bipolar disorder.
- *JZP-8 (benzodiazepine).* We plan to commence a Phase II clinical trial of JZP-8 for the treatment of acute repetitive seizure clusters in refractory epilepsy patients in the fourth quarter of 2007.
- *JZP-7 (dopamine agonist).* We intend to conduct an additional pharmacokinetic study of JZP-7 in 2007 prior to commencing Phase II clinical trials for the treatment of restless legs syndrome.
- *JZP-2 (benzodiazepine).* We have developed a target formulation for JZP-2 and plan to commence one or more clinical trials of JZP-2 for the acute treatment of panic attacks associated with panic disorder in 2007.

Although we generate product revenues, we have funded our operations primarily through the sale of convertible preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates and our collaboration with UCB related to Xyrem and JZP-6. Our sources of funding have included the following:

- *Equity Financings*. Our preferred stock financings raised gross proceeds of $265.0 million.
- *Debt Financings*. In connection with our acquisition of Orphan Medical, we issued $80.0 million aggregate principal amount of senior secured notes and warrants to purchase 785,728 shares of our Series BB convertible preferred stock. Additionally, in September 2006, we entered into a one year line of credit agreement with a financial institution under which we may borrow up to 80% of eligible accounts receivable, up to a maximum borrowing limit of $5.0 million.
- *Development Financing*. In August 2005, we entered into an agreement with a third party under which the third party agreed to provide $30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development for the treatment of general anxiety disorder. Under that agreement, we received $15.0 million in 2005 and $15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development of the product candidate and not to seek product marketing approval from the FDA. As a result of our notification, we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3.
- *Collaboration*. Under the terms of our agreement with UCB for Xyrem and JZP-6, we received an upfront payment of $5.0 million and a $10.0 million payment upon election by UCB to exercise its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia syndrome. We are also entitled to additional development and commercialization milestone payments of up to $146.0 million and royalties on all commercial sales of Xyrem and JZP-6 by UCB.

Since our inception, we have incurred significant net losses, and we expect to continue to incur net losses for the next several years as we develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We will need to expand our commercial organization to launch additional products. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

While we believe that our current cash, cash equivalents and marketable securities and the anticipated net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations for the next 12 to 15 months, we expect to raise additional funds within this period of time through development financings, collaborations, or public or private debt or equity financings.

Revenues

Product Sales, Net

The following is a summary of our product sales, net for the years ended December 31, 2005 and 2006 and the three months ended March 31, 2006 and 2007. We had no product sales prior to our acquisition of Orphan Medical in June 2005.

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
	(In thousands)			
Xyrem	$ 11,200	$ 29,049	$ 6,153	$ 8,624
Antizol(1)	6,782	12,813	3,131	2,636
Cystadane	814	1,437	487	365
Total	$ 18,796	$ 43,299	$ 9,771	$ 11,625

(1) Includes sales of Antizol-Vet, which were $99,000 and $313,000 in 2005 and 2006, respectively, and $80,000 and $65,000 in the three months ended March 31, 2006 and 2007, respectively.

Xyrem (sodium oxybate) oral solution. Revenues from sales of Xyrem represented primarily sales in the United States to Express Scripts. Revenues from sales of Xyrem under our agreements with UCB and Valeant have not been material. Orphan drug exclusivity for Xyrem expires in 2009 and in 2012 for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy, respectively.

Antizol (fomepizole). Revenues from sales of Antizol in the United States represented primarily sales to pharmaceutical wholesalers. Our sales of Antizol to distributors outside of the United States have not been material. The orphan drug exclusivity for Antizol expired for ethylene glycol poisoning in 2004 and is scheduled to expire in December 2007 for methanol poisoning. We expect annual sales to remain at approximately the 2006 level unless generic competition enters the market.

Cystadane (betaine anhydrous). We sold our rights to Cystadane in March 2007 for $9.0 million, and, accordingly, we will not receive future revenues from the sale of this product.

Royalties, Net

We receive royalties primarily from international distributors of our products, typically based on their net sales of our products. Approximately half of our royalties in the year ended December 31, 2006 resulted from minimum royalty payments under our agreement with UCB. Royalty income was $146,000 and $594,000 in the years ended December 31, 2005 and 2006, respectively, and $66,000 and $211,000 in the three months ended March 31, 2006 and 2007, respectively. We had no royalty revenues prior to the acquisition of Orphan Medical in June 2005. Although we do not expect royalty revenues to comprise a substantial portion of our revenues, we expect royalty revenues to increase in the future as UCB launches Xyrem in additional countries and Valeant launches Xyrem in Canada.

Contract Revenues

All of our contract revenues relate to upfront or milestone payments received from UCB. UCB made a nonrefundable development milestone payment to us of $2.5 million in November 2005 and nonrefundable commercial milestone payments of $500,000 and $2.0 million in June 2006 and March 2007, respectively, which we recognized upon achievement of the milestones. In connection with the expansion of our agreement with UCB in 2006, UCB made an upfront payment of $5.0 million and subsequently an additional payment of $10.0 million upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia syndrome. These payments are being amortized through 2019, the estimated performance period of the contract. This amortization resulted in $463,000 and $252,000 of contract revenues during the year ended December 31, 2006 and the three months ended March 31, 2007, respectively.

Significant Customers

The following table presents a summary of revenues from significant customers as a percentage of our total revenues:

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
Express Scripts	51%	65%	63%	61%
Cardinal Health	*	12%	15%	*
Amerisource Bergen	15%	*	*	*
UCB	12%	*	*	17%
McKesson Corporation	*	*	11%	*

* Less than 10% of our total revenues.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in identifying, developing and testing our product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing our clinical trials, clinical trial costs paid to sites and investigators' salaries, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates or drug delivery or formulation technologies that we have licensed, allocated expenses, such as facilities and information technology that support our research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under our license agreements for product candidates in development.

Conducting a significant amount of research and development is central to our business model. Through March 31, 2007, we had incurred approximately $133.6 million in research and development expenses since our formation in 2003, and we plan to continue to make significant investments in research and development for the foreseeable future in order to realize the potential of our portfolio of development candidates and earlier-stage research and development projects. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and length of the clinical trials.

The following table summarizes our research and development expenses for each of the years ended December 31, 2004, 2005 and 2006 and the three months ended March 31, 2007. Prior to 2004, we did not undertake any substantial research and development efforts. We designate development projects to which we have allocated significant research and development resources with the term "JZP" and a unique number. All of the product candidates designated with "JZP" in the following table, other than JZP-3, remain in development. Development projects in addition to JZP-3 that were designated with a JZP number but later terminated are included in "Other terminated projects" in the following table. Earlier-stage development and product lifecycle extension projects are included in "Other projects" in the following table. Early product concept feasibility studies and other research activities are included in "R&D support" in the following table. The expenditures summarized in the following table reflect costs directly attributable to each development candidate and to our "Other projects." We do not allocate salaries, benefits or other indirect costs to our development candidates or "Other projects," and we have included these costs in "R&D support" in the following table.

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2007	Total
	(In thousands)				
Luvox CR	$ —	$ —	$ —	$ 2,254	$ 2,254
Ongoing JZP Projects:					
JZP-6	—	—	14,209	5,219	19,428
JZP-4	2,077	2,141	6,699	1,963	12,880
JZP-8	—	313	1,403	162	1,878
JZP-7	4	150	1,328	386	1,868
JZP-2	58	1,570	395	272	2,295
Terminated Projects:					
JZP-3(1)	12,577	27,305	14,797	—	54,679
Other terminated projects	1,437	5,878	752	10	8,077
Other projects	1	97	1,834	151	2,083
R&D support	1,834	8,329	13,539	4,450	28,152
Total	$17,988	$45,783	$54,956	$ 14,867	$133,594

(1) Development has been terminated. This project was partially financed through $30.0 million of development financing discussed above.

In July 2004, we commenced our JZP-3 development efforts when we entered into a development and commercialization agreement, a product supply agreement and a technology transfer agreement with a pharmaceutical company and made a $1.0 million payment to this company. We made additional development milestone payments under these agreements of $2.0 million and $5.0 million in 2004 and 2005, respectively. We commenced a Phase III clinical trial of JZP-3 in late 2004. In June 2006, following analysis of the results of the Phase III clinical trial, we discontinued development of JZP-3 and terminated the program.

The process of developing and obtaining FDA approval of products is costly and time consuming. Development activities and clinical trials can take years to complete, and failure can occur any time during the clinical trial process. In addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. For example, we ceased our development of JZP-3 after its Phase III clinical trial was not successful and after we had incurred significant development costs. Although our program for identifying and developing new product candidates is designed to mitigate risk, the successful development of our product candidates is highly uncertain. Further, even if our product candidates are approved for sale, we may be unable to successfully commercialize them in which case we would not generate the revenues we anticipate. Our ability to successfully develop, obtain FDA approval for and commercialize our products may be affected by a variety of factors including, among others:

- our ability, and the ability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials;

- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;
- safety issues, including adverse events associated with product candidates; and
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines.

Development timelines, probability of success and development costs vary widely among product candidates. As a result, we are unable to determine the time and completion costs related to the development of our product candidates or estimate when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates other than Luvox CR, which we expect to commence promoting in the United States in the first quarter of 2008.

Critical Accounting Policies and Significant Estimates

Revenue Recognition

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. In evaluating arrangements with multiple elements we consider whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on their respective fair values when there is reliable evidence of fair value for all elements of the arrangement. If there is no evidence of fair value for all the elements of the arrangement, consideration is allocated based on the residual value method for the delivered elements. Under the residual method, the amount of revenues allocated to the delivered elements equals the total arrangement consideration less the aggregate fair value of any undelivered elements. The applicable revenue recognition criteria are applied to each of the separate units. Payments received in advance of work performed are recorded as deferred revenues and recognized when earned.

Product Sales, Net

Revenues from sales of Xyrem within the United States are recognized upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment to a patient. Antizol is, and prior to the sale of our rights Cystadane was, shipped to our wholesaler customers in the United States with free on board destination shipping terms, and we recognize revenues when delivery occurs. Our international sales often have customer acceptance clauses and therefore we recognize revenues when we are notified of acceptance or the time to inspect and reject the shipment has lapsed. When sales to international customers do not have acceptance clauses, we recognize revenues when title transfers, which is generally when the product leaves our logistics providers' facilities.

Revenues from sales of products within the United States are recorded net of estimated allowances for specialty distributor and wholesaler fees, prompt payment discounts, Medicaid rebates, government chargebacks and a customer rebate. Calculating these items involves estimates and judgments based primarily on sales or invoice data and historical experience. Due to the nature of our current products, product returns have been infrequent and immaterial. Our allowances and adjustments to estimates for allowances have not historically been material.

Specialty Distributor and Wholesaler Fees. Express Scripts, our sole Xyrem distributor in the United States, provides services such as collecting patient registry information, providing reimbursement support, and distributing educational materials. The fee we pay to Express Scripts for these services is recorded as a reduction of Xyrem product sales and is based on actual invoices for services performed rather than estimates. Since the fee

is based primarily on product shipments, our allowance related to these fees would generally increase in proportion to increases in sales. Fees paid to Express Scripts totaled $546,000 and $1.4 million for the years ended December 31, 2005 and 2006, respectively, and $298,000 and $363,000 for the three months ended March 31, 2006 and 2007, respectively.

Our service agreements with certain U.S. wholesaler customers for Antizol require, and, prior to the sale of our rights, our service agreements for wholesale customers for Cystadane required, us to pay fees to the customer based on actual product sales made to such customer. If the gross product sales of Antizol sold to U.S. wholesaler customers with such service agreements increases, our allowance related to these discounts could increase. Wholesaler fees totaled $64,000 and $203,000 for the years ended December 31, 2005 and 2006, respectively, and $60,000 and $10,000 for the three months ended March 31, 2006 and 2007, respectively.

Prompt Payment Discounts. We offer Express Scripts and our U.S. wholesaler customers a 2% prompt payment discount as an incentive to remit payment within the first 30 days after the date of our invoice. Because Express Scripts and our U.S. wholesaler customers typically take the prompt payment discount, we accrue 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of our original sale to them, and we apply earned discounts at the time of payment. We adjust the allowance to reflect actual experience as necessary and, as a result, the actual amount recognized in any period may be slightly different from our allowance amount. Adjustments have not been material and we do not anticipate that changes to estimates will have a material impact on product sales, net. Prompt payment discounts were $381,000 and $880,000 for the years ended December 31, 2005 and 2006, respectively, and $198,000 and $240,000 for the three months ended March 31, 2006 and 2007, respectively.

Medicaid Rebates. Our products are subject to state government-managed Medicaid programs under which rebates are provided to participating state governments. We record accruals for rebates to be provided through the Medicaid drug rebate program as a reduction of product sales when the product is sold. We pay rebates to states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is derived from our average manufacturer price. We determine our estimate of the Medicaid rebate accrual primarily based on historical experience regarding Medicaid rebates, as well as current and historical prescription activity and our current sales prices. We also examine the historical rebate trends and any changes expected to these trends. We adjust the accrual throughout each period to reflect actual experience, expected changes in future prescription volumes and any changes in business circumstances or trends. Rebate amounts are generally invoiced quarterly in arrears and paid 30 days after they are invoiced. As a result, our accrual consists of an estimate of the amount expected to be incurred for the current quarter's prescriptions and an estimate for prior quarters' unpaid rebates. Based on our history of estimating Medicaid rebates, we do not anticipate that changes to our estimated allowance for Medicaid rebates for our current commercial products will have a material impact on product sales, net. Medicaid rebates totaled $135,000 and $229,000 for the years ended December 31, 2005 and 2006, respectively, and $108,000 and $94,000 for the three months ended March 31, 2006 and 2007, respectively.

Chargebacks. Our products are subject to certain programs with federal government entities under which pricing on our products is extended below U.S. wholesaler list price to participating entities. These entities purchase our products through U.S. wholesalers at the lower vendor price, and the U.S. wholesalers charge the difference between their acquisition cost and the lower vendor price back to us. We account for chargebacks by establishing an accrual in an amount equal to our estimate of chargeback claims. We determine our estimate of the chargebacks primarily based on historical experience regarding chargebacks and current contract prices under the vendor programs. We consider vendor payments and our claim processing time lag and adjust the accrual throughout each period to reflect actual experience and any changes in business circumstances or trends. Due to estimates and assumptions inherent in determining the amount of chargebacks, the actual amount of claims for chargebacks may be slightly different from our estimates. Based on our experience with chargebacks, we do not believe that a material change to our estimated allowance for chargebacks is reasonably likely or will have a material impact on product sales, net. Chargebacks from U.S. wholesalers were $57,000 and $212,000 for the

years ended December 31, 2005 and 2006, respectively, and $56,000 and $70,000 for the three months ended March 31, 2006 and 2007, respectively.

Customer Rebate. Under our agreement with our Antizol distributor in Canada, we pay a rebate, either in cash or as a credit against future purchases, based upon year-over-year unit sales increases. We account for the rebate by establishing an accrual equal to our estimate of the rebate amount. We determine our estimate of the rebate primarily based on historical experience regarding rebate payments and our Antizol distributor's current year sales forecast. The rebate was $44,000 for the year ended December 31, 2006 and $5,000 for the three months ended March 31, 2007. There was no rebate for the year ended December 31, 2005 or the three months ended March 31, 2006.

Royalties, Net

We receive royalties from third parties based on sales of our products under out-licensing and distributor arrangements. For those arrangements where royalties are reasonably estimable, we recognize revenues based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenues upon receipt of royalty statements from our licensee or distributor.

Contract Revenues

Nonrefundable fees where we have no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where we have continuing performance obligations, nonrefundable fees are deferred and recognized ratably over our projected performance period. We recognize at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when our performance obligations are completed.

UCB Agreement

In June 2006, we entered into an agreement with UCB that amended and restated a prior agreement between Orphan Medical and UCB. Under the terms of the amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia syndrome in 54 countries outside of the United States. Under the prior agreement, UCB made a nonrefundable development milestone payment to us of $2.5 million in November 2005 and nonrefundable commercial milestone payments of $500,000 and $2.0 million in June 2006 and March 2007, respectively, which we recognized upon achievement of the milestones. UCB also made an upfront payment of $5.0 million upon execution of the amended agreement in June 2006 and an additional payment of $10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia syndrome. We recognized contract revenues of $463,000 and $252,000 related to these upfront payments during the year ended December 31, 2006 and the three months ended March 31, 2007, respectively. The remaining $14.3 million was recorded as deferred revenues as of March 31, 2007 and is being recognized ratably through 2019, the expected performance period under the agreement. There has been no change in the expected performance period since its establishment in 2006 at the time of the initial upfront payment. The amended agreement requires UCB to make additional milestone payments of up to $146.0 million, of which up to $6.0 million relate specifically to Xyrem for the treatment of narcolepsy, up to $40.0 million relate to the development and approval of JZP-6 for the treatment of fibromyalgia syndrome and up to $100.0 million relate primarily to the commercialization of JZP-6 for the treatment of fibromyalgia syndrome as well as additional sales of Xyrem for the treatment of narcolepsy.

Goodwill and Intangible and Long-Lived Assets

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates an impairment, then the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. We test goodwill for impairment annually in October and have concluded that no impairment existed as of October 1, 2006. We will also test for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There have been no changes since October 1, 2006 that would cause us to reevaluate our conclusion.

Intangible assets consist primarily of developed technology, agreements not to compete and trademarks. Intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from three to ten years. The estimated useful lives associated with other intangible assets are consistent with underlying agreements, or the estimated lives of the products. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. We evaluate purchased intangibles and other long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value, calculated using discounted cash flows. Since our inception, there has been no such impairment.

As a result of our acquisition of Orphan Medical in June 2005, we had recorded goodwill and intangible assets at March 31, 2007 as follows:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Weighted Average Remaining Useful Life
		(In thousands)		(Years)
Developed technology—Xyrem	$ 39,700	$ 7,370	$32,330	7.8
Developed technology—Antizol	31,100	5,773	25,327	7.8
Agreements not to compete	5,600	2,379	3,221	2.8
Trademarks	2,600	483	2,117	7.8
Other	400	156	244	2.8
Amortizable intangible assets	79,400	16,161	63,239	
Goodwill	38,213			
Total	$117,613			

Stock-Based Compensation

Stock-Based Compensation Under SFAS 123

Prior to January 1, 2006, we accounted for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25") and related interpretations. Prior to January 1, 2006, we complied with the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, ("SFAS 123") as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123*. Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of our common stock over the exercise price of the option on the date of grant. No stock-based compensation expense was recorded under APB 25 during the years ended December 31, 2004 and 2005.

Change in Accounting Principle—Stock-Based Compensation Under SFAS 123R

Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment* ("SFAS 123R"), which requires compensation expense related to share-based transactions, including employee stock options, to be measured and recognized in the financial statements based on fair value. SFAS 123R revises SFAS 123, as amended, and supersedes APB 25. We adopted SFAS 123R using the modified prospective approach. Under the modified prospective approach, SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date are recognized as the requisite service is rendered on or after the required effective date. The compensation expense for that portion of awards is based on the grant-date fair value of those awards. The compensation expense for awards with grant dates prior to January 1, 2006, are attributed to periods beginning on or after the effective date using the attribution method that was used under SFAS 123, except that the method of recognizing forfeitures only as they occur is not continued.

We are using the straight-line method to allocate compensation cost to reporting periods under SFAS 123 and SFAS 123R.

Under both SFAS 123 and SFAS 123R we elected to use the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of stock options was estimated at the grant date using the following assumptions:

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
Weighted-average volatility	80%	60%	61%	61%	61%
Weighted-average expected term	5.0	5.0	6.0	6.0	6.5
Range of risk-free rates	3.0-4.0%	3.9-4.4%	4.6-5.1%	4.6%	4.5-4.8%
Expected dividend yield	0%	0%	0%	0%	0%

The weighted-average grant date fair value per share of employee stock options granted during the years ended December 31, 2004, 2005 and 2006 was $8.96, $8.66 and $10.68, respectively. The weighted-average grant date fair value per share of employee stock options granted during the three months ended March 31, 2006 and 2007 was $10.05 and $12.07, respectively.

Volatility. As we do not have any trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the median historic stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the specialty pharmaceutical industry similar in size, stage of life cycle and financial leverage. We did not rely on the implied volatilities of traded options in our industry peers' common stock, because either the term of those traded options was much shorter than the expected term of our stock option grants, or the volume of activity was relatively low.

Expected Term. We have very little historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock option grants. As a result, for stock option grants made during the year ended December 31, 2006 and the three months ended March 31, 2007, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107 *Share-Based Payment*. For stock options granted during the years ended December 31, 2004 and 2005 we estimated the expected term of stock options based on the expected term of options granted by publicly traded industry peers.

Risk-free Rate. The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of our stock option grants.

Expected Dividend Yield. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

Common Stock Fair Value. The fair value of our common stock during the years ended December 31, 2004 and 2005 was determined by our board of directors with assistance from management. In May 2006, our board of directors directed management to perform an in-depth contemporaneous valuation of our common stock. In conducting this valuation, we used a two-step methodology that first estimated the fair value of the company as a whole, and then allocated a portion of the enterprise value to our common stock. This approach is consistent with the methods outlined in the AICPA Practice Aid *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The valuation methodology utilized the "income approach" to estimate enterprise value. This enterprise value was then validated utilizing the "market approach." The income approach involved projecting future cash flows, discounting them to present value using a discount rate of 15% based upon a risk adjusted weighted average cost of capital of comparable companies, and applying probabilities for success of our product candidates to the resulting discounted cash flows. The projection of future cash flows, the determination of an appropriate discount rate and the estimates of probability for success of our product candidates each involved a significant degree of judgment. For product candidates other than JZP-6 and an alternative dosage form of Xyrem, the probabilities for success ranged from five percent to 30%. For JZP-6, a project for which we were preparing to commence Phase III clinical trials, the probability of success ranged from 60% to 70% and for an alternative dosage form of Xyrem, probabilities of success ranged from 50% to 100%. The present value of projected future cash flows after application of the discount rate and, for product candidates, our probabilities of success, ranged from $113.5 million to $124.1 million for our existing products, $112.8 to $156.1 million for JZP-6 and $66.7 million to $142.8 million for our other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $293.0 million to $423.0 million. The market approach used to validate the determination of enterprise value involved selecting a range of possible valuations by comparing a group of 14 publicly-traded specialty pharmaceutical and biotechnology companies with products and product candidates in similar stages of development. The range of enterprise values derived through application of the market approach method was $300.0 million to $350.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, we determined that the market approach provided an appropriate validation of our estimated enterprise value.

In order to allocate the enterprise value to the various securities that comprise our capital structure, the option-pricing method was used. For purposes of applying the option-pricing method, we estimated our stock price volatility to be 60% and our time to liquidity to be one year. A 10% discount was then applied to account for a lack of marketability of our common stock based upon the assumed time to liquidity. The contemporaneous valuation of our common stock suggested a range of probable fair values from $12.17 per share to $17.26 per share. On June 28, 2006, our board of directors made a determination that the fair market value of our common stock was $16.60 per share, after taking into consideration the contemporaneous valuation as well as other factors including our financial performance, the development status of our product candidates and our research and development efforts and the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions. The fair market value determination made by our board of directors as of June 28, 2006 represents a discount of $3.90 per share from our assumed initial public offering price of $20.50 per share, which discount is attributable to our receipt of the FDA's approvable letter to Solvay for Luvox CR, our progress in the development of our product candidates and our financial performance in the period from June 28, 2006 to the date of this prospectus and our progress towards our initial public offering and the related reduction in market and liquidity risk associated with our common stock over the period from June 28, 2006 to the date of this prospectus.

In December 2006, our board of directors directed management to perform a second in-depth contemporaneous valuation with an effective date of December 31, 2006. In conducting this valuation, we used the same methodology and assumptions as in the prior contemporaneous valuation for determining enterprise value, with the exception of adjustments in our estimated future cash flows for certain of our existing products and product candidates and our estimated probabilities of success for certain of our product candidates for

purposes of the income approach. We also made modifications to the comparison group of companies utilized for the market approach to reflect business developments at comparable companies and achieve an appropriate sample size. The present value of projected future cash flows after application of the discount rate and, for product candidates, our probabilities of success ranged from $83.6 million to $93.2 million for our existing products, $138.5 to $186.0 million for JZP-6 and $94.9 million to $184.8 million for our other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $317.0 million to $464.0 million. A number of companies included in the comparison group for purposes of the market approach in the June 28, 2006 contemporaneous valuation were not included in the comparison group as of December 31, 2006 as a result of material adverse events associated with significant development projects at these companies that we believe made their market values incomparable to our own. Appropriate specialty pharmaceutical and biotechnology companies were added to the comparison group for purposes of the December 31, 2006 contemporaneous valuation to provide an appropriate sample size of 13 comparable companies. The range of enterprise values derived through the application of the market approach method was $350.0 million to $425.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, we determined that the market approach provided an appropriate validation of our estimated enterprise value.

For purposes of allocating enterprise value to our common stock, time to liquidity assumed in the option pricing method was reduced to six months and the discount for marketability was consequently reduced to five percent. In addition to the option-pricing method, we also considered the probability weighted expected return method. The application of this method yielded a result within the range of probable fair values suggested by the option pricing method. For purposes of applying the probability-weighted expected return method we considered six potential liquidity scenarios. Two potential scenarios were each given a probability of five percent and involved the distressed sale or liquidation of the company at alternative valuations of $10.0 million and $100.0 million. Two other potential scenarios were each given a probability of 7.5% and involved the sale of the company following the failure to achieve positive clinical trial results for certain of our product candidates at alternative valuations of $200.0 million and $270.0 million. The remaining potential scenarios involved the successful sale of the company or an initial public offering of our common stock at alternative valuations of $500.0 million and $800.0 million, which were given probabilities of 70% and five percent, respectively. The contemporaneous valuation of our common stock suggested a range of probable fair values from $13.94 per share to $21.36 per share. On February 13, 2007, our board of directors made a determination that the fair market value of our common stock was $19.37 per share after taking into consideration the contemporaneous valuation as well as other factors, including our financial performance, the development status of our product candidates and our research and development efforts, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions and initial estimates of the potential initial public offering price of our common stock based on initial valuation discussions by and between management and the proposed underwriters for our initial public offering. This determination was confirmed by the compensation committee of our board of directors as of February 27, 2007, the last date in the three month period ended March 31, 2007 on which we granted stock options. The fair market value determination made by our board of directors as of February 13, 2007, and confirmed as of February 27, 2007, represents a discount of $1.13 per share from our assumed initial public offering price of $20.50, which discount is primarily attributable to our receipt, on February 28, 2007, of the FDA's approvable letter to Solvay for Luvox CR, and, to a lesser extent, to our progress towards our initial public offering and the related reduction in market and liquidity risk associated with our common stock over the periods from February 13, 2007 and February 27, 2007 to the date of this prospectus and our progress in the development of our product candidates and our financial performance in the periods from February 13, 2007 and February 27, 2007 to the date of this prospectus.

In connection with the preparation of our financial statements for the year ended December 31, 2006, we reassessed the fair value of our common stock at option grant dates from June 28, 2006 through December 31, 2006 by reviewing our corporate developments from June 28, 2006 through February 13, 2007. In undertaking this assessment, we determined that the increase in value from June 28, 2006 to December 31, 2006 was

attributable to a decrease in expected timing to liquidity and general progress in the development status of our product candidates and not the achievement of any particular business milestones that individually would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows. We also determined that no such milestones had been achieved during the period from December 31, 2006 to February 13, 2007. As a result, we concluded that a ratable increase to the estimated fair value of our common stock from $16.60 to $19.37 over the period from June 28, 2006 to December 31, 2006 for purposes of calculating stock-based compensation expense associated with our stock option grants under SFAS 123R was appropriate. In connection with the grant of stock options on February 27, 2007, the compensation committee of our board of directors confirmed that the fair market value of our common stock was $19.37 on the basis that we had not achieved any particular business milestone that would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows in the period from February 13, 2007 to February 27, 2007. Therefore, we have determined that no reassessment of the fair value of our common stock as of February 27, 2007 was appropriate.

On February 28, 2007, Solvay informed us that the FDA had issued an approvable letter to Solvay for Luvox CR dated February 27, 2007. In April 2007, the audit committee of our board of directors determined that as of March 31, 2007, the fair value of our common stock was $24.79 per share after taking into account the valuation conducted in December 2006, the achievement of a significant business milestone associated with the issuance of the approvable letter for Luvox CR to Solvay, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions and our then ongoing process to prepare for an initial public offering, and estimates of the potential initial public offering price of our common stock based on valuation discussions by and between management and the proposed underwriters for our initial public offering. We did not perform a contemporaneous valuation of our enterprise value or common stock using the income approach or market approach as of March 31, 2007. The fair market value determination made by our board of directors as of March 31, 2007 was based on the midpoint of the valuation range then suggested by our proposed underwriters in connection with the contemplated initial public offering.

Forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In determining our historic forfeiture rate, we have excluded stock option grants totaling 1,133,862 shares issued to executives in February 2004. We believe these stock option grants will not be cancelled due to termination, and therefore have applied a forfeiture rate of 0% for those stock option grants. The annualized forfeiture rate used for the remaining stock option grants was 7%. The forfeiture rate selected did not have a material impact on stock-based compensation expense in the year ended December 31, 2006 or the three months ended March 31, 2007. Prior to adoption of SFAS 123R, we accounted for forfeitures of stock option grants as they occurred.

As a result of our Black-Scholes option fair value calculations and the allocation of value to the vesting periods using the straight-line vesting attribution method, we recognized $3.5 million of stock-based compensation expense in 2006, of which $8,000, $661,000, and $2.8 million were charged to cost of product sales, research and development expenses and selling, general and administrative expense, respectively. During the three months ended March 31, 2007, we recognized $940,000 of stock-based compensation expense, of which $4,000, $201,000 and $735,000 were charged to cost of product sales, research and development and selling, general and administrative expense, respectively. During the three months ended March 31, 2006, we recognized $820,000 of stock-based compensation expense, of which $1,000, $144,000 and $675,000 were charged to cost of product sales, research and development and selling, general and administrative expense, respectively. The adoption of SFAS 123R caused basic and diluted net loss per common share to increase by $267.71 in 2006. No income tax benefit was recognized in the statement of operations for 2006. Compensation cost capitalized as a component of inventory during 2006 was $18,000.

The total compensation cost related to unvested stock option grants not yet recognized as of March 31, 2007 was $7.2 million, and the weighted-average period over which these grants are expected to vest is 2.7 years.

Based on an assumed initial public offering price of $20.50 per share, the intrinsic value of stock options outstanding at March 31, 2007 was $6.3 million, of which $3.9 million and $2.4 million related to stock options that were vested and unvested, respectively, at that date.

Beneficial Conversion Feature

We account for potentially beneficial conversion features under Emerging Issues Task Force No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF Issue No. 00-27, *Application of Issue 98-5 to Certain Convertible Instruments*. In January and December 2006, we issued 2,319,264 and 4,307,211 shares, respectively, of Series B preferred stock and Series B Prime preferred stock at a purchase price of $15.09 per share. At the time of each of these issuances, the value of the common stock into which the Series B preferred stock and Series B Prime preferred stock is convertible had a fair value greater than the proceeds for such issuances. Accordingly, we recorded a deemed dividend on the Series B preferred stock and Series B Prime preferred stock of $3.5 million in January 2006 and $18.4 million in December 2006, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series B preferred stock and Series B Prime preferred stock exceeded the proceeds from such issuances.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include marketing and promotional materials, professional service fees, such as fees to lawyers and accountants, and contract service fees, such as amounts paid to clinical monitors, data management organizations, clinical research organizations and fees paid to contract manufacturers in conjunction with the production of clinical materials. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or overestimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to our judgment. We make these judgments in accordance with the facts and circumstances known to us through our internal processes. Our internal processes require substantially all of our spending for services to be under contracts with our service providers and to be documented and tracked under internally-generated purchase orders based on designated spending authorizations. As of each balance sheet date, company personnel who are responsible for managing the contracts, and who are in contact with the outside service providers as to progress or stage of completion of the services and the agreed upon fee to be paid for such services, review current contracts and the related open purchase orders. We adjust for spending not already reflected in our accounting records in accordance with generally accepted accounting principles. To date, there have been no material differences between the amounts of expenses accrued at our balance sheet dates and the amount at which such expenses were subsequently invoiced. Although we do not expect our current estimates to be materially different when invoiced, our understanding of the status and timing of services provided relative to the actual timing and levels of service provided may vary and may result in adjustments in future periods.

In-Process Research and Development

In connection with the acquisition of Orphan Medical, we recorded a charge of $21.3 million in 2005 for acquired in-process research and development. This amount represented the estimated fair value related to three

incomplete product candidate development projects for which technological feasibility had not been established and that had no alternative future use at the time of the acquisition.

The fair value of the in-process research and development was determined using the "income approach." This method requires a forecast of all the expected future net cash flows associated with the in-process technology discounted to present value by applying an appropriate discount rate. The discount rate used reflects the weighted-average cost of capital for companies in our industry, as well as specific risks associated with the cash flows being discounted.

In January 2005, Orphan Medical submitted a supplemental New Drug Application, or sNDA, to the FDA seeking an expanded label indication for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy. At the time of the acquisition, the FDA had not yet approved the sNDA. We used a discount rate of 26% to calculate the fair value of the expanded label indication for Xyrem and accounted for $15.2 million associated with the expanded label indication as in-process research and development expense. The sNDA was approved by the FDA in November 2005. At the time of acquisition, Orphan Medical was also conducting a Phase II clinical trial to evaluate the use of sodium oxybate, the active pharmaceutical ingredient in Xyrem, to treat fibromyalgia syndrome. We used a 50% discount rate to calculate the fair value associated with this development project and accounted for $5.9 million associated with the project as in-process research and development. In August 2006, we initiated a Phase III clinical trial of sodium oxybate for the treatment of fibromyalgia syndrome. In addition, at the time of acquisition, Orphan Medical was conducting initial research into new dosage forms of Xyrem. We used a 50% discount rate to calculate the fair value of these research efforts and accounted for $200,000 associated with this research to in-process research and development expense.

Results of Operations

Comparison of Three Months Ended March 31, 2006 and 2007

	2006	2007	Increase/ (Decrease)	% Increase/ (Decrease)
		(In thousands)		
Product sales, net	$ 9,771	$11,625	$ 1,854	19%
Royalties, net	66	211	145	220%
Contract revenues	—	2,252	2,252	N/A(1)
Cost of product sales	1,569	2,003	434	28%
Research and development expenses	12,894	14,867	1,973	15%
Selling, general and administrative expenses	12,219	14,339	2,120	17%
Amortization of intangible assets	2,400	2,362	(38)	(2)%
Interest income	581	1,091	510	88%
Interest expense	3,777	3,268	(509)	(13)%
Other income (expense)	62	(3,069)	(3,131)	N/A(1)
Gain on sale of product	—	5,145	5,145	N/A(1)

(1) No comparable data for prior quarter or comparison to prior quarter is not meaningful.

Product Sales, Net

The increase in product sales, net in the three months ended March 31, 2007 compared to the three months ended March 31, 2006 was primarily due to the growth of our Xyrem product sales, which increased by $2.5 million. The increase in Xyrem product sales was attributable to an increase in the price we charge Express Scripts instituted in August 2006 and, we believe, our investments in Xyrem marketing programs and sales training programs during 2006. Sales of Antizol and Antizol-Vet decreased by $495,000 in the three months ended March 31, 2007 compared to the three months ended March 31, 2006. Antizol is stocked by hospitals for use in emergency poisonings and sales are typically uneven from quarter to quarter. Sales of Cystadane decreased

by $122,000 in the three months ended March 31, 2007 compared to the three months ended March 31, 2006. This decrease resulted from the sale of our rights to Cystadane in March 2007.

Royalties, Net

The increase in royalties, net in the three months ended March 31, 2007 compared to the three months ended March 31, 2006 was primarily due to an increase in royalties on sales of Xyrem by UCB from $19,000 in the three months ended March 31, 2006 to $127,000, the pro rata portion of the minimum royalty payable pursuant to the agreement with UCB, in the three months ended March 31, 2007.

Contract Revenues

Contract revenues in the three months ended March 31, 2007 consisted of a $2.0 million milestone payment from UCB in March 2007, triggered by regulatory approval of Xyrem in Europe for the treatment of narcolepsy with cataplexy, and $252,000 related to the amortization of deferred revenues on $15.0 million of payments received in the second half of 2006 from UCB related to JZP-6. There were no contract revenues recognized in the three months ended March 31, 2006.

Cost of Product Sales

The increase in cost of product sales in the three months ended March 31, 2007 compared to the three months ended March 31, 2006 was primarily due to an increase in product sales. Cost of product sales in the three months ended March 31, 2007 increased to 17.2% of product sales as compared to 16.1% of product sales in the three months ended March 31, 2006, primarily due to a failed production run of Antizol.

Research and Development Expenses

Higher research and development expenses in the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 resulted primarily from our initial $2.0 million payment to Solvay in January 2007 for the exclusive right to market and distribute Luvox CR and Luvox in the United States under the terms of a product license agreement.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 primarily due to growth in headcount. This growth resulted in a $1.2 million increase in salaries and benefits and a $1.3 million related increase in departmental operating expenses. In addition, selling, general and administrative expenses in the three months ended March 31, 2007 include $1.0 million of legal costs associated with the U.S. Attorney’s investigation of activities by Orphan Medical related to the promotion of Xyrem. These increases were partially offset by a decrease of $1.4 million in product launch costs associated with an expanded label indication of Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy that we incurred in the three months ended March 31, 2006.

Amortization of Intangible Assets

Our intangible assets consist primarily of developed technology, agreements not to compete and trademarks, all of which were recorded as a result of the acquisition of Orphan Medical in June 2005, that are amortized on a straight-line basis over their estimated useful lives. Amortization costs in the three months ended March 31, 2007 were lower as compared to the three months ended March 31, 2006 as a result of the sale of our rights to Cystadane in March 2007.

Interest Income

Interest income was higher in the three months ended March 31, 2007 as compared to the three months ended March 31, 2006 primarily due to higher average cash balances.

Interest Expense

Interest expense in the three months ended March 31, 2007 primarily related to interest on our $80.0 million principal amount of senior secured notes. Interest on the notes was comprised of the accretion of a discount related to warrants that were issued in conjunction with the notes, amortization of debt issuance costs and quarterly cash payments for interest. In the three months ended March 31, 2006, interest expense also included $599,000 of accrued interest on the development financing of JZP-3.

Other Income (Expense)

On July 1, 2005, we adopted the provisions of Financial Accounting Standards Board, or FASB, Staff Position No. 150-5, *Issuer's Accounting under Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable*, or FSP 150-5, an interpretation of FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*, which required us to classify our preferred stock warrants as current liabilities and adjust the carrying value to fair value at the end of each reporting period. This resulted in $3.1 million of expense and a benefit of $62,000 in the three months ended March 31, 2007 and March 31, 2006, respectively. We will continue to adjust the liability for changes in the fair value of the warrants until the earlier of the exercise of the warrants to purchase shares of convertible preferred stock, at which time the liability will be reclassified to temporary equity, or the conversion of the underlying Series BB preferred stock into common stock, at which time the liability will be reclassified to stockholders' equity (deficit). Upon completion of this offering, any outstanding warrants will automatically become warrants to purchase common stock, and the liabilities will be reclassified to stockholders' equity.

Gain on Sale of Product

In March 2007, we entered into an agreement under which an unrelated third party purchased our rights to Cystadane, along with the associated product registrations, commercial inventory and trademarks, for $9.0 million in cash. In connection with this transaction, we recorded a $5.1 million gain in the three months ended March 31, 2007.

Comparison of Years Ended December 31, 2005 and 2006

	2005	2006	Increase/ (Decrease)	% Increase/ (Decrease)
		(In thousands)		
Product sales, net	$18,796	$43,299	$ 24,503	130%
Royalties, net	146	594	448	307%
Contract revenues	2,500	963	(1,537)	(61)%
Cost of product sales	4,292	6,968	2,676	62%
Research and development expenses	45,783	54,956	9,173	20%
Selling, general and administrative expenses	23,551	51,384	27,833	118%
Purchased in-process research and development	21,300	—	(21,300)	N/A(1)
Amortization of intangible assets	4,960	9,600	4,640	94%
Interest income	1,318	2,307	989	75%
Interest expense	7,129	14,129	7,000	98%
Other expense	901	1,109	208	23%
Gain on extinguishment of development financing obligation	—	31,592	31,592	N/A(1)

(1) No comparable data for comparable year.

Product Sales, Net

The increase in product sales, net in 2006 compared to 2005 was primarily due to the inclusion of only approximately six months of product sales in 2005, subsequent to our acquisition of Orphan Medical in June 2005, compared to a full year in 2006. Other factors affecting this increase included:

- expansion of the Xyrem sales force from 36 to 55 employees in late 2005;
- receipt from the FDA in November 2005 of expanded marketing approval for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy and a corresponding launch of the new indication in early 2006;
- increases in the price that we charge our central pharmacy for Xyrem of 6.4% and 7.7% in December 2005 and August 2006, respectively; and
- increases in the price that we charge our wholesale customers for Antizol of 4.2% and 5.0% in December 2005 and November 2006, respectively.

Royalties, Net

The increase in royalties, net in 2006 compared to 2005 was principally due to an increase in royalties on sales of Xyrem by UCB from $9,000 in 2005 to $305,000 in 2006. Royalties we received from other products accounted for the remainder of the increase.

Contract Revenues

Contract revenues in 2006 primarily consisted of a $500,000 milestone payment from UCB in June 2006, triggered by pricing approval in France for Xyrem, and amortization of deferred revenues on payments totaling $15.0 million from UCB in 2006 related to JZP-6. Contract revenues in 2005 consisted of a $2.5 million milestone payment from UCB received in November 2005, triggered by the approval by the European Agency for the Evaluation of Medical Products of Xyrem for the treatment of cataplexy associated with narcolepsy.

Cost of Product Sales

The increase in the cost of product sales in 2006 compared to 2005 was primarily due to the inclusion of a full year of product sales in 2006 compared to approximately six months of product sales in 2005, subsequent to our acquisition of Orphan Medical in June 2005. Our gross margin increased from 77% in 2005 to 84% in 2006. The primary reason for this increase was a lower fair value adjustment to inventory acquired as part of the acquisition of Orphan Medical in 2006 compared to 2005. Our cost of product sales reflected a fair value adjustment of $1.6 million and $775,000 during 2005 and 2006, respectively. This fair value adjustment will not have a material impact on cost of product sales in future periods.

Research and Development Expenses

Higher research and development expenses in 2006 as compared to 2005 resulted primarily from higher spending in 2006 on early phase development and preclinical studies, along with higher salaries and benefits expenses related to a growth in research and development headcount during 2006. Research and development expenses did not increase substantially as a result of the Orphan Medical acquisition. Although total spending on late-stage programs did not change substantially from 2005 to 2006, the components of spending on late-stage programs changed. During 2005, a substantial portion of our research and development expenses related to JZP-3, and, during 2006, a substantial portion of our research and development expenses were attributable to JZP-3 and JZP-6.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in 2006 than in 2005 as a result of a number of factors, including:

- inclusion of only six months of Xyrem sales and marketing activities in 2005, compared to a full year of activities in 2006;
- costs associated with the launch of a new indication for Xyrem in early 2006;
- an increase in the Xyrem sales force from 36 at the time of the Orphan Medical acquisition to 55 in November 2005;
- outside legal costs of $5.4 million incurred during 2006 in connection with an investigation by the U.S. Attorney's Office of activities related to the promotion of Xyrem;
- building a medical affairs department; and
- an increase in headcount and related salaries and benefits.

Purchased In-process Research and Development

In connection with our June 2005 acquisition of Orphan Medical, we recorded a charge of $21.3 million for acquired in-process research and development, representing the estimated fair value related to three incomplete projects for which, at the time of the acquisition, technological feasibility had not been established and that had no alternative future use.

Amortization of Intangible Assets

Amortization expense was higher in 2006 as compared to 2005 primarily due to the inclusion of only six months of amortization in 2005 as compared to a full year of amortization in 2006.

Interest Income

Interest income was higher in 2006 as compared to 2005 primarily due to higher average balances of investable assets coupled with higher interest rates.

Interest Expense

Interest expense primarily related to interest on our $80.0 million principal amount of senior secured notes and interest on the development financing of JZP-3, both of which were recorded using the effective interest method. $5.6 million of the increase in interest expense in 2006 as compared to 2005 was attributable to the fact the notes were outstanding for the full year in 2006. Interest expense related to the development financing was $445,000 in 2005, compared with $1.1 million 2006.

Other Expense

We recorded $901,000 and $1.1 million of expense as a result of an increase in the fair value of our preferred stock warranty liability in 2006 and 2005, respectively.

Gain on Extinguishment of Development Financing Obligation

In August 2005, we entered into an agreement with a third party under which the third party agreed to provide $30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development. We were obligated to repay the third party $37.5 million subject to, and conditioned upon, approval by the FDA to market the product in the United States. In addition, we agreed to pay royalties at specified rates based on sales

of the product within the United States. Under that agreement, we received $15.0 million in 2005 and $15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development of JZP-3 and not to seek product marketing approval from the FDA. As of the date we notified the third party of our intention to discontinue development of JZP-3, we had recorded $31.6 million for future possible payments as a liability on our balance sheet, of which $30.0 million related to principal and $1.6 million related to interest accrued using the effective interest method. As a result of our notification, we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3, and we recorded a gain of $31.6 million resulting from the extinguishment of liabilities related to this development financing.

Comparison of Years Ended December 31, 2004 and 2005

	2004	2005	Increase	% Increase
		(In thousands)		
Research and development expenses	$17,988	$45,783	$27,795	155%
Selling, general and administrative expenses	7,459	23,551	16,092	216%
Interest income	643	1,318	675	105%

Effect of Orphan Medical Acquisition

Our June 2005 acquisition of Orphan Medical caused a significant change in our business and results of operations. The following line items were not applicable to our 2004 results of operations but became applicable in 2005 as a result of the acquisition:

- all product sales, net and cost of product sales during 2005 related to sales of our Xyrem, Antizol and Cystadane products acquired in connection with our acquisition of Orphan Medical;
- royalties, net recorded in 2005 related primarily to a product that Orphan Medical had divested in 2003;
- contract revenues in 2005 consisted of a $2.5 million milestone payment from UCB in November 2005, triggered by the approval by the European Agency for the Evaluation of Medical Products of Xyrem for the treatment of cataplexy associated with narcolepsy;
- acquired in-process research and development charge recorded in 2005 represented the estimated fair value related to three incomplete projects for which, at the time of the Orphan Medical acquisition, technological feasibility had not been established and that had no alternative future use; for additional information regarding this in-process research and development charge, see Note 5 to our financial statements appearing elsewhere in this prospectus;
- amortization expense recorded during 2005 related to developed technology, agreements not to compete and trademarks, all of which were recorded as a result of the acquisition of Orphan Medical; see Note 5 to our financial statements appearing elsewhere in this prospectus for more information regarding intangible assets and related amortization;
- interest expense during 2005 related to interest on the $80.0 million principal amount of senior secured notes issued in connection with the Orphan Medical acquisition; and
- we adopted the provisions of FSP 150-5 on July 1, 2005, which required us to classify our preferred stock warrants as current liabilities and adjust the carrying value to fair value at the end of each reporting period. This resulted in $901,000 of expense in 2005 arising from the increase in value of preferred stock warrants.

Research and Development Expenses

The increase in research and development expenses in 2005 compared to 2004 was primarily due to more activity and higher spending in 2005 on the Phase III clinical development of JZP-3, a product candidate that we initiated in the second half of 2004 and discontinued in mid-2006. We made an initial payment of $5.0 million to

a third party in July 2005 for the North American rights to a product candidate, the development of which was terminated in late 2005. The remainder of the increase primarily related to salaries and benefits expenses associated with increased headcount.

Selling, General and Administrative Expenses

The majority of the increase in 2005 selling, general and administrative expenses compared to 2004 was due to selling expenses incurred following the acquisition of Orphan Medical in June 2005, primarily related to Xyrem promoting and marketing activities in the United States. At the time of the acquisition, we retained all of the Orphan Medical sales force, consisting of 32 specialty sales consultants and 4 sales managers focused on selling Xyrem. In November 2005, we added 19 additional employees to the sales force. In addition to these expenses, salaries and benefits expenses increased because of increases in headcount in our commercial and general and administrative organizations.

Interest Income

The increase in interest income in 2005 as compared to 2004 was driven primarily by higher interest rates in 2005 than in 2004.

Liquidity and Capital Resources

Since our inception, we have incurred significant net losses, and, as of March 31, 2007, we had an accumulated deficit of $197.2 million. We have not achieved profitability, and we anticipate that we will continue to incur net losses for the next several years. We expect that our development, selling, marketing and general and administrative expenses will continue to increase and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability. Our audit report in our 2006 consolidated financial statements contains an explanatory paragraph stating that our recurring losses from operations and cash used in operating activities raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern. If we are unable to successfully complete this offering, we will need to execute alternative financing or operational plans to continue as a going concern.

Our operations have been financed primarily through the sale of convertible preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates and our collaboration with UCB related to one of our products and product candidates. In addition to amounts received from UCB, we have raised a total of $375.0 million (net of issuance costs), as follows:

Date	Amount (In thousands)	Financing
April 2003	$ 2,078	Series A convertible preferred stock
August 2003	4,998	Series A convertible preferred stock
January 2004	7,850	Series A convertible preferred stock
February 2004	48,683	Series B and B Prime convertible preferred stock
April 2004	400	Series B convertible preferred stock
June 2005	99,853	Series B and B Prime convertible preferred stock
June 2005	77,999	Senior secured notes and warrants(1)
July 2005 – February 2006	30,000	Project-specific financing(2)
January 2006	34,990	Series B and B Prime convertible preferred stock
December 2006	65,000	Series B and B Prime convertible preferred stock
September 2006 – March 2007	3,104	Line of credit(3)

(1) In June 2005, we issued $80.0 million aggregate principal amount of 15% senior secured notes and warrants to purchase 785,728 shares of our Series BB convertible preferred stock to certain third parties, some of whom are affiliated with investors in our preferred stock. Cash interest payments of $12.0 million per year are due on the notes, payable quarterly in arrears. The principal of $80.0 million is due

in full in June 2011. Under the terms of the notes we are required to maintain a minimum cash balance of $12.0 million, which is shown as long-term restricted cash and investments on our consolidated balance sheet. The notes contain customary covenants, including limitations on our ability to pay dividends, make investments or other restricted payments, incur debt, grant liens, sell assets or enter into sale-leaseback transactions. Upon the occurrence of certain events, we may be required to repay the notes at a premium. At our option, the notes can be repaid prior to June 2011 by paying a premium, which was 28.3% of the principal amount of the notes as of March 31, 2007 and is reduced to zero ratably over the remaining term of the notes.

(2) In August 2005, we entered into an agreement with a third party under which the third party agreed to provide $30.0 million to fund a Phase III clinical trial of JZP-3, a product candidate then in development. Under that agreement, we received $15.0 million in 2005 and $15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development of JZP-3 and not to seek product marketing approval from the FDA. As a result of our notification, we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization of JZP-3.

(3) In September 2006, we entered into a one year line of credit agreement with a financial institution under which we may borrow up to 80% of eligible accounts receivable, up to a maximum of $5.0 million of borrowings. Borrowings under the line of credit bear interest at the financial institution's prime rate, which was 8.25% as of March 31, 2007. At March 31, 2007, $3.1 million was outstanding under the agreement. See Note 7 to our financial statements appearing elsewhere in this prospectus for additional information.

As of March 31, 2007, we had $67.7 million in cash and cash equivalents, excluding $12.4 million in restricted cash required to be retained at all times pursuant to our senior secured notes and certain other agreements, held primarily in obligations of U.S. government agencies, corporate debt securities and money market funds.

The following table shows a summary of our cash flows for the periods indicated:

	Years ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
			(In thousands)	(Unaudited)	
Cash provided by (used in):					
Operating activities	$(21,156)	$ (52,162)	$ (57,350)	$(21,913)	$(20,914)
Purchases of property and equipment	(992)	(1,413)	(1,682)	(121)	(271)
Acquisition of Orphan Medical	—	(146,116)	—	—	—
Other investing activities	(5,796)	(6,225)	175	—	8,915
Financing activities	57,162	192,852	117,191	49,994	989

Net cash used in operating activities during the three months ended March 31, 2007 primarily reflected the net loss and changes in working capital, offset in part by depreciation and amortization and the change in the preferred stock warrant liability. Net cash used in operating activities in 2006 primarily reflected the net loss, less the gain on extinguishment of development financing, offset in part by depreciation and amortization and changes in working capital. Net cash used in operating activities in 2005 primarily reflected the net loss offset in part by depreciation and amortization, in-process research and development and changes in working capital. Net cash used in investing activities related to the purchase, sale and maturity of short-term investments used to fund the day-to-day needs of the business. In addition, investing activities during the three months ended March 31, 2007 included proceeds of $9.0 million from the sale of our rights to Cystadane. Purchases of property and equipment have not been material to date. Net cash provided by financing activities was primarily attributable issuance of stock, notes and project specific financing, as discussed above.

We believe that our current cash, cash equivalents and marketable securities and the anticipated net proceeds from this offering, and interest earned thereon, together with anticipated revenues from product sales, royalties and funding that we expect to receive from our current collaboration arrangement with UCB, will be sufficient to satisfy our current operations for the next 12 to 15 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available financial resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the amount of sales and other revenues from our commercial products, including selling prices for products that we may begin selling and price increases for our current products;

- market acceptance of and the number of prescriptions written for our products;
- promotional and marketing costs associated with Luvox CR and Xyrem in the United States, including the cost and timing of expanding our marketing and sales capabilities;
- revenues from current and potential future development and/or commercial collaboration partners;
- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the number and characteristics of product candidates that we pursue;
- the cost and timing of establishing clinical and commercial supplies of our product candidates;
- the cost and timing of obtaining regulatory approval;
- payments of milestones to third parties;
- hiring of new employees to support our continued growth;
- the cost of investigations, litigation and/or settlements, in particular the investigation by the U.S. Attorney for the Eastern District of New York;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the extent to which we acquire, in-license or invest in new businesses, products or product candidates.

We will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through development financings, collaborations, or public or private debt or equity financings. If we raise funds through collaborations, we may be required to relinquish, on terms that are not favorable to us, rights to some of our product candidates that we would otherwise seek to develop or commercialize ourselves. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development of our product candidates or commercialization of our products. Our failure to raise capital when needed may harm our business and operating results.

Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2006:

	Payments due by period				
Contractual Obligations(1)	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
			(In thousands)		
Senior secured notes(2)	$ 133,800	$12,000	$24,000	$97,800	$ —
Line of credit	2,191	2,191	—	—	—
Operating lease obligations(3)	2,411	1,227	1,167	17	—
Other obligations(4)	1,543	1,543	—	—	—
Total	$139,945	$16,961	$25,167	$97,817	$ —

(1) Milestone payments and royalty payments under our license and collaboration agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.

(2) On June 24, 2005, to partially finance the acquisition of Orphan Medical, we issued $80.0 million of senior secured notes. The notes bear interest at a rate of 15% per annum, payable quarterly in arrears. The amounts in the table above include interest and principal repayments on these notes. See Note 7 to our consolidated financial statements appearing elsewhere in this prospectus for additional information.

(3) Includes the minimum rental payments for our corporate office building in Palo Alto, California and automobile lease payments for the sales force. In March 2007, we entered into a lease agreement for approximately 13,000 square feet of office space in Palo Alto, California, which is not reflected in the table above. The annual lease payments for this space are approximately $460,000. The fixed term expires in August 2008, after which we may extend the term for up to six months subject to certain conditions.

(4) Consists of commitments to third party manufacturers of two of our commercial products. Does not include obligations under contracts with a contract research organization that are not cancellable without the payment of liquidated damages of $3.1 million.

The table above reflects only payment obligations for development products that are fixed and determinable. We also have contractual payment obligations, the amount and timing of which are contingent upon future events. Amounts and estimated timing of significant payments related to licensing and other arrangements not included in the contractual obligations table above are as follows:

- In January 2007, we entered into a product license agreement with Solvay for the right to market and distribute Luvox and Luvox CR in the United States. Under the terms of the agreement, we made a $2.0 million payment upon execution of the agreement, and we are required to make additional payments of up to $138.0 million if various commercial and development milestones are achieved. These payments include $10.0 million triggered by FDA marketing approval for the first indication for Luvox CR, $5.0 million triggered by FDA marketing approval for the second indication for Luvox CR, $13.0 million triggered by the first commercial sale of Luvox CR, $8.0 million triggered by the first commercial sale of Luvox CR after FDA approval of the second indication and $5.0 million triggered by FDA approval of a Luvox CR label with expiration dating of at least 18 months, any or all of which could occur in late 2007 or early 2008. In addition, we agreed to pay royalties at specified rates based on net product sales.
- In October 2004, we entered into an agreement with GlaxoSmithKline to acquire worldwide rights to the active pharmaceutical ingredient in JZP-4. We paid $2.0 million upon execution of the agreement and $3.0 million in July 2006 upon achievement of a development milestone. We also agreed to pay up to $113.5 million upon the achievement of future development and commercial milestones and royalties at specified rates based on net product sales. We will owe a $5.0 milestone payment to GlaxoSmithKline upon the enrollment of the first patient in a JZP-4 Phase II clinical trial, which could occur as early as late 2007.

Recent Accounting Pronouncements

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We adopted the provisions of FIN 48 effective January 1, 2007. No cumulative adjustment to our accumulated deficit was required upon adoption.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, or SAB 108. SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of our balance sheets and statement of operations and the related financial statement disclosures. SAB 108 was adopted by us in the first quarter of 2007. We have determined that the adoption of SAB 108 has no material effect on our results of operations or financial position.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and is required to be adopted by us effective January 1, 2008. We are currently evaluating the effect that the adoption of SFAS 157 will have on our results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Most of the provisions in SFAS 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS 159 will have on our results of operations and financial position.

Off-Balance Sheet Arrangements

Since inception, except for standard operating leases, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is confined to our cash, cash equivalents and restricted cash and investments, all of which have maturities of less than one year. The goals of our investment policy are liquidity and capital preservation. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including U.S. government agencies, corporate bonds, commercial paper and money market funds. Our cash and investments as of March 31, 2007 consisted primarily of obligations of United States government agencies and money market funds.

Our senior secured notes have fixed interest payments, and, therefore, we are not subject to market risk with respect to this debt. Our line of credit bears interest at the prime rate of the financial institution from which we borrow, which is subject to change. However, interest expense in connection with this facility is not material.

We have no operations outside the United States, and almost all of our operating expenses and capital expenditures are denominated in United States dollars. We receive royalties on certain net product sales that are denominated in other currencies, primarily in Euro, but these royalties comprise a small portion of our revenues.

BUSINESS

Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development and acquisition and in-licensing activities and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies, we also explore potential new indications for known drug compounds. Since our inception in 2003, our experienced executive management team has built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of $41.9 million in 2006, one product candidate for which an approvable letter has been issued by the U.S. Food and Drug Administration, or FDA, and five product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our marketed products and late-stage product candidates are:

- *Xyrem (sodium oxybate) oral solution*. Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain's inability to regulate sleep-wake cycles normally. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our 55 person specialty sales force. We have significantly increased domestic net product sales of Xyrem since our acquisition of Orphan Medical, Inc. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB has commercially launched Xyrem in 12 countries. In 2006, Xyrem represented $29.0 million, or 69%, of our net product sales from our currently marketed products.
- *Antizol (fomepizole)*. Antizol is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisonings in dogs. In 2006, Antizol and Antizol-Vet represented $12.8 million, or 31%, of our net product sales from our currently marketed products.
- *Luvox CR (fluvoxamine maleate extended release capsules).* Our most advanced product candidate is Luvox CR, an extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, which has been developed for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are a class of antidepressants used in the treatment of depression, anxiety disorders and some personality disorders. According to the National Institute of Mental Health, obsessive compulsive disorder and social anxiety disorder affect approximately 2.2 million and 15 million adults in the United States, respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Solvay submitted a new drug application, or NDA, to the FDA for Luvox CR in April 2006, and, in February 2007, the FDA issued an approvable letter to Solvay. Subject to the satisfaction

of the requirements set forth in the approvable letter and FDA approval, we expect to commence promotion of Luvox CR in the United States in the first quarter of 2008 through a significantly expanded specialty sales force. During 2007, we expect to make significant expenditures relating to the planned commercial launch of Luvox CR.

- *JZP-6 (sodium oxybate).* We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia syndrome. According to the American College of Rheumatology, between two and four percent of the U.S. population suffers from fibromyalgia syndrome. There are currently no products approved by the FDA for the treatment of fibromyalgia syndrome. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia syndrome. We are currently conducting two Phase III pivotal clinical trials, and we expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. In Phase II clinical trials, JZP-6 demonstrated statistically significant improvement in the composite endpoint accepted by the FDA and the European Agency for the Evaluation of Medicinal Products as the primary endpoint for our Phase III pivotal clinical trials. Subject to successful completion of Phase III clinical trials, we plan to submit an NDA for JZP-6 by late 2009. If our NDA is approved by the FDA, we expect to market JZP-6 in the United States to rheumatologists and other specialists who treat fibromyalgia syndrome patients through an expanded specialty sales force. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

In addition to our product candidates in late-stage development, our clinical development pipeline consists of the following product candidates:

- *JZP-4 (type IIa sodium channel antagonist).* JZP-4, a controlled release formulation of an anticonvulsant that is in the same chemical class as Lamictal (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline, or GSK, is being developed for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy, and, according to the National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder.
- *JZP-8 (benzodiazepine).* JZP-8, a novel formulation incorporating a benzodiazepine, is being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who have been unresponsive to previous treatments. Recurrent acute repetitive seizures are bouts of multiple seizures occurring over a short period of time. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are unresponsive, or refractory, to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures.
- *JZP-7 (dopamine agonist).* JZP-7, a novel formulation incorporating a dopamine agonist, is being developed for the treatment of restless legs syndrome. Dopamine is naturally produced by the human body, and in the brain, dopamine functions to help nerve cells communicate. A dopamine agonist is a drug compound that mimics the effects of dopamine. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome.
- *JZP-2 (benzodiazepine).* JZP-2, a formulation of a benzodiazepine that is designed to enter the bloodstream faster than a dose from a conventional tablet form, is being developed for the acute, or short-term, treatment of panic attacks associated with panic disorder. Benzodiazepines are a class of psychoactive drugs with varying hypnotic, sedative, anti-anxiety, anticonvulsant, muscle relaxant and amnesic properties. According to the National Institute of Mental Health, approximately six million people in the United States suffer from panic disorder in any given year.

We have an ongoing program for generating, identifying and conducting feasibility studies for new product candidates. Our JZP-2, JZP-7 and JZP-8 product candidates resulted from this program. Several other product candidates identified through this program are in various stages of early development, including the use of

sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of movement disorders. We are working on ways to expand our Xyrem franchise by developing improvements to Xyrem, such as new dosage forms that could be more convenient for patients. These activities are in the early stages of development.

Our executive management team has substantial experience in developing and commercializing novel therapeutic products. During their ten years working together as part of the executive management team at ALZA Corporation, a pharmaceutical company acquired by Johnson & Johnson in 2001, our executive management team participated in the successful development and commercialization of a broad portfolio of products and product candidates to address specialized markets.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company developing and commercializing new medicines in neurology and psychiatry and, over the longer term, in additional specialty therapeutic areas. Key elements of our strategy to achieve this goal include:

- *Focusing on specialty markets of neurology and psychiatry.* We will continue to focus our activities in specialty markets, particularly neurology and psychiatry, where our specialty sales force can establish strong relationships with the relatively small number of healthcare providers who write a large percentage of prescriptions for the indications we target. We have targeted neurology and psychiatry because we believe that these therapeutic areas provide numerous opportunities to improve upon existing treatments and to commercialize the products we develop through our commercial organization. In the future, we may seek to expand into additional specialty markets in which we believe there are attractive opportunities to develop novel therapies and to leverage our commercial organization.
- *Expanding and leveraging our focused U.S. sales and marketing capabilities.* We currently have a focused and experienced 55 person specialty sales force promoting Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists. We expect to expand and leverage this sales force to promote and sell additional products for target indications in which specialists significantly influence the market. For example, we expect to significantly expand our commercial organization, including our sales force, to market Luvox CR to psychiatrists in the United States, subject to receipt of FDA approval. We intend to complete our ongoing Phase III clinical trials of JZP-6 for the treatment of fibromyalgia syndrome and, subject to regulatory approval, to market this product in the United States to rheumatologists and potentially, through a co-promotion arrangement or contract sales organization, to primary care physicians. For international markets, we intend to establish commercialization partnerships with other pharmaceutical companies to accelerate the introduction of our products outside of the United States and to maximize the commercial opportunity for these products.
- *Mitigating risks and reducing the costs and time associated with the development and commercialization of products.* We seek to mitigate the risks and reduce the costs and time associated with product development by focusing on known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products. We intend to continue to apply rigorous development criteria designed to provide us with the basis to make efficient development decisions with respect to each of our product candidates as early as possible in the development process. We also seek to structure our development and commercial relationships, including our strategic licenses and acquisitions of products and product candidates, to minimize financial risk until we can effectively demonstrate a significant likelihood of commercial success.
- *Continuing to expand our product portfolio.* We will continue to identify and develop through our internal research and development efforts product candidates that we believe have significant commercial potential. We will also seek to continue to acquire and in-license product candidates and products to complement our portfolio, enabling us to make efficient use of our commercial

organization. We continually assess our existing portfolio to ensure a mix of late-stage and earlier-stage opportunities, advancement of product candidates in our target markets and a balance of expected risk and return.

- *Leveraging the expertise of our experienced executive management team.* We intend to continue to leverage the expertise of our experienced executive management team in developing and commercializing novel therapeutic products. We will also seek to capitalize on our executive management team's expertise in identifying and pursuing the most effective mix of financings and collaborations to address our capital needs and limit the risk profile of our product pipeline. Since our inception, we have raised over $400 million from a range of sources, including equity, debt and development financings, and we have engaged in various collaborations related to our product candidates to limit our product development risk.

Products and Product Candidates

Product/Product Candidate	Active Pharmaceutical Ingredient/Mechanism of Action	Primary Indication(s)	Status	Commercialization Rights
Xyrem	Sodium oxybate	Cataplexy and excessive daytime sleepiness in patients with narcolepsy	Marketed	U.S. and countries not licensed to UCB or Valeant
Antizol	Fomepizole	Ethylene glycol and methanol poisoning	Marketed	Worldwide
Luvox CR	Fluvoxamine maleate	Obsessive compulsive disorder Social anxiety disorder	Approvable letter issued	U.S.
Luvox	Fluvoxamine maleate	Obsessive compulsive disorder	Approvable letter issued	U.S.
JZP-6	Sodium oxybate	Fibromyalgia syndrome	Phase III	U.S. and countries not licensed to UCB
JZP-4	Type IIa sodium channel antagonist	Epilepsy Bipolar disorder	Phase I/II	Worldwide
JZP-8	Benzodiazepine	Recurrent acute repetitive seizures	Phase II	Worldwide
JZP-7	Dopamine agonist	Restless legs syndrome	Phase I/II	Worldwide
JZP-2	Benzodiazepine	Panic attacks	Phase I/II	Worldwide

Marketed Products

Xyrem (sodium oxybate oral solution)

Xyrem is a sodium oxybate oral solution approved in the United States for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy. Sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a formulation of the sodium salt of g-hydroxybutyrate, an endogenous neurotransmitter and metabolite of g-aminobutyric acid. Xyrem is currently the only FDA-approved treatment for both cataplexy and excessive daytime sleepiness in patients with narcolepsy. In 2006, our net product sales of Xyrem were $29.0 million.

Market Opportunity

Narcolepsy is a chronic neurologic disorder caused by the brain's inability to regulate sleep-wake cycles normally. According to the National Institutes of Health, 150,000 or more individuals in the United States are

affected by narcolepsy. The primary symptoms of narcolepsy include excessive daytime sleepiness, cataplexy, sleep paralysis, hallucinations and fragmented nighttime sleep. These symptoms can lead to a variety of complications, such as limitations on education and employment opportunities, driving or machine accidents, difficulties at work resulting in disability, forced retirement or job dismissal, and depression.

Cataplexy. Cataplexy, the sudden loss of muscle tone, is the most well-recognized symptom of narcolepsy. According to a 1996 article published in *Neurologic Clinics*, cataplexy is present in between 60% and 100% of patients with narcolepsy. Cataplexy can range from slight weakness or a drooping of the face to the complete loss of muscle tone and it is often triggered by strong emotional reactions such as laughter, anger or surprise.

Excessive Daytime Sleepiness. Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. Excessive daytime sleepiness results in the individual becoming drowsy or falling asleep, often at inappropriate times and places.

Attributes of Xyrem

Xyrem is the only product approved by the FDA to treat both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Xyrem is administered at night and quickly metabolized so that during the daytime, very little of the active drug is present in the patient. Xyrem has a well established safety profile. As published in *SLEEP* in 2002, the Phase III clinical trial results indicated that Xyrem significantly increased daytime wakefulness and reduced cataplexy attacks in patients with narcolepsy. Approximately 80% of patients in Phase III clinical trials maintained concomitant stimulant use. As published in *Sleep Medicine* in 2004, clinical trial results indicated that Xyrem is an effective treatment for the long-term management of cataplexy in patients with narcolepsy.

Product Development

In June 2005, we obtained the rights to Xyrem as a result of our acquisition of Orphan Medical. Initial FDA approval for Xyrem as a treatment for cataplexy in patients with narcolepsy was obtained in July 2002. In November 2005, the FDA approved a supplemental NDA, or sNDA, for the treatment of excessive daytime sleepiness in patients with narcolepsy.

Commercialization

We promote Xyrem in the United States through our 55 person specialty sales force. Pursuant to an agreement originally executed in 2003 and subsequently amended, we have licensed to UCB the exclusive right to register and market Xyrem for the treatment of narcolepsy in 54 countries throughout Europe, South America, the Middle East and Asia in exchange for milestone and royalty payments to us. Pursuant to the original agreement, UCB and its predecessor paid upfront and milestone payments totaling $9.5 million in connection with Xyrem for the treatment of narcolepsy. UCB has commercially launched the product in 12 countries. In October 2005, the European Agency for the Evaluation of Medical Products approved the product for the treatment of cataplexy in adult patients with narcolepsy, and in March 2007, the European Agency for the Evaluation of Medical Products approved the product for the treatment of narcolepsy with cataplexy in adult patients. In December 2006, we licensed to Valeant the Canadian marketing rights to Xyrem for the treatment of narcolepsy, subject to our right to later reacquire these rights. We expect Valeant to launch the product in Canada in 2007.

In June 2006, we significantly expanded the scope of our agreement with UCB to cover JZP-6, our product candidate for the treatment of fibromyalgia syndrome in exchange for additional upfront and milestone payments. We are entitled to additional commercial milestone payments of up to $6.0 million specifically associated with Xyrem and royalties on all commercial sales of Xyrem and JZP-6 by UCB under this amended agreement. The term of our agreement with UCB, as it applies to Xyrem, extends to the later of the expiration of our associated patent rights in the territories covered by the agreement or ten years from the date of European

Agency for the Evaluation of Medical Products approval to commercially promote and distribute the product for the treatment of narcolepsy, subject to automatic extension unless and until UCB terminates the agreement upon not less than 12 months' notice. UCB may terminate our agreement for any reason upon 18 months' notice. We are responsible for supplying Xyrem to UCB and Valeant in exchange for supply price payments. Beginning in 2008, if we are materially unable to comply with our obligations to supply Xyrem to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months' notice.

The FDA has granted Xyrem orphan drug exclusivity in the United States for both cataplexy and excessive daytime sleepiness in patients with narcolepsy. This provides marketing exclusivity in the United States until July 2009 for the cataplexy indication and November 2012 for the excessive daytime sleepiness indication, which exclusivity periods run concurrently with a period of five-year new chemical entity exclusivity period expiring in July 2007. In addition to orphan drug exclusivity, Xyrem is covered by a formulation patent that is listed in the FDA's approved drug products with therapeutic equivalence evaluation document, or Orange Book, and expires in 2019, and a process patent that expires in 2019. The Orange Book, among other things, lists drug products approved by the FDA and identifies applicable patent and non-patent marketing exclusivities. The listing of our formulation patent in the Orange Book may require potential competitors to certify as to non-infringement or invalidity of the patent prior to FDA approval of their product candidates. A patent application covering Xyrem's distribution system is currently pending, and the patent, if issued, would expire in 2022. In addition, we believe that the strict manufacturing and distribution controls on sodium oxybate and Xyrem, and the complicated risk management procedures required to market and sell the product, may make it difficult for other companies to manufacture and market generic formulations of Xyrem.

Our marketing and sale of Xyrem is subject to a risk management program required by the FDA and the U.S. Drug Enforcement Agency, or DEA, in conjunction with Xyrem's approval by the FDA. Under the Xyrem risk management program, Xyrem must be distributed through a single central pharmacy, Express Scripts Specialty Distribution Services, Inc., or Express Scripts. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy must verify the prescription and obtain additional information by contacting the physician's office and the patient's insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign for the package. The initial shipment may only be for a one-month supply, and patients may not receive more than a three-month supply at any time.

Pursuant to our agreement with Express Scripts, Express Scripts provides distribution and other customer support services to us related to the sale and marketing of Xyrem in the United States. We are billed monthly for the services performed by Express Scripts. The term of the agreement with Express Scripts expires on July 31, 2008, subject to automatic one-year extensions thereafter until either party provides notice to the other of its intent to terminate the agreement at least 120 days prior to the end of the term. We may terminate the agreement with Express Scripts upon five days' notice if Express Scripts is not in compliance with applicable regulatory requirements.

We have contracted separately with third parties to supply the sodium oxybate used to produce Xyrem and to manufacture the product. We rely on a single source for our supply of sodium oxybate. Quotas from the DEA are required in order to manufacture and package sodium oxybate. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for the request, obtaining a DEA quota is a difficult and time consuming process.

Competition

As an alternative to Xyrem, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, although none of these compounds has been approved by the FDA for the treatment of cataplexy. Tricyclic antidepressants are a class of antidepressant drugs first used in the 1950s. The use of these drugs can often result in somnolence, which exacerbates excessive daytime sleepiness already experienced by all patients with narcolepsy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil (modafinil). Xyrem and Provigil are both approved for the treatment of excessive daytime sleepiness in patients with narcolepsy, but Xyrem is also approved for the treatment of cataplexy, the most well-recognized symptom of narcolepsy. Provigil is also approved for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder, which may help make it more well-known to physicians and patients.

Xyrem is a liquid solution that is taken twice nightly. Provigil is a pill that is usually taken once in the morning for excessive daytime sleepiness by patients with narcolepsy. Provigil is distributed by numerous pharmacies. Xyrem's risk management program requires that it be distributed in the United States through a single central pharmacy, and it takes longer for a patient to receive medicine under the Xyrem distribution system than it takes to fill a typical prescription at a pharmacy. Xyrem is administered at night and can be used in conjunction with Provigil, which is administered during the day. During the pivotal Phase III trials of Xyrem, approximately 80% of patients maintained concomitant stimulant use, and clinical trial results indicated that Xyrem reduced the severity of daytime sleepiness when used alone or in combination with stimulants during the day.

Antizol (fomepizole)

Antizol, an injectable formulation of fomepizole, is the only FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. According to the 2005 annual report of the American Association of Poison Control Centers, more than 6,000 exposures to ethylene glycol were reported in the United States in 2005, resulting in 41 fatalities. More than 2,300 exposures to methanol were reported in the United States in 2005, resulting in 13 fatalities. If ingested, ethylene glycol, commonly found in antifreeze, and methanol, commonly found in windshield wiper fluid, can lead to death or permanent, serious physical damage. When administered promptly after ingestion of either of these poisons, Antizol inhibits the formation of toxic metabolites and helps prevent renal damage or death. Guidelines issued by the American Academy of Clinical Toxicologists have established Antizol as the standard of care for such poisonings.

In 2006, our net product sales of Antizol were $12.5 million. We obtained the rights to Antizol in connection with our acquisition of Orphan Medical. Orphan Medical had obtained the worldwide rights to develop and market Antizol through a sublicense agreement with Mericon Investment Group. The license expires in July 2013, subject to a five-year renewal option that may be exercised by either party. We pay Mericon quarterly royalties on sales of Antizol through the duration of the sublicense.

Antizol is primarily used in a hospital setting, and we estimate that over one-third of all U.S. hospitals with emergency rooms currently stock the product. We market the product primarily to hospitals and emergency rooms. In addition to domestic sales, Antizol is marketed by our distributors in Canada and Israel.

We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisonings in dogs. In 2006, our net product sales of Antizol-Vet were $313,000.

Product Candidates

Luvox CR (fluvoxamine maleate extended release capsules)

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox CR, an extended release formulation of fluvoxamine maleate developed by Solvay in collaboration with Elan, is a selective serotonin reuptake inhibitor for which Solvay is seeking approval from the FDA for the treatment of obsessive compulsive disorder and social anxiety disorder. Luvox, an immediate release formulation of fluvoxamine maleate, was previously approved by the FDA and marketed by Solvay for the treatment of obsessive compulsive disorder, and generic fluvoxamine remains one of the leading treatments for the disorder. Luvox CR incorporates extended release beads designed to provide delivery of fluvoxamine with lower peak plasma levels compared to the immediate-release formulation. In February 2007, the FDA issued an approvable letter to Solvay for Luvox CR setting forth certain conditions necessary for receiving approval to market Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder. Subject to satisfaction of the conditions set forth in the approvable letter and approval by the FDA, we expect to commence promotion of Luvox CR in the first quarter of 2008.

Market Opportunity

Obsessive Compulsive Disorder. Obsessive compulsive disorder is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health, Obsessive compulsive disorder affects approximately 2.2 million adults in the United States. According to an article published in the *International Journal of Clinical Practice*, it is estimated that 60% of patients with obsessive compulsive disorder worldwide receive no treatment for their disorder. As physicians have improved their ability to recognize symptoms, the number of diagnosed cases of obsessive compulsive disorder has increased by 78% from 1995 to 2005, as measured by the 2005 Physicians Drug and Diagnosis Audit conducted by Verispan, Inc. Patients with obsessive compulsive disorder use rituals to help control anxiety related to their obsessive thoughts, and these rituals become disruptive to their daily life. While these patients often realize that their obsessions and compulsions are irrational or excessive, they frequently have little or no control over them. Typical obsessions include concerns with dirt, germs and contamination, fear of acting on violent or aggressive impulses or feeling overly responsible for the safety of others. Rituals adopted by obsessive compulsive disorder patients may provide them with transient relief from anxiety, but the rituals do not provide sustained comfort. Frequently, the rituals become so overwhelming that patients are unable to function normally in their daily lives. Symptoms of obsessive compulsive disorder typically appear in childhood, adolescence or early adulthood. According to an article published in the *Journal of Clinical Psychiatry*, a significant portion of obsessive compulsive disorder patients are believed to have one or more concomitant psychiatric disorders, such as depression or social anxiety disorder.

Social Anxiety Disorder. Social anxiety disorder is characterized by the fear and avoidance of social or performance situations where patients feel that others may scrutinize them and they may embarrass themselves. According to the National Institute of Mental Health, Social anxiety disorder affects approximately 15 million adults in the United States. Despite the prevalence of the disorder, social anxiety disorder remains underdiagnosed and undertreated by clinicians. Social anxiety disorder patients have anticipatory anxiety about these situations, and this anxiety can become so pronounced that patients cannot function normally in their daily lives. Social anxieties can be limited to a particular situation or apply to a variety of situations. In addition to anxiety, patients experience physical symptoms including blushing, sweating, trembling, and nausea. Symptoms of social anxiety disorder typically appear in childhood or adolescence with a mean age of onset of approximately 13 years, and the symptoms are often preceded by a history of social inhibition or shyness. According to an article published in the *Journal of Clinical Psychiatry*, mood and other anxiety disorders are prevalent among social anxiety disorder patients.

Competition

Selective serotonin reuptake inhibitors have become the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. According to the Pharmaceutical Audit Suite published by Wolters Kluwer Health, more than 142 million total prescriptions were written for selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors in the United States in 2006, accounting for approximately $16 billion in sales. Serotonin-norepinephrine reuptake inhibitors are a class of antidepressants used in the treatment of clinical depression and sometimes used to treat anxiety disorders, obsessive compulsive disorder and other conditions. Since the approval of Prozac (fluoxetine) in the United States in 1987, the use of selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors has increased dramatically due to their efficacy and reduced side effect profile relative to previously approved antidepressants. Based on available market data, we estimate that the majority of selective serotonin reuptake inhibitor and serotonin-norepinephrine reuptake inhibitor prescriptions are for the treatment of depression and that obsessive compulsive disorder and social anxiety disorder constitute approximately three percent of total selective serotonin reuptake inhibitor and serotonin-norepinephrine reuptake inhibitor prescriptions.

Four branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including three selective serotonin reuptake inhibitors: Paxil (paroxetine HCl), which is marketed by GlaxoSmithKline, Zoloft (sertraline HCl), which is marketed by Pfizer, and Prozac (fluoxetine hydrochloride), which is marketed by Eli Lilly. Anafranil (clomipramine hydrochloride), the other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the United States. The relative use of each of these products for the treatment of obsessive compulsive disorder has varied over the past ten years, and each currently has generic equivalents. Generic products are generally sold at significantly lower prices than branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Fluvoxamine, the generic equivalent of Luvox and a selective serotonin reuptake inhibitor, is the only other drug currently approved for the treatment of obsessive compulsive disorder.

Based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that fluvoxamine use represented approximately 11% of total drug usage for the treatment of obsessive compulsive disorder in 2006. Prior to the introduction of generic fluvoxamine in 2000, Luvox was considered one of the preferred treatments of obsessive compulsive disorder. Based on data from the 2005 Physicians Drug and Diagnosis Audit, we estimate that Luvox accounted for 21% of total drug usage for the treatment of obsessive compulsive disorder in 1999.

The market for drugs to treat obsessive compulsive disorder is extremely fragmented. Based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that Paxil, Zoloft, Prozac and Anafranil (and each of their generic equivalents) and fluvoxamine accounted for 48% of the total drug usage for the treatment of obsessive compulsive disorder in 2006. Although not FDA-approved for the treatment of obsessive compulsive disorder, based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that more than 15 additional products and their generic equivalents accounted for over 47% of total drug usage for the treatment of obsessive compulsive disorder in 2006. Given the prevalence of generic products, in order to gain significant market acceptance, we will need to demonstrate that the benefits of Luvox CR to patients justify the higher price of a branded product.

Four products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR (venlafaxine HCl). Paxil CR and Effexor XR, developed and sold by GlaxoSmithKline and Wyeth, respectively, do not have generic equivalents, whereas Paxil and Zoloft have generic equivalents. Paxil CR was approved for the treatment of social anxiety disorder in 2003, and Effexor XR was approved for the treatment of social anxiety disorder in 2003.

Based on limited data from the 2005 Physicians Drug and Diagnosis Audit, we estimate that Paxil CR use represented approximately 5%, and Effexor XR use represented approximately 9%, of total drug usage for the

treatment of social anxiety disorder in 2006. As is the case with obsessive compulsive disorder, the market for drugs to treat social anxiety disorder is extremely fragmented. Based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that Zoloft, Paxil and their generic equivalents, and Paxil CR and Effexor XR, in the aggregate accounted for only 27% of the total drug usage for the treatment of social anxiety disorder in 2006. Although they are not approved for the treatment of social anxiety disorder, based on data from the 2006 Physicians Drug and Diagnosis Audit, we estimate that approximately 18 other products accounted for over 59% of total drug usage for the treatment of social anxiety disorder in 2006. As with obsessive compulsive disorder, in order to gain significant market acceptance, we will need to demonstrate that the benefits of Luvox CR to patients justify the higher price of a branded product.

The presence in a particular patient of more than one psychiatric condition is an important consideration by physicians in the selection of drugs to treat social anxiety disorder. For patients with multiple conditions, a selective serotonin reuptake inhibitor or a serotonin-norepinephrine reuptake inhibitor with demonstrated efficacy in multiple indications is generally the preferred treatment option. Zoloft, Paxil, Paxil CR and Effexor XR are approved for additional psychiatric disorders, such as depression, in addition to social anxiety disorder, which may give them broader recognition by physicians and patients. These products therefore may be more likely to be prescribed than Luvox CR which, if approved, would at most be indicated for the treatment of obsessive compulsive disorder and social anxiety disorder.

Although selective serotonin reuptake inhibitors have a favorable side-effect profile compared to other classes of agents, the current selective serotonin reuptake inhibitor products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Adverse side effects associated with selective serotonin reuptake inhibitors include nausea, sleep disturbances, sexual dysfunction, weight gain, adverse drug interactions, risk of hypertension and, in adolescents, increased suicidal tendencies. Selective serotonin reuptake inhibitors are known to have little effect on patients' disease condition during the initial six to eight weeks of therapy. As a result, multiple psychotropic drugs are often prescribed during this time period to provide patients with more immediate relief. Additional adverse effects associated with immediate release formulations of selective serotonin reuptake inhibitors include significant incidence of nausea and reduced compliance as a result of multiple daily dosing.

Attributes of Luvox CR

We believe that there is a significant market opportunity for the reintroduction of the Luvox brand for the treatment of obsessive compulsive disorder and for its introduction for the treatment of social anxiety disorder, and that Luvox CR offers a compelling opportunity to improve upon existing formulations of fluvoxamine, the active pharmaceutical ingredient in Luvox CR, in treating these disorders. Fluvoxamine, in its immediate release form, is already a broadly prescribed therapy for the treatment of obsessive compulsive disorder. The market potential for Luvox CR is demonstrated by the significant ongoing prescription rates for the generic formulations of fluvoxamine despite the absence of active marketing and sales activity. No extended release fluvoxamine products have been approved by the FDA, and if approved by the FDA, Luvox CR would be the first fluvoxamine product approved for the treatment of social anxiety disorder.

In a Phase III clinical trial for obsessive compulsive disorder, patients taking Luvox CR demonstrated a statistically significant improvement compared to patients receiving placebo as assessed by the Yale-Brown Obsessive Compulsive Scale as early as week two of the trial. In Phase III clinical trials for social anxiety disorder, patients receiving Luvox CR demonstrated statistically significant improvement compared to patients receiving placebo as assessed by the Liebowitz Social Anxiety Scale total score as early as week four of the trial. Patients taking Luvox CR also did not show an increase in hypertension.

We believe the once-a-day dosing regimen afforded by the extended release formulation of Luvox CR could significantly improve compliance and patient acceptability. Furthermore, we believe that Luvox CR has a favorable tolerability profile as a result of its altered pharmacokinetic profile and lower maximum plasma concentration of fluvoxamine.

Product Development

In January 2007, we licensed the exclusive rights to market and distribute Luvox CR in the United States from Solvay. Solvay submitted an NDA for Luvox CR in December 2000. As a result of difficulties associated with manufacturing large-scale batches of the product candidate, Solvay and Elan mutually agreed to withdraw the NDA for Luvox CR in June 2001. We believe that Solvay and Elan have adequately addressed these manufacturing difficulties and that Elan, the party responsible for the manufacturing of Luvox CR, will be able to manufacture the product in commercial quantities. In April 2006, Solvay resubmitted the NDA for Luvox CR for treatment of obsessive compulsive disorder and social anxiety disorder. Under our agreement with Solvay, Solvay retains primary responsibility for the NDA for Luvox CR and communications with the FDA until after such time, if ever, as the FDA approves the NDA. In February 2007, the FDA issued an approvable letter for Luvox CR to Solvay. The approvable letter sets forth the requirements that must be met in order for the FDA to approve Luvox CR for marketing in the United States. The requirements set forth in the approvable letter include the completion of certain toxicology studies on the impurities that are generated by fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR, and the submission of additional information relating to the chemistry, manufacturing and controls section of the NDA. The approvable letter also requires Solvay to re-analyze certain data set forth in the NDA. We will need to commit to conducting certain post-approval, or Phase IV, studies, including a pediatric study for social anxiety disorder and a long-term safety study. We, with Solvay, will also need to finalize product labeling with the FDA. Under the terms of our license agreement, Solvay is responsible for conducting the additional toxicology studies and submitting the information to the FDA. We expect that Solvay will submit its response to the requests in the approvable letter to the FDA in the second or third quarter of 2007.

Obsessive Compulsive Disorder Phase III Clinical Trial Results. Solvay conducted one Phase III pivotal clinical trial with Luvox CR for the treatment of obsessive compulsive disorder. Since fluvoxamine is currently approved for the treatment of obsessive compulsive disorder, the FDA only requires one successful Phase III trial for approval of the extended release formulation for use in obsessive compulsive disorder. In the 12-week, multi-center, placebo-controlled trial of roughly 250 patients, patients receiving Luvox CR demonstrated statistically significant improvements on the Yale-Brown Obsessive Compulsive Scale compared to patients receiving placebo as early as week two of the study. The Yale-Brown Obsessive Compulsive Scale is a ten-item clinician-administered scale developed to assess the severity of obsessions and compulsions, independent of the number and type of obsessions or compulsions present. The Yale-Brown Obsessive Compulsive Scale has been the primary outcome measure in virtually all multi-center clinical trials of selective serotonin reuptake inhibitors for the treatment of obsessive compulsive disorder. The Luvox CR group mean total change from baseline on the Yale-Brown Obsessive Compulsive Scale was -8.5 compared to -5.6 for placebo, for a p-value of $p<0.01$ at 12 weeks. A p-value is a statistical measure intended to predict when a result of a study is likely the result of an intended outcome, such as a drug having a therapeutic effect in a clinical trial, and not by random chance. A value of $p<0.05$ means the likelihood of a result by chance is less than five in 100. As p-values become smaller, the probability of a result by chance decreases and the standard convention is to consider a p-value of 0.05 or less a statistically significant result.

Social Anxiety Disorder Phase III Clinical Trial Results. The effectiveness of Luvox CR in the treatment of social anxiety disorder was demonstrated in two 12-week, multi-center, placebo-controlled Phase III clinical trials in over 550 patients. In both studies, the effectiveness of Luvox CR compared to placebo was evaluated on the basis of change from baseline in the Liebowitz Social Anxiety Scale. The Liebowitz Social Anxiety Scale was the first clinician-administered scale to evaluate the wide range of social situations that are difficult for individuals with social phobia. The scale contains 24 items, 13 concerning performance anxiety and 11 concerning social situations. The Liebowitz Social Anxiety Scale is used as an outcome measure in most pharmacological trials for social phobia, as well as in many studies of cognitive-behavioral treatment. Patients receiving Luvox CR demonstrated statistically significant improvement compared to patients receiving placebo as assessed by the Liebowitz Social Anxiety Scale total score as early as week four of the study. As presented in the *Journal of Clinical Pharmacology* in April 2004, in one study of 279 patients, mean change in the Liebowitz Social Anxiety Scale total score was -26.7 for Luvox CR and -12.9 for placebo, for a p-value of $p<0.01$ at 12

weeks. As presented in the *Journal of Clinical Pharmacology* in February 2004, in the other study of 300 patients, mean change in the Liebowitz Social Anxiety Scale total score was -36.1 for Luvox CR and -27.3 for placebo, for a p-value of $p<0.02$ at 12 weeks.

Commercialization Strategy

If Luvox CR is approved by the FDA, we expect to commence promotion in the United States in the first quarter of 2008. To effectively market Luvox CR, we intend to significantly expand our already established specialty sales force. A substantial majority of prescriptions for the treatment of obsessive compulsive disorder and social anxiety disorder are written by psychiatrists. We believe that this concentration provides an attractive, focused market opportunity for us.

Through our license agreement with Solvay, we have obtained the exclusive rights to market and distribute Luvox CR in the United States, and Solvay retained the rights to market and distribute Luvox CR outside of the United States. In addition, Solvay assigned to us its rights and obligations under its license and supply agreement with Elan, and we have sublicensed back to Solvay the rights under that agreement outside of the United States. If Solvay decides not to pursue marketing of Luvox CR in any countries to which it has rights, we have a right of first offer with respect to any license of rights to market and distribute Luvox CR in those countries. Pursuant to a supply agreement with Solvay, we are responsible for purchasing, and Solvay is responsible for providing us with, the active pharmaceutical ingredient necessary to manufacture Luvox CR. We are responsible for providing the active pharmaceutical ingredient free of charge to Elan pursuant to the license and supply agreement with Elan. Pursuant to that license and supply agreement with Elan, Elan has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. We will be responsible for satisfying Solvay's commercial requirements of Luvox CR outside of the United States in exchange for supply price payments to us. We paid Solvay $2.0 million upon signing of the license agreement, and we are obligated to pay Solvay up to $138.0 million in development and commercial milestone payments associated with Luvox CR, as well as royalties on any net product sales. Up to $41.0 million of the milestone payments are payable at or prior to commercial launch. We are obligated to pay Elan development and commercial milestone payments, royalties on net product sales and supply price payments for the supply of Luvox CR. Solvay will be responsible for paying us for a portion of any payments due to Elan under the license and supply agreement with Elan, including those payments that relate to the countries in which Solvay holds marketing and distribution rights, as well as certain remaining development milestones owed to Elan.

Our license and supply agreements with Solvay will remain in force until terminated by either us or Solvay as a result of an uncured breach by the other party. We may also terminate the agreements with Solvay if the FDA has not approved Luvox or Luvox CR by a date specified in the license agreement or upon 180 days' notice to Solvay. The license and supply agreement with Elan that was assigned to us by Solvay will expire upon the later of 10 years after commercial launch of Luvox CR, or the last to expire patent licensed under the agreement with Elan. In addition, either we or Elan may terminate the license agreement in the event of an uncured material breach or in the event of a change of ownership of the other party in excess of 40% or an acquisition of 20% or more of the equity of the other party by a third party offering competing products. Elan may also terminate our license if we fail to meet specified clinical and commercialization events, within specified time periods.

We expect Luvox CR will receive three years of new marketing exclusivity if approved by the FDA. In addition, a patent application has been filed by Elan covering the orally administered formulation of extended-release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours. If this patent issues in the United States, it could provide patent protection for this formulation until 2020.

Luvox (fluvoxamine maleate)

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox, an immediate release formulation of fluvoxamine maleate, was approved by the FDA for the treatment of obsessive compulsive disorder in 1994. However, Solvay withdrew Luvox from the market in 2002 as a result of discrepancies in data identified by the FDA. Solvay resubmitted the NDA for Luvox to the FDA in June 2002 and received an approvable letter from the FDA in February 2004. In May 2006, Solvay submitted its response to the approvable letter and in

November 2006, the FDA issued a second approvable letter for Luvox setting forth certain conditions necessary for receiving approval to market Luvox for treatment of obsessive compulsive disorder. The second approvable letter requires certain standard toxicology studies on the impurities present in the drug product to be conducted. No carcinogenicity or other studies are required. Because numerous generic formulations of fluvoxamine are on the market, and no serious adverse events associated with toxicity have been reported, we do not believe that the required testing poses a significant risk for the ultimate approval of Luvox. Pursuant to the terms of our license agreement, Solvay is responsible for conducting the additional tests and submitting the information to the FDA. We expect that Solvay will submit the additional data to the FDA in the second or third quarter of 2007.

Through our license agreement with Solvay, we have the right to market and distribute Luvox in the United States and to manufacture or to have manufactured Luvox for use and sale in the United States, but we have not yet determined if we will market Luvox if it is approved by the FDA for the treatment of obsessive compulsive disorder. In the event that we market Luvox supplied to us by Solvay in the United States, we will make a milestone payment to Solvay of $2.0 million and royalties on commercial sales.

JZP-6 (sodium oxybate)

We are developing a liquid dosage form of sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia syndrome. We are currently conducting two Phase III pivotal clinical trials for JZP-6 in fibromyalgia syndrome. We have completed a Phase II clinical trial for JZP-6 in which fibromyalgia syndrome patients taking sodium oxybate achieved a statistically significant improvement compared to placebo on the composite endpoint accepted by the FDA and the European Agency for the Evaluation of Medicinal Products as the primary endpoint for our Phase III pivotal clinical trials.

Market Opportunity

Fibromyalgia syndrome is a chronic pain syndrome defined by widespread pain lasting at least three months. According to the American College of Rheumatology between two and four percent of the U.S. population suffers from fibromyalgia syndrome. Fibromyalgia syndrome is believed to be a central nervous system condition. In addition to pain, fibromyalgia syndrome patients often suffer from a combination of muscle stiffness, fatigue, disturbed sleep, restless legs and impaired memory and concentration. Although physicians do not understand the cause of fibromyalgia syndrome, it may be triggered by physical trauma, emotional stress or infection. The criteria established by the American College of Rheumatology for the classification of fibromyalgia require the application of pressure at 18 different points on the body and measurement of pain induced by such pressure. If at least 11 of the 18 points are painful and have been painful for three months, the patient is diagnosed with fibromyalgia syndrome.

Competition

There are currently no products approved by the FDA for the treatment of fibromyalgia syndrome. In clinical practice, a variety of drugs are often prescribed to address individual symptoms of fibromyalgia syndrome, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants. Based on available market data, we estimate that more than 6.3 million total prescriptions were written to treat fibromyalgia syndrome symptoms in 2006, of which approximately 32% were for antidepressants, 25% were for opioids and 30% were for muscle relaxants. Physicians generally prescribe one or more drug therapies based on the dominant symptom or symptoms of fibromyalgia syndrome in a particular patient. This “polypharmacy” approach has significant limitations as none of the current therapies used to address the symptoms of fibromyalgia syndrome is designed to comprehensively address the syndrome and many of its related symptoms.

In addition to JZP-6, there are currently four programs that have completed or are in Phase III clinical development for the treatment of fibromyalgia syndrome. These include Lyrica (pregabalin), an anticonvulsant being developed by Pfizer, which has previously been approved by the FDA for the treatment of partial seizures,

post herpetic neuralgia and diabetic peripheral neuropathy. In December 2006, Pfizer submitted a supplemental NDA seeking FDA approval of Lyrica for the treatment of fibromyalgia syndrome, or certain symptoms associated with fibromyalgia syndrome.

Attributes of JZP-6

JZP-6 is being developed to provide an effective treatment for fibromyalgia syndrome and pain associated with fibromyalgia syndrome. While the primary symptom of fibromyalgia syndrome is widespread pain, fatigue and mood disturbances are also common symptoms. We believe that JZP-6 will provide significant advantages over current treatments by offering improvements in pain relief and physical functioning that may address the overall syndrome and many of its related symptoms.

The primary endpoint for our pivotal trials measuring the efficacy of JZP-6 is a composite of change from baseline in three co-primary measures of patients' pain: the pain visual analog scale, the fibromyalgia impact questionnaire and patient global impression of change. This composite of change endpoint was accepted by the FDA and the European Agency for the Evaluation of Medical Products as the primary endpoint for our Phase III pivotal clinical trials. An efficacious response by a patient in the trial for each of the three co-primary measures of patient's pain is defined as follows: by the FDA as a greater than 20%, and by the European Agency for the Evaluation of Medical Products as a greater than 30%, reduction in the pain visual analog scale; by the FDA as a greater than 20%, and by the European Agency for the Evaluation of Medical Products as a greater than 30%, improvement in the fibromyalgia impact questionnaire score; and by the FDA and the European Agency for the Evaluation of Medical Products as a self-rating describing themselves as "very much better" or "much better" on the patient global impression of change.

Product Development

Phase II Clinical Trial Results. In August 2005, we completed a Phase II clinical trial of 195 patients with fibromyalgia syndrome in a randomized, double blind placebo-controlled safety and efficacy study. Patients received a fixed dose of 4.5 grams of sodium oxybate divided into two nightly doses, 6.0 grams of sodium oxybate divided into two nightly doses, or placebo twice nightly for an eight-week period. The primary endpoint for this trial was a composite of change from baseline in three co-primary measures of patients' pain: the pain visual analog scale, the fibromyalgia impact questionnaire and patient global impression of change. Secondary endpoints included measurement of a tender point count, tender point index, Epworth sleepiness scale, Jenkins scale for sleep, global score on the functional outcome of sleep questionnaire, severity of fatigue and clinical global impression of change. The Phase II clinical trial demonstrated significant improvement in the composite endpoint results in both dosage strengths. In addition, the study demonstrated significant improvements in secondary measures of fatigue, sleepiness and sleep quality. There were no unexpected adverse events in the study.

JZP-6 also demonstrated statistically significant improvement in each of the co-primary measures that comprise the composite endpoint in either one or both dosage strengths. The visual analog scale is a self-assessed measurement of pain in which zero is no pain at all and 100 is the worst pain experienced. The baseline pain for the fibromyalgia syndrome patients in the trial was roughly 65. Patients on both dosage strengths experienced a statistically significant improvement in pain at eight weeks. In addition, the study measured pain throughout the day. Patients experienced pain relief in the morning, at midday and in the evening, which represents an important clinical benefit for patients. The fibromyalgia impact questionnaire is a 20 item questionnaire that asks patients to assess their ability to complete activities of daily living such as shopping, preparing a meal, visiting or doing housework. The total score is normalized to 100 points. The questionnaire also has a single inquiry about anxiety and depression. The Phase II clinical trial results demonstrated that patients on both dosage strengths experienced statistically significant improvement in the total score. The patient global impression of change is a seven point scale on which patients assess how much better or worse they feel throughout the trial. Our Phase II clinical trial demonstrated a statistically significant improvement for this measure for patients on the 4.5 gram dose.

Ongoing Phase III Clinical Trials. We are currently conducting two Phase III pivotal clinical trials, each in approximately 525 patients, and an open-label continuation trial in at least 500 patients, to confirm the results of our Phase II clinical trial. The primary endpoint in both of our ongoing Phase III pivotal clinical trials is the same as in our Phase II clinical trial. Each of our Phase III pivotal clinical trials involve randomized, double blind studies. The first of these trials commenced in September 2006 and is ongoing in 45 sites located exclusively in the United States. As of March 31, 2007, more than 100 patients had been enrolled in the first trial. Screening for the second trial commenced in February 2007. Between 30% and 40% of the subjects for the second trial are expected to reside outside of the United States. We expect to commence clinical pharmacology studies in the fourth quarter of 2007. Dosages being studied in the ongoing Phase III trials are consistent with our Phase II clinical trial with the exception that subjects assigned to higher doses will be titrated from the lower dose to the higher dose over a period of two weeks. We believe this titration regimen will provide for a more clinically relevant comparison of the relative safety, efficacy and tolerability of the dosages being studied and assist in determining the benefits, if any, of flexible dosing.

We expect preliminary data from the first Phase III pivotal clinical trial in the second half of 2008. Based on the results of our Phase III clinical trials and further discussions with the FDA, we will determine when and if we will submit an NDA for JZP-6 for the treatment of fibromyalgia syndrome or other, more limited indications such as pain associated with fibromyalgia syndrome.

Commercialization Strategy

If JZP-6 is approved by the FDA, we believe that the majority of prescriptions for the product to treat fibromyalgia syndrome will be written by rheumatologists, with some prescriptions written by neurologists and psychiatrists. Because the number of rheumatologists in the United States is relatively small we expect to be able to expand our specialty sales force to promote JZP-6 in the United States. We may also identify one or more pharmaceutical company partners or a contract sales organization to promote JZP-6 to other audiences, including primary care physicians who are treating patients with fibromyalgia syndrome.

In 2006, we amended our agreement with UCB to grant UCB the right to market JZP-6 for the treatment of fibromyalgia syndrome in 54 countries throughout Europe, South America, the Middle East and Asia. Under the terms of the amended agreement, UCB paid us $15.0 million to develop and commercialize JZP-6 for the treatment of fibromyalgia syndrome. We are entitled to up to $40.0 million in additional development milestone payments associated with JZP-6, and additional commercial milestone payments of up to $100.0 million related primarily to JZP-6 for the treatment of fibromyalgia syndrome as well as Xyrem for the treatment of narcolepsy. The term of our agreement with UCB, as it applies to JZP-6, extends to the later of the expiration of our associated patent rights in the territories covered by the agreement or ten years from the date of European Agency for the Evaluation of Medical Products approval to commercially promote and distribute the product for the treatment of fibromyalgia syndrome, subject to automatic extension unless UCB provides 12 months' notice. UCB may terminate our agreement for any reason upon 18 months' notice. We are responsible for supplying commercial quantities of JZP-6 to UCB in exchange for supply price payments. If we are unable to comply with our obligations to supply JZP-6 to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months' notice.

Pursuant to our agreement with Valeant, Valeant has the option to acquire the rights to market JZP-6 for treatment of fibromyalgia syndrome in Canada if it is then commercializing Xyrem for narcolepsy in Canada, subject to our right to later reacquire these rights. We are responsible for supplying commercial quantities of JZP-6 to Valeant in exchange for supply price payments.

We have contracted with our current supplier of sodium oxybate for the manufacture of Xyrem and our current manufacturer of Xyrem for the manufacture of JZP-6 to conduct our clinical trials. Because sodium oxybate is a controlled substance requiring manufacturing quotas from the DEA, our current active pharmaceutical ingredient supplier and contract manufacturer may be unable to provide us with sufficient clinical

and commercial quantities. In cooperation with our manufacturing partners, we intend to seek increased quotas from the DEA to supply and manufacture JZP-6 to complete our clinical trials and, if it is approved, to commercialize the product. We expect that the manufacture and distribution of JZP-6 will be subject to similar restrictions and risk management policies as our existing processes in place for Xyrem. These restrictions may present a meaningful obstacle for the eventual introduction of generic versions of JZP-6.

We expect that our patents associated with Xyrem will cover JZP-6. In addition, we hold a U.S. patent and patents in 29 other countries that cover the use of sodium oxybate for the treatment of fibromyalgia syndrome. Our U.S. patent expires in 2017 and our patents in other countries expire in 2018.

JZP-4 (type IIa sodium channel antagonist)

We are developing JZP-4, a controlled release formulation of an anticonvulsant that has a similar chemical structure and is believed to work through the same mechanism of action as Lamictal (lamotrigine), an antiepileptic drug marketed by GSK for the treatment of epilepsy and bipolar disorder. We have completed a number of preclinical studies related to antiepileptic activity that suggest that JZP-4 may be effective in treating epilepsy. Subject to the results of a proof of concept clinical trial, long-term toxicology studies and formulation studies, we plan to commence a Phase II clinical trial for the treatment of epilepsy in the fourth quarter of 2007.

Market Opportunity

Epilepsy. Epilepsy, a seizure disorder, is a serious neurological illness affecting people of all ages. A seizure is a sudden surge of electrical activity in the brain that affects how a person feels or acts for a short time. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy. In 2005, over $6.0 billion of seizure disorder drugs were sold in the United States as measured by the Pharmaceutical Audit Suite. Based on available market data, we estimate that approximately $2.3 billion of these drugs were prescribed for the treatment of epilepsy. Epileptic seizures are classified as either partial or generalized depending upon how the abnormal brain activity begins. Partial seizures begin with abnormal activity in part of the brain. Generalized seizures have abnormal activity in most or all of the brain. Seizure symptoms may be hardly noticeable, such as confusion and staring, or totally disabling, such as convulsions, shaking and falling down.

Bipolar disorder. Bipolar disorder is a serious, chronic psychiatric disorder that causes shifts in mood, energy and ability to function. According to National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder. Based on available market data, we estimate that approximately $1.3 billion of antiepileptic drugs were sold for the treatment of bipolar disorder in 2005. People suffering from the condition experience dramatic mood swings from an overly “high” mania state to an overly “low” or depressive state, often with periods of normal mood in between.

Competition

Epilepsy. Seizures in epileptic patients are typically controlled by treatment with one or more antiepileptic drugs. In 2006, there were approximately 6.2 million prescriptions written for Lamictal. While up to 70% of epilepsy patients respond to therapy and become seizure-free with chronic treatment with antiepileptic drugs, the remaining patients fail treatment either because the drugs do not stop their seizures or because they cannot tolerate the side effects. These patients usually end up taking more than one antiepileptic drug at a time and are therefore more susceptible to adverse effects associated with drug interactions. Selection of the appropriate medication for an individual patient is typically based on the type of epilepsy from which a patient suffers, the genesis of the disease, and the patient’s age and gender. Side effects and tolerability are significant concerns with currently available antiepileptic drugs. Side effects for most antiepileptic drugs include sleepiness, cognitive impairment, weight gain, mood changes, dizziness and potentially life-threatening immune system reactions. Doctors generally start their patients on a low dose of antiepileptic drugs, and titration may take up to 12 weeks. During this period, patients often continue to suffer from epileptic seizures of various severities.

Bipolar Disorder. Bipolar disorder is typically managed with drugs from a variety of different drug classes. While treatment duration varies for each patient, treatment of an acute phase of the disease generally lasts approximately three weeks, followed by a continuation phase of approximately two months, and a maintenance phase of up to 18 months. Generally, the treatment is chosen based on the mood episode a patient is experiencing at a particular time. Treatment for patients in the acute mania phase includes a mood stabilizer, such as lithium or an antiepileptic drug, in addition to an atypical antipsychotic. Patients in the acute depression phase are initially treated with Lamictal, Symbyax (olanzapine and fluoxetine HCl capsules), a combination antidepressant and antipsychotic, or Seroquel (quetiapine), an antipsychotic. For long-term maintenance, the same medications that were effective for the acute episodes are typically continued at the same or lower doses. Many of the drugs currently used in the treatment of bipolar disorder have adverse drug interactions affecting each drug's efficacy and safety as well as adverse tolerability and other negative side effects such as sedation, weight gain, involuntary movements, tremors, stiffness orthostatic hypotension and potentially life-threatening immune system reactions. These side effects discourage compliance and may pose serious health risks. Antidepressants are also often prescribed to treat bipolar depression, even though they are not indicated for such treatment and there is a risk that such antidepressants can induce a bipolar patient to switch from depression to mania.

Attributes of JZP-4

We are developing JZP-4 to address the unmet needs of epilepsy and bipolar patients for a more effective drug with fewer side effects. JZP-4 is being developed as a controlled release product that can be taken once a day, with a shorter titration schedule and fewer interactions with other drugs than current therapies. JZP-4 is an antiepileptic drug in the same class of drugs, and with a similar chemical structure, as Lamictal, an antiepileptic drug approved for the treatment of epilepsy and bipolar disorder. We believe that JZP-4 has the potential to provide the demonstrated efficacy of antiepileptic drugs in treating these conditions while addressing many of the adverse side effects of current therapies. In particular, our pharmacokinetic studies indicate that the active pharmaceutical ingredient in JZP-4 may result in a favorable titration schedule. Preclinical studies also indicate that the active pharmaceutical ingredient in JZP-4 may have fewer adverse drug interactions than current therapies. In addition, we believe that JZP-4 has the potential to be effective in treating bipolar depression with minimal sedation, low incidence of weight gain and limited risk of causing mood switches, thereby addressing a significant unmet need for this patient population.

Product Development

We acquired the worldwide rights to the active pharmaceutical ingredient in JZP-4 from GSK in 2004. Since acquiring these rights, we have completed our initial early preclinical development to show that the drug can be formulated as a once-a-day product, and we have conducted preclinical studies which we believe have confirmed studies previously completed by GSK showing that the drug has central nervous system activity comparable to Lamictal and other antiepileptic drugs.

Our preclinical development has involved a range of preclinical studies to determine how the active pharmaceutical ingredient in JZP-4 works and its potential to treat epilepsy. The results of these studies indicate that the active pharmaceutical ingredient in JZP-4 is a broad spectrum antiepileptic drug with sodium and calcium channel blockade as the primary mechanisms of action. From the results of these preclinical studies, we believe that the active pharmaceutical ingredient has a broad spectrum of activity, which indicates that it may be effective in treating many different types of epileptic seizures. We have also completed preliminary toxicology and pharmacology tests that have provided early indications of safety and a low potential for adverse drug interactions. These tests involved exposure of more than 170 healthy individuals in eight single dose and multi-dose studies. We have developed a prototype formulation and tested it in a pharmacokinetic study that showed the viability of once-a-day dosing. Following completion of this study we are continuing development activities for a once-a-day formulation, and we currently expect to complete these activities in the fourth quarter of 2007.

In addition, we have designed two proof of concept clinical trials designed to provide evidence of therapeutic activity for JZP-4. The first, a transcranial magnetic stimulation study, is a non-randomized, single blind placebo-

controlled study of JZP-4 in healthy volunteers with lamotrigine as a positive control. The transcranial magnetic stimulation model is predictive of central nervous system activity and efficacy in partial epilepsy. Three patients have completed all four doses of JZP-4 and one dose of lamotrigine. Results from these subjects indicate potential central nervous system activity of JZP-4. The second, a photic-induced paroxysmal electroencephalographic study in photosensitive epilepsy patients, is a non-randomized, single blind placebo- controlled study of JZP-4 with a higher dose of baseline antiepileptic drug as a positive control. The results from this study will provide information on the effective dose range in epilepsy patients and possible adverse drug interactions with other antiepileptic drugs. Initial dosing for this study is expected to commence in the third quarter of 2007.

Our completed toxicology studies support use of the active pharmaceutical ingredient in JZP-4 in humans for up to 13 weeks. We began additional long-term toxicology studies in March 2006 and expect to receive results from these studies in the second quarter of 2007. Subject to satisfactory results from these long-term toxicology studies, formulation studies, a proof of concept study and certain drug-drug interaction studies, we plan to commence a Phase II clinical trial of JZP-4 for the treatment of epilepsy beginning in the fourth quarter of 2007. We believe that the initial results of this trial will be available in mid-2008.

Commercialization Strategy

Our strategy to market any approved formulation of JZP-4 will depend on the outcome of our clinical trials, the nature of any indications it is approved to treat and the specialties of the physicians most likely to prescribe the product. Any such sales efforts may involve the utilization of our internal sales force, collaborations with partners, or a combination of both. Pursuant to our agreement with GSK, we have paid upfront and development milestone payments of $5.0 million and will pay up to $113.5 million in additional development and commercial milestone payments as well as royalties on commercial sales. Under that agreement, we are obligated to use diligent efforts to develop and commercialize JZP-4 in accordance with a specified timeline. If we fail to use such efforts, then GSK may elect, following notice and opportunity to cure, to terminate the agreement and reclaim all product rights. In addition, if we elect to discontinue development of JZP-4, GSK has a right to re-acquire the product upon payment of specified amounts.

We have identified and are in the process of qualifying a manufacturer to produce clinical trial materials for all late-stage clinical trials of JZP-4. Following development of our once-a-day formulation we intend to seek a contract manufacturer for commercial quantities of JZP-4.

The composition of matter for the active pharmaceutical ingredient in JZP-4 is covered by patents in 53 countries, including in the United States and countries in Europe. The U.S. composition of matter patent expires in 2018. In addition, we hold a U.S. patent covering the use of the active pharmaceutical ingredient in JZP-4 for the treatment of bipolar disorder that expires in 2018, and a U.S. patent that covers the process used for preparing of the active pharmaceutical ingredient in JZP-4 that expires in 2021. A patent application covering a sustained release composition for delivering the active pharmaceutical ingredient in JZP-4 is currently pending in the U.S. Patent and Trademark Office and would, if issued, expire in 2026. The use of JZP-4 in specified indications is covered by GSK patents that are licensed non-exclusively to us under the asset purchase agreement with GSK.

JZP-8 (benzodiazepine)

We are developing JZP-8, a novel formulation incorporating a benzodiazepine, for the treatment of recurrent acute repetitive seizures in refractory epilepsy patients. Our initial development work suggests that JZP-8 has the potential to provide fast-acting efficacy associated with currently available therapies while addressing problems associated with administration that make such therapies largely impractical to employ.

Market Opportunity

Recurrent acute repetitive seizures are bouts of acute seizure activity within a 24-hour period in adults and a 12-hour period in children. According to the Epilepsy Foundation, approximately 2.7 million people in the United States have epilepsy. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are refractory to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures. Recurrent acute repetitive seizures are an acute and repetitive reaction to the abnormal electrical activity that

builds up and releases in the brain. Epilepsy patients and their caregivers are usually able to distinguish between a regular seizure and the first seizure in a series of recurrent acute repetitive seizures.

Competition

Quick identification and treatment of the first seizure in a series of recurrent acute repetitive seizures can often interrupt the ongoing seizure, reduce its severity, and prevent subsequent seizures. Interrupting a seizure cluster may also lessen the severity of post-seizure symptoms. In the United States, Diastat (diazepam rectal gel), marketed by Valeant Pharmaceuticals, is the only FDA-approved, acute, outpatient treatment for patients on stable antiepileptic drugs who experience bouts of increased seizure activity. In 2006, sales of Diastat totaled approximately $73.0 million in the United States as measured by the Pharmaceutical Audit Suite. Although generally considered safe and effective for patients of all ages, because it is a rectally administered gel, Diastat is currently prescribed primarily for children under the age of ten and is administered to them by caregivers or parents. Diastat's rectal administration has made it impractical for most of the adolescent, adult and elderly population. Patients with seizure clusters who do not use Diastat have no other outpatient treatment option and thus, typically, are treated through the emergency medical system.

In paramedic and hospital settings, benzodiazepines such as diazepam, lorazepam and midazolam are the first line of emergency treatment for patients presenting with recurrent acute repetitive seizures. These medications, all available in intravenous formulations, provide rapid onset of action and known efficacy for patients. However, treatment in an emergency room setting results in significantly increased costs to the individual and health care system as well as the potential increased harm and danger associated with the time delay in obtaining emergency treatment.

Attributes of JZP-8

JZP-8 is being developed as a fast-acting benzodiazepine, or a benzodiazepine that enters the bloodstream faster than a dose from a conventional tablet form. Like other benzodiazepines, JZP-8 will likely be regulated as a controlled substance by the DEA if approved for marketing by the FDA. We believe JZP-8 will provide a far easier means of administration while patients are actively seizing and a delivery form that will be accepted for use by adolescent and adult patients as well as caregivers. In addition, we believe that JZP-8 will have sufficient duration of action to prevent recurrence of subsequent seizures.

Product Development

We have completed development activities to select the active pharmaceutical ingredient for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We have completed a pharmacokinetics and pharmacodynamics study in healthy volunteers. Pharmacokinetics deals with the absorption, distribution, biotransformation and excretion of drugs, which, coupled with dosage, determines the concentration of a drug in the body and, hence, the intensity of its effects as a function of time. Pharmacodynamics is the study of the biochemical and physiological effects of drugs and their mechanisms of action. These pharmacokinetic and pharmacodynamic results demonstrate that JZP-8 has an acceptable plasma profile. We plan to commence a Phase II clinical trial of JZP-8 for the treatment of recurrent acute repetitive seizures in refractory epilepsy patients in the fourth quarter of 2007. Subject to satisfactory results from this clinical trial, we plan to begin Phase III clinical trial activities for JZP-8 in the second quarter of 2008.

Commercialization Strategy

Our marketing strategy for JZP-8 will depend on the outcome of our clinical trials, the nature of any indications JZP-8 is approved to treat and the specialties of the physicians most likely to prescribe the product. Any sales efforts may involve the utilization of our internal sales force, collaborations with sales partners or a combination of both.

We have entered into a license agreement with a technology provider for the development of JZP-8. Pursuant to that agreement we are obligated to make clinical and commercial milestone payments to this provider and to pay royalties on commercial sales of the product.

We have contracted for the supply of the active pharmaceutical ingredient in JZP-8 in sufficient quantities to complete clinical trials. We intend to seek a contract manufacturer for commercial quantities of JZP-8.

JZP-7 (dopamine agonist)

We are developing JZP-7, a novel formulation incorporating a dopamine agonist, for the treatment of restless legs syndrome. Based on our preclinical development, we believe JZP-7 offers the potential for effective treatment of restless legs syndrome while reducing adverse effects associated with existing treatments.

Market Opportunity

Restless legs syndrome is a common, underdiagnosed neurological disorder that frequently manifests itself as a sleep disorder. According to the Restless Legs Syndrome Foundation, up to ten percent of the U.S. population suffers from restless legs syndrome. A study published in the May 2004 issue of Sleep Medicine indicated that approximately ten percent of patients visiting primary care physicians in the United States and four European countries experience restless legs syndrome symptoms at least weekly, with approximately two percent of patients visiting primary care physicians suffering from symptoms severe enough to disrupt their quality of life. Patients who suffer from restless legs syndrome experience an irresistible urge to move their legs. This urge is usually accompanied by unpleasant sensations of burning, creeping, tugging or tingling inside the patients' legs, ranging in severity from uncomfortable to painful. These restless legs syndrome-related symptoms typically begin or worsen during periods of rest or inactivity, particularly when lying down or sitting, and may be temporarily relieved by movement such as walking or massaging the legs. Symptoms often worsen at night and disturbed sleep is a common result of restless legs syndrome. Left untreated, restless legs syndrome may cause exhaustion, daytime fatigue, inability to concentrate and impaired memory.

Competition

Requip (ropinirole), marketed by GSK, was the first product approved by the FDA for the treatment of restless legs syndrome. In 2006, Mirapex (pramipexole), marketed by Boehringer Ingelheim, was approved by the FDA for the treatment of moderate to severe restless legs syndrome. Schwarz Pharma is also developing a rotigotine transdermal patch for restless legs syndrome under the trade name Neupro, for which the FDA has issued an approvable letter. The symptoms of restless legs syndrome are also currently treated by dopamine agonists, opioids, benzodiazepines and anticonvulsants. While Requip and Mirapex have been shown to be effective in treating restless legs syndrome, they have been associated with adverse side effects, including nausea, vomiting, orthostatic hypotension and sudden onset of sleep. In a study of patients on dopamine agonist treatments reported in the *Archives of Neurology*, approximately 48% of patients who had continued treatment for longer than six months developed augmentation, with approximately 22% of these patients having severe augmentation. Augmentation refers to the earlier onset of symptoms, increase in symptoms, and spread of symptoms to involve other extremities. For these patients, physicians often add an additional, earlier dose of the existing treatment, increase dosage, or switch to an alternative therapy.

Attributes of JZP-7

We are developing JZP-7 as a novel formulation incorporating a dopamine agonist to provide the effective treatment of restless legs syndrome while addressing adverse events associated with current therapies. We are seeking to develop JZP-7 as a once daily formulation. We believe this formulation has the potential to significantly reduce the titration schedule associated with Requip and adverse events associated with more commonly dosed products, including nausea, vomiting, orthostatic hypotension and sudden onset of sleep. JZP-7

may also have the potential to provide extended relief of restless legs syndrome for those patients needing longer symptom relief than may be provided by existing oral therapies.

Product Development

We have completed development activities to select the active pharmaceutical ingredient for this product candidate and are conducting further development activities related to formulation, safety and tolerance. We have completed a pharmacokinetic study in healthy volunteers. The pharmacokinetic results demonstrated that our JZP-7 product has a pharmacokinetic profile consistent with our development target. We intend to conduct an additional pharmacokinetic study in 2007 prior to commencing Phase II clinical trials for the treatment of restless legs syndrome.

Commercialization Strategy

Our marketing strategy for JZP-7 will depend on the outcome of our clinical trials, the nature of any indications JZP-7 is approved to treat, and the specialties of the physicians most likely to prescribe the product. Any sales efforts may involve the utilization of our internal sales force, collaborations with partners, or a combination of both.

We have entered into an agreement with technology provider to conduct feasibility studies associated with the formulation and method of delivery of JZP-7. If these studies are successful we have the option to enter into a license agreement that will provide for clinical milestone payments to this technology provider and royalties on commercial sales of the product.

We have contracted for the supply of the active pharmaceutical ingredient in JZP-7 in sufficient quantities to complete clinical trials. We intend to seek a contract manufacturer for commercial quantities of JZP-7.

JZP-2 (benzodiazepine)

We are developing JZP-2, a fast-acting formulation of a benzodiazepine, for the acute treatment of panic attacks associated with panic disorder. There are currently no products approved for the treatment of panic attacks.

Market Opportunity

A panic attack is an isolated period of intense fear or discomfort that is associated with numerous symptoms, including feelings of imminent danger, heart palpitations, sweating, shortness of breath, chest pain, nausea and a fear of dying. According to the National Institute of Mental Health, approximately six million people in the United States suffer from panic disorder in any given year. A panic attack typically starts without warning, building to maximum intensity within ten to 15 minutes. A panic attack is distinguished from other forms of anxiety by its intensity and its sudden occurrence. To be diagnosed with panic disorder, patients must have two or more unexpected panic attacks, and develop persistent concerns or worries about having subsequent attacks.

Competition

Currently there is no drug approved for the acute treatment of a panic attack. The current leading treatments for panic disorder are selective serotonin reuptake inhibitors taken prophylactically on a daily basis. Alternative treatments to selective serotonin reuptake inhibitors include drugs in other classes, such as benzodiazepines, tricyclic antidepressants and monoamine oxidase inhibitors. Based on data from the 2005 Physicians Drug and Diagnosis Audit, we estimate that approximately 27% of drug usages for benzodiazepines are taken on an “as-needed” basis, indicating a level of ineffective treatment with selective serotonin reuptake inhibitors alone. In

addition, patients initiating selective serotonin reuptake inhibitor drug therapy often take several weeks to experience therapeutic effects and during this time, continue to experience panic attacks. According to an article published in the American Family Physician, approximately 30% of patients treated with selective serotonin reuptake inhibitors cannot tolerate these medications or will have an unfavorable or incomplete response to treatment. Benzodiazepines are well-understood drugs, and physicians continue to prescribe them despite the availability of a number of selective serotonin reuptake inhibitors in the market. Long-term benzodiazepine use is considered to be safe and effective treatment for panic disorder patients who have no history of substance abuse. We believe that some physicians may prescribe oral benzodiazepines for patients to take as needed, when they feel a panic attack coming on, or during an attack. However, because the symptoms of a panic attack typically have a rapid onset and last less than 30 minutes, we believe oral benzodiazepines often do not work quickly enough to provide patients with adequate relief. In addition, patients treated with benzodiazepines often develop increased tolerance to the activity of the drug over time, requiring substantial increases in dosages to obtain and maintain clinical effectiveness.

Attributes of JZP-2

We believe that JZP-2 has the potential to provide rapid relief from a panic attack and enable the patient to quickly resume functionality after an attack. We are developing JZP-2 as a fast-acting formulation of a benzodiazepine. Like other benzodiazepines, JZP-2 will likely be regulated as a controlled substance by the DEA if approved for marketing by the FDA. We believe JZP-2 could be used as an adjunct to chronic treatment with selective serotonin reuptake inhibitors. In addition, severe panic disorder patients continue to experience multiple panic attacks per week while on chronic selective serotonin reuptake inhibitor treatment and other therapies. JZP-2 could be used as a supplementary therapy on an as-needed basis for patients on chronic medication who continue to experience panic attacks. Patients using JZP-2 on an as-needed basis would have reduced exposure to the active pharmaceutical ingredient. As a result, we believe that JZP-2 has the potential to have a favorable tolerance profile.

Product Development

We have developed a target formulation for JZP-2 and plan to commence one or more clinical trials of JZP-2 in 2007 with this formulation for the acute treatment of panic attacks associated with panic disorders. The first clinical trial will evaluate how fast the product gets into the bloodstream in human subjects. Subject to the successful completion of this trial, we expect to commence a Phase II clinical trial of JZP-2. If successful, the outcome from these clinical trials will be used to determine clinical endpoints for Phase III clinical trials. The focus of our completed and ongoing development activities on JZP-2 has been to identify the preferred formulation of benzodiazepine and most effective delivery technology while balancing sedative effects, panic alleviation, risks and speed of action.

Commercialization Strategy

Our marketing strategy for JZP-2 will depend on the outcome of our clinical trials, the nature of any indications JZP-2 is approved to treat, and the specialties of the physicians most likely to prescribe the product. Any sales efforts may involve the utilization of our internal sales force, collaborations with partners, or a combination of both.

We have entered into an agreement with a technology provider to conduct feasibility studies associated with the formulation and method of delivery of JZP-2. If these studies are successful, we have the option to enter into a license agreement that will provide for the payment of royalties to our technology provider on commercial sales.

We currently have an agreement for supply of the active pharmaceutical ingredient in JZP-2 and ongoing manufacture of the drug product in sufficient quantities to complete clinical trials. Pursuant to our agreement, our technology provider will manufacture commercial quantities of JZP-2.

New Product Candidate Identification and Development

Our program for identifying and developing new product candidates involves many disciplines across our company. We identify unmet patient needs and opportunities to improve upon existing therapies through market research, new product planning activities, interactions with thought leaders in neurology and psychiatry, and research and development. Once a potential product candidate is identified, we conduct feasibility activities to help us determine whether we can develop a product that may improve patients' lives. In developing new product candidates, we access a broad range of available technologies and services from third party providers to help ensure our products will have the characteristics we desire.

Through our feasibility activities and proof of concept studies, we attempt to determine if a product candidate has the requisite pharmacological activity, would be valuable to patients and healthcare providers, and could be developed within the timeframe and budget we find acceptable. We focus our early-stage activities on obtaining proof of concept for each product candidate at a relatively low cost, in order to eliminate some risks before we incur significant development expenses for the product candidate. We then execute a development program with a defined set of goals for the product candidate, and a series of development milestones by which we measure progress. The activities at each stage of development are designed to reduce risk, so that as a product candidate moves through the stages of development we can more confidently allocate additional resources to it.

Our program is designed to shorten the development cycle for our product candidates as compared with most new chemical entities. Because we generally work with known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, we can often move from a proof of concept study directly into pivotal clinical trials. In certain cases where we develop new formulations of existing marketed compounds, we may only be required to complete one Phase III clinical trial, rather than the two Phase III clinical trials generally required for new chemical entities. If we are able to complete product development with fewer clinical trials than are required for a new chemical entity, we may have lower costs of development and shorter development timelines.

Our JZP-2, JZP-7 and JZP-8 product candidates resulted from this program. We currently have several other product candidates identified through this program in various stages of early development, including the use of sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of movement disorders. We are also conducting activities intended to develop new dosage forms of sodium oxybate.

We expect to begin more early-stage projects than will progress into later-stage development. If a product candidate does not successfully meet our requirements at any stage of development, we terminate the project. We also review our portfolio periodically to ensure that we have a balanced mix of product candidates moving into later stages of development across our therapeutic areas on a regular basis.

Sales and Marketing

We have a specialty sales force consisting of 55 full-time sales professionals, including five regional sales managers, who promote Xyrem. Our sales representatives are experienced, with an average of five years of specialty selling experience. Our sales management team has an average of nine years of specialty sales management experience. Our sales force calls on neurologists, psychiatrists, pulmonologists and sleep specialists. In the near term, we anticipate more than doubling our specialty sales force to prepare for the commercial launch, subject to receipt of FDA approval, of Luvox CR, with additional sales professionals focusing on psychiatrists who treat obsessive compulsive disorder and social anxiety disorder. If JZP-6 is approved by the FDA, we expect to further expand our specialty sales force to include additional sales professionals who would focus on rheumatologists treating fibromyalgia syndrome.

We have established marketing and commercial operations departments to support our sales efforts. Our marketing and commercial operations departments consist of marketing professionals who are responsible for

brand management and market research, and commercial operations professionals who are responsible for business analytics and commercial technology, commercial administration, training and development, pharmacy relations and patient affairs. Our marketing team develops and implements brand strategies to maximize product uptake and adoption with our target physician audiences in accordance with our approval labeling. We expect to significantly expand commercial operations in 2007 to accommodate promotional and marketing activities necessary to prepare for the potential commercial launch of Luvox CR, including the addition of a trade relations team and a national accounts, or managed care, team. We also employ numerous third party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support related services.

Medical Affairs Department

We have a Medical Affairs department consisting of approximately ten professionals that provides medical information regarding our products to health care providers and handles related medical issues. Our Medical Affairs Department answers medical questions from health care professionals and provides them with publications on request. The medical education activities of our Medical Affairs department focus on grants for continuing medical education activities and the creation of enduring educational materials. Our five Medical Affairs scientists, who are based around the country, foster our relationships with thought leaders and work with investigators who are interested in exploring novel uses of our products.

Manufacturing

We do not have, and do not intend to establish in the near term, any of our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. We have entered into manufacturing and supply agreements with third parties for our marketed products. For each of our marketed products, we utilize a single supplier for the active pharmaceutical ingredient and a separate drug product manufacturer. We have agreements with these suppliers and manufacturers for Xyrem, Antizol and Antizol-Vet.

Pursuant to an agreement with Lonza, Inc., or Lonza, which was originally executed in November 1996 and subsequently amended, we must purchase our worldwide supply of sodium oxybate, the active pharmaceutical ingredient in Xyrem, from Lonza. Our purchase price for this supply is volume-based. Our agreement with Lonza will continue until August 1, 2008 and will automatically extend for three-year terms thereafter until either party gives notice of its intent to terminate the agreement at least 18 months prior to the end of any such term. We may terminate the agreement upon 30 days' notice if Lonza is unable to meet our minimum requirements or timeframes for supply. We also have an agreement with DSM Pharmaceuticals, Inc., or DSM, under which DSM supplies us with Xyrem. We and DSM have mutually agreed to terminate our agreement, effective January 1, 2008. In connection with this planned termination, we entered into an agreement with Patheon Pharmaceuticals, Inc., or Patheon, in March 2007 under which we agreed to purchase, and Patheon agreed to supply us with Xyrem commencing in 2008. Under the agreement with Patheon, our price for the manufacture and supply of Xyrem is volume-based. The initial term of the agreement with Patheon will extend until five years following the commencement of manufacturing activities by Patheon, and may be extended, at our option, for additional two-year terms.

We believe that qualified suppliers and manufacturers for our marketed products will continue to be available in the future, at a reasonable cost to us, although there can be no assurance that this will be the case.

We are also seeking, have identified or have entered into manufacturing and supply arrangements for our product candidates. In particular, if Luvox CR is approved, Solvay will supply us with the active pharmaceutical ingredient, and Elan will manufacture our commercial requirements, for Luvox CR. We are also obligated under our agreement with Solvay to supply Solvay with its commercial requirements of Luvox CR for sale outside of the United States. We have contracted with our existing contract manufacturers of Xyrem for the active pharmaceutical ingredient and drug product for our clinical requirements of JZP-6. As with Xyrem, we will be

responsible for supplying JZP-6 to UCB and, if applicable, to Valeant. We are also seeking or have identified qualified suppliers and contract manufacturers for JZP-4, JZP-8, JZP-7 and JZP-2.

Because sodium oxybate is a controlled substance subject to manufacturing quotas by the DEA, our supplier and contract manufacturer of Xyrem and JZP-6 may be unable to provide us with sufficient quantities necessary to complete our clinical trials or, if approved, commercialize the product. The DEA requires substantial evidence and documentation of expected need before assigning quotas to manufacturers. Therefore, obtaining sufficient quotas can be very difficult and time consuming, which may provide a meaningful obstacle for the introduction of generic formulations of Xyrem and the eventual introduction of generic versions of JZP-6.

In an effort to minimize the risks associated with shortages of our products and product candidates for commercial and clinical trial needs, we have adopted a production planning program to assess and manage manufacturing logistics among the vendors supplying the required finished product components of active pharmaceutical ingredient, drug product and packaging.

Manufacturers and suppliers of our products and product candidates are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and other rules and regulations prescribed by foreign regulatory authorities. We depend on our third party suppliers and manufacturers for continued compliance with cGMP requirements and applicable foreign standards.

Government Regulation

The testing, manufacturing, labeling, advertising, promotion, distribution, export and marketing of our products are subject to extensive regulation by governmental authorities in the United States and in other countries. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, regulates pharmaceutical products. Several of our products and product candidates are regulated as controlled substances and are subject to additional regulation by the DEA under the Controlled Substances Act. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, withdrawal of approval of approved products, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, civil penalties and/or criminal prosecution.

Drug Approval Process

To obtain FDA approval of a product candidate, we must, among other things, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product candidate and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory tests and animal tests;
- submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication;
- the submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMP;

- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

Preclinical studies may include laboratory evaluations of the product chemistry, toxicity, and formulation, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials typically are conducted in three sequential phases prior to approval, but the phases may overlap. A fourth, or post-approval, phase may include additional clinical studies. These phases generally include the following:

- *Phase I.* Phase I clinical trials involve the initial introduction of the drug into human subjects, frequently healthy volunteers. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the adverse effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase I, the drug is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamic properties.
- *Phase II.* Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the drug for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Although there are no statutory or regulatory definitions for Phase IIa and Phase IIb, Phase IIa is commonly used to describe a Phase II clinical trial evaluating efficacy, adverse effects, and safety risks and Phase IIb is commonly used to describe a subsequent Phase II clinical trial that also evaluates dosage tolerance and optimal dosage. Some of our product candidates, particularly those using the same active pharmaceutical ingredient as products already on the market, may be able to skip or have abbreviated Phase II studies.
- *Phase III.* If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) studies, the clinical trial program will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites. Phase III studies usually include several hundred to several thousand patients. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA, but for some product candidates, particularly those using the same active pharmaceutical ingredient as products already on the market, only one Phase III trial may be required.

- *Phase IV.* Phase IV clinical trials are studies required of or agreed to by a sponsor that are conducted after the FDA has approved a product for marketing. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase III/IV post approval clinical trials. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter. Sponsors that receive either an approvable letter or a not approvable letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission, and six months to review a Class 2 resubmission. The FDA may also refer an application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval (Subpart H), that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis surrogate endpoints or restricted distribution. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drug candidates will qualify for any of these programs, or that, if a drug does qualify, that the review time will be shorter than a standard review.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approval for new indications for any product will be approved on a timely basis, or at all.

Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval

conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to:

- report certain adverse reactions to the FDA;
- submit annual and periodic reports summarizing product information and safety data;
- comply with certain requirements concerning advertising and promotional labeling for their products; and
- continue to have quality control and manufacturing procedures conform to cGMP after approval.

The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Section 505(b)(1) New Drug Applications

The approval process described above is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a "full" or "stand-alone" NDA, is governed by Section 505(b)(1) of the FDCA. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval of, for example, new indications or improved formulations of previously-approved products, a company may submit a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA filing under Section 505(b)(1). Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug product for all or some of the label indications for which the referenced product has been approved, or for a new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved drug product, the applicant is required to certify that there are no Orange Book-listed patents for that drug product or that for each Orange Book-listed patent that:

- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

A certification that the new product will not infringe the already approved product's Orange Book-listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, as well as any additional period of exclusivity that might be obtained for

completing pediatric studies pursuant to the FDA's written request. The Section 505(b)(2) application may also not be approved until any applicable non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the holder of the NDA and the relevant patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity, such as Xyrem, if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the NDA with the five-year exclusivity period. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's 505(b)(2) NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

In the NDA submissions for our product candidates, we intend to follow the development pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates.

The Hatch-Waxman Act

Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits the submission of an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another "full" NDA; however, the applicant would be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the FDCA to require each NDA sponsor to submit with its application information on any patent that claims the active pharmaceutical ingredient, drug product (formulation and composition), and method-of-use for which the applicant submitted the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our product candidates, and to vigorously defend any Orange Book-listed patents for our approved drug products.

The Hatch-Waxman Act also permits a patent term extension of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years after the FDA approves a marketing application. The patent term extension period is generally equal to the sum of one-half the time between the effective date of an IND and the submission date of an NDA, and all of the time between the submission date of an NDA and the approval of that application, up to a total of five years. Only one patent applicable to an approved drug, that represents the first commercial marketing of that active pharmaceutical ingredient, is eligible for the extension, and it must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We will consider applying for a patent term extension for some of our patents, to add patent life beyond the expiration date, depending on our ability to meet certain legal requirements permitting such extension, and the expected length of clinical trials and other factors involved in the submission of an NDA.

Orphan Drug Designation and Exclusivity

Some jurisdictions, including Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.

Xyrem is currently protected by five years of new chemical entity exclusivity, which expires in July 2007. The FDA designated and approved Xyrem as an orphan drug for each of cataplexy and excessive daytime sleepiness in patients with narcolepsy. The periods of orphan drug exclusivity, which run concurrently with the period of five-year new chemical entity exclusivity, expire in July 2009 and November 2012, respectively for cataplexy and excessive daytime sleepiness in patients with narcolepsy. We anticipate receiving three years of marketing exclusivity for Luvox CR if the FDA approves the marketing application for Luvox CR, and if the FDA determines that the requirements for granting three-year exclusivity are met.

Pediatric Exclusivity

The FDCA provides an additional six months of non-patent marketing exclusivity and patent protection for any such protections listed in the Orange Book for new or marketed drugs for specific pediatric studies conducted at the written request of the FDA. The Pediatric Research Equity Act of 2003 authorizes the FDA to require pediatric studies for drugs to ensure the drugs' safety and efficacy in children. The Pediatric Research Equity Act of 2003 requires that certain new NDAs or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from the Pediatric Research Equity Act of 2003. Unless otherwise required by regulation, the Pediatric Research Equity Act of 2003 does not apply to any drug for an indication with orphan designation. We plan to work with the FDA to determine the need for pediatric studies for our product candidates, and may consider attempting to obtain pediatric exclusivity for some of our product candidates.

Fast Track Designation

The FDA's fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, applicants may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA will determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

If the FDA grants fast track designation, it may initiate review of sections of an NDA before the application is complete. This so-called "rolling review" is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant has paid applicable user fees. The FDA's PDUFA review clock for both a standard and priority NDA for a fast track product does not begin until the complete application is submitted. Additionally, fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by emerging data, or if the designated drug development program is no longer being pursued.

In some cases, a fast track designated drug candidate may also qualify for priority NDA review. When appropriate, we intend to seek fast track designation or priority review for our product candidates. We cannot predict whether any of our product candidates will obtain fast track or priority review designation, or the ultimate impact, if any, of these expedited review mechanisms on the timing or likelihood of the FDA approval of any of our product candidates.

Other Regulatory Requirements

In addition to regulation by the FDA and certain state regulatory agencies, the DEA imposes various registration, recordkeeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the Controlled Substances Act. A principal factor in determining the particular requirements, if any, applicable to a product is the actual or potential abuse profile. The DEA regulates drug substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Sodium oxybate in its base form is regulated by the DEA as a Schedule I controlled substance but when contained in a drug product approved by FDA it is regulated as a Schedule III controlled substance. Xyrem is a Schedule III controlled substance and JZP-6, along with certain of our early-stage product candidates, contains sodium oxybate. These product candidates, if approved for marketing by FDA, will also likely be Schedule III controlled substances. In addition, JZP-8, JZP-2 and certain of our early-stage product candidates will likely be regulated as controlled substances if approved for marketing by the FDA. Controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of the scheduled substance that would be available for clinical trials and commercial distribution. Sodium oxybate, as a Schedule I substance, is subject to additional controls, including quotas on the amount of product that can be manufactured. As a Schedule III drug, Xyrem is subject to limitations on prescription refills. The third parties who perform our clinical and commercial manufacturing for Xyrem and JZP-6 have received necessary registrations from the DEA. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, and could harm our business and financial condition.

We are also subject to a variety of foreign regulations governing clinical trials and the marketing of other products. Outside of the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical

trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

Pharmaceutical Pricing and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include:

- controls on government funded reimbursement for drugs;
- controls on healthcare providers;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- reform of drug importation laws; and
- expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our ability to operate profitably.

We may also face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers' ability to import lower priced versions of our and competing products from Canada. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

Patents and Proprietary Rights

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products, inventions and improvements that we consider important to the development of our business. We own seven issued U.S. patents. In addition to the issued U.S. patents, we own or have rights to 13 pending U.S. patent applications and more than 100 issued and pending foreign patents and patent applications. Our owned and licensed patents and patent applications cover formulations of our products and product candidates, uses of our products and product candidates to treat particular conditions, drug delivery technologies and delivery profiles relating to our products and product candidates and methods for producing our products and product candidates. However, patent protection is not available for the active pharmaceutical ingredients in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. The patents and patent applications that relate to our products and product candidates include the following:

- *Xyrem*. Xyrem is covered by a U.S. formulation patent that will expire on December 22, 2019. Our Xyrem formulation patent has issued in 17 other countries and will expire on December 22, 2019. It is currently pending in three additional countries. Xyrem is also covered by a U.S. patent that covers a process for preparing the formulation that expires on December 22, 2019. We also have filed a U.S. patent application with claims covering the method for distributing sodium oxybate using a centralized distribution system that, if issued, would expire on December 17, 2022.
- *Luvox CR*. Luvox CR is covered by a U.S. patent application filed by Elan with claims covering the orally administered formulation of extended release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours that, if issued, would expire on May 10, 2020. We obtained a license to this patent application and any resulting patent that issues as a result of Solvay's assignment of its license and supply agreement with Elan to us in connection with our exclusive license of the rights to market and distribute Luvox CR in the U.S.
- *JZP-6*. We expect that our current patents associated with Xyrem will be applicable to JZP-6. We also own patents with claims covering the use of sodium oxybate for the treatment of fibromyalgia syndrome that will expire in the United States on August 29, 2017 and in 29 other countries on August 27, 2018.
- *JZP-4*. JZP-4 is covered by a U.S. composition of matter patent that we acquired from GSK that will expire on February 26, 2018. The JZP-4 composition of matter is covered by patents in 52 other countries that expire in 2018. In addition, we hold a U.S. patent that covers the use of JZP-4 for the treatment of bipolar disorder, pain or functional bowel disorder that will expire on February 26, 2018, and a U.S. patent that covers the preparation of the active pharmaceutical ingredient in JZP-4 that will expire on May 2, 2021. Further, we have filed a U.S. patent application with claims covering a sustained release composition for delivering JZP-4 that, if issued, would expire on February 14, 2026.
- *JZP-8*. We have filed a provisional U.S. patent application with claims covering JZP-8. A patent claiming priority from this application would, if issued, expire in 2027. The claims do not cover the JZP-8 composition of matter.
- *JZP-7*. We have filed a provisional U.S. patent application with claims covering JZP-7. A patent claiming priority from this application would, if issued, expire in 2027. The claims do not cover the JZP-7 composition of matter.
- *JZP-2*. We have an option for an exclusive license to four U.S. formulation patents covering JZP-2 from the technology provider with which we are conducting feasibility studies associated with JZP-2. These patents will expire on August 1, 2017.

Because the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any further patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products or ensure that others will not be issued patents that may prevent the sale of our products or require licensing and the payment of significant fees or royalties. In addition, we cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents. Furthermore, to the extent that any of our future products or methods is not patentable or infringe the patents of third parties, or in the event that our patents or future patents fail to give us an exclusive position in the subject matter claimed by those patents, our business could be adversely affected. We may be unable to avoid infringement of third party patents and may have to obtain a license, defend an infringement action, or challenge the validity of the patents in court. A license may be unavailable on terms and conditions acceptable to us, if at all. Patent litigation is costly and time consuming, and we may be unable to prevail in any such patent litigation or devote sufficient resources to even pursue such litigation. If we do not obtain a license under necessary patents, are found liable for infringement, or are not able to have such patents declared invalid, we may be liable for significant money damages, encounter significant delays in bringing products to market, or be precluded from participating in the manufacture, use or sale of products or methods of treatment requiring such licenses.

We have also applied for a number of trademarks and service marks to further protect the proprietary position of our products. We own 18 registered trademarks and service marks in the United States and 29 registered trademarks and service marks in other countries. We also have 9 pending trademark and service mark applications in the United States and 11 pending trademark and service mark applications in other countries. We also rely on our trade secrets and those of our licensors, as well as other unpatented proprietary information, to protect our products. To the extent that our products have a competitive edge as a result of our reliance on trade secrets and unpatented know-how, our competitive position may be compromised if others independently develop products using the same or similar technologies or trade secrets. We seek to protect our trade secrets and proprietary knowledge in part through confidentiality agreements with our employees, consultants, advisors and collaboration partners. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of our confidential information. If our employees, consultants, advisors or collaboration partners develop inventions or processes independently or jointly with us that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those third parties or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on our business.

Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, such as Pfizer and GlaxoSmithKline, as well as specialty pharmaceutical companies that market psychiatry and neurology products. Most of these companies have financial resources and marketing capabilities substantially greater than ours. Our ability to remain competitive in the marketplace is also impacted by our ability to compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. Some of these competitors include Cephalon, Inc., Shire Pharmaceuticals Group plc, Endo Pharmaceuticals Holdings Inc. and Forest Laboratories. These established companies may have a competitive advantage over us due to their size and financial resources.

Our products and product candidates may also compete with new products currently under development by others, alternate therapies during the period of patent protection and generic equivalents once patent protection is no longer available. Any products that we develop are likely to be in a highly competitive market, and many of our competitors may succeed in developing products that may render our products obsolete or noncompetitive. In

particular, our most significant marketed product and late stage product candidates face competition from the following products:

- *Xyrem*. We believe that the primary competition for Xyrem is Provigil, a wakefulness promoting agent and the only other FDA-approved product for the treatment of excessive daytime sleepiness in patients with narcolepsy.
- *Luvox CR*. We believe that the primary competition for Luvox CR in the treatment of obsessive compulsive disorder is Prozac, Zoloft and Paxil, and their generic equivalents. In the treatment of social anxiety disorder, we believe that Luvox CR's primary competition will also include Paxil CR and Effexor XR.
- *JZP-6*. Although there currently are no FDA-approved treatments for fibromyalgia syndrome, several large pharmaceutical companies, including Pfizer and Eli Lilly, have stated that they have products for the treatment of fibromyalgia syndrome in development. In particular, in December 2006, Pfizer filed a supplemental NDA for Lyrica for the treatment of fibromyalgia syndrome.

For a more detailed description of current products that compete with Xyrem, please see "—Marketed Products—Xyrem (sodium oxybate oral solution)—Competition." For a more detailed description of current products that may be competitive with our product candidates, please see the descriptions under the headings "—Competition" for each our product candidates described under "—Product Candidates."

With respect to our current and potential future product candidates, we believe that our ability to successfully compete will depend on, among other things:

- efficacy, safety and reliability of our product candidates;
- the timing and scope of regulatory approvals;
- product acceptance by physicians and other health care providers;
- our ability to expand and grow our specialty sales force;
- protection of our proprietary rights and the level of generic competition;
- the speed at which we develop product candidates;
- our ability to complete clinical development and obtaining regulatory approvals for our product candidates;
- our ability to supply commercial quantities of a product to the market;
- obtaining reimbursement for product use in approved indications;
- our ability to recruit and retain skilled employees; and
- availability of substantial capital resources to fund development and commercialization activities.

Employees

As of March 31, 2007, we had 203 full-time employees. Of the full-time employees, 87 were engaged in sales and marketing, 66 were engaged in manufacturing, product development and clinical activities, and 50 were engaged in general and administrative activities. We plan to continue to expand our product development programs and product commercialization activities. To support this growth, we will need to expand managerial, operations, development, manufacturing, regulatory, sales, marketing, financial and other functions. In particular, our potential future commercial products, including Luvox CR and JZP-6, will require a significantly expanded sales force and a significant sales support organization. None of our employees is represented by a labor union, and we consider our employee relations to be good. We currently utilize TriNet Employer Group, Inc., an employer services company, to provide human resource services. TriNet is the employer of record for payroll, benefits, employee relations and other employment-related administration.

Facilities

Our corporate headquarters are located in Palo Alto, California, where we occupy approximately 44,000 square feet of office space. The annual lease payments for corporate headquarters building are approximately $735,000. Thereafter, at our option, we may extend the term for up to an additional nine years to August 2017. We also lease approximately 13,000 square feet of additional office space in Palo Alto, California. The annual lease payments for this space are approximately $460,000. The fixed lease term expires in August 2008, after which we may extend the term for up to six months subject to certain conditions. We believe that the facilities that we currently lease are sufficient for approximately the next three months and that anticipated future growth thereafter can be accommodated by leasing additional space near our current facilities.

Legal Proceedings

In April 2006, we and our subsidiary Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. In April 2006, a physician who was a speaker for Orphan Medical, and for a short time for us, was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for us, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce. This investigation has resulted in adverse publicity for Xyrem and for us.

We and Orphan Medical are discussing a possible settlement with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services, relating to this matter. If we complete a settlement on the terms that we are currently discussing, Orphan Medical would plead guilty to one felony count of introducing a misbranded drug into interstate commerce and would pay a total of approximately $20.5 million in civil and criminal payments over the next several years in connection with this matter, with approximately $1.5 million payable in 2007, $2.0 million payable in 2008, $2.5 million payable in 2009, $3.0 million payable in 2010, $3.0 million payable in 2011 and $8.5 million payable in 2012. We would guarantee payment of these amounts by Orphan Medical.

If we complete a settlement on the terms that we are currently discussing, the U.S. Attorney has indicated that we would not be prosecuted. As part of the settlement, we would enter into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which would require us to maintain a comprehensive compliance program. We previously have implemented, in certain cases prior to learning of the investigation, some of the compliance obligations likely to be included in a corporate integrity agreement, such as designation of a senior-level compliance officer and adoption of sales and marketing compliance policies. We would have additional ongoing compliance-related operating costs related to this compliance program, which we do not expect to be material, as a result of the corporate integrity agreement.

The settlement terms described above are subject to the negotiation and execution of definitive agreements. Even if we reach a settlement agreement with the U.S. Attorney's Office, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states' attorneys general with respect to activities covered by the settlement. If we do not reach a settlement, we could be required to spend significant amounts to defend ourselves and Orphan Medical, and the investigation could involve criminal charges, as well as criminal and/ or civil fines and penalties, against us, Orphan Medical, or both. If we are unable to complete the settlement described above, we cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome, and such an outcome could have a material adverse effect on our financial position, liquidity and results of operations.

In April 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against Orphan Medical, John H. Bullion, and Timothy G. McGrath in the U.S. District Court for the District of Minnesota. The case is captioned Little Gem Life Sciences LLC v. Orphan Medical, Inc., John H. Bullion, and Timothy G. McGrath, Civ. Action No. 06-CV-1377 (ADM/AJB). The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by Orphan Medical in connection with the solicitation of proxies to be voted at the special meeting of Orphan Medical stockholders held on June 22, 2005 for the purpose of considering and voting upon a proposal to adopt the definitive merger agreement pursuant to which we acquired Orphan Medical. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys' fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the U.S. District Court for the District of Minnesota. On February 16, 2007, the U.S. District Court for the District of Minnesota granted the defendants' motion to dismiss the complaint, but granted the plaintiff a one-month leave to amend the plaintiff's complaint. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. We are unable to predict the outcome of this lawsuit and amounts ultimately payable, if any, resulting from an adverse outcome in this lawsuit cannot be reasonably estimated.

MANAGEMENT

Directors and Executive Officers

The following table sets forth certain information concerning our directors and executive officers as of March 31, 2007:

Name	Age	Position
Bruce C. Cozadd	43	Executive Chairman and Director
Samuel R. Saks, M.D.	52	Chief Executive Officer and Director
Robert M. Myers	43	President
Matthew K. Fust	42	Senior Vice President and Chief Financial Officer
Carol A. Gamble	54	Senior Vice President, General Counsel and Corporate Secretary
Janne L.T. Wissel	51	Senior Vice President of Development
Adam H. Clammer	36	Director
Samuel D. Colella(2)(3)	67	Director
Bryan C. Cressey	57	Director
Michael W. Michelson(2)	56	Director
James C. Momtazee(1)(3)	35	Director
Kenneth W. O'Keefe(1)	40	Director
Jaimin R. Patel	25	Director
Alan M. Sebulsky(1)	48	Director
James B. Tananbaum, M.D.(2)	44	Director

(1) Member of audit committee.
(2) Member of compensation committee.
(3) Member of nominating and corporate governance committee.

Executive Officers

Bruce C. Cozadd is a co-founder and has served as our Executive Chairman since 2003. From 2001 to 2003, he served as a consultant to companies in the biopharmaceutical industry and worked on a part-time basis for Prospect Ventures Partners and Versant Ventures, both venture capital firms. From 1991 until 2001, he held various positions with ALZA Corporation, a pharmaceutical company now owned by Johnson & Johnson, most recently as its Executive Vice President and Chief Operating Officer, with responsibility for research and development, manufacturing and sales and marketing. Previously at ALZA Corporation he held the roles of Chief Financial Officer and Vice President, Corporate Planning and Analysis. He serves on the boards of Cerus Corporation, a biopharmaceutical company, Threshold Pharmaceuticals, a biotechnology company, The Nueva School and Stanford Hospital and Clinics, both non-profit organizations, as well as the Stanford Molecular Imaging Advisory Board. He received a B.S. from Yale University and an M.B.A. from the Stanford Graduate School of Business.

Samuel R. Saks, M.D. is a co-founder and has served as our Chief Executive Officer since 2003. From 2001 until 2003, he was Company Group Chairman of ALZA Corporation and served as a member of the Johnson & Johnson Pharmaceutical Group Operating Committee. From 1992 until 2001, he held various positions with ALZA Corporation, most recently as its Chief Medical Officer and Group Vice President, where he was responsible for clinical and commercial activities. He serves on the board of Trubion Pharmaceuticals, a biopharmaceutical company. He received a B.S. and an M.D. from the University of Illinois.

Robert M. Myers is a co-founder and was appointed as our President in March 2007. From 2003 until 2007, he served as our Executive Vice President and Chief Business Officer. From 2002 until 2003, he served as Executive Vice President, Pharmaceuticals at Exelixis, Inc., a biotechnology company. He previously held various positions with ALZA Corporation from 1992 to 2001, most recently as its Senior Vice President,

Commercial Development. In this role, he was responsible for ALZA Corporation's corporate development, mergers and acquisitions, new product planning and corporate planning. He received B.S. and M.S. degrees from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

Matthew K. Fust was appointed as our Senior Vice President in 2004 and has served as our Chief Financial Officer since 2003. From 2002 to 2003, he served as Chief Financial Officer at Perlegen Sciences, a biopharmaceutical company. He previously held various positions with ALZA Corporation from 1996 to 2002, most recently as its Chief Financial Officer. He serves on the board of Sunesis Pharmaceuticals, a biopharmaceutical company. He received a B.A. from the University of Minnesota and an M.B.A. from the Stanford Graduate School of Business.

Carol A. Gamble was appointed as our Senior Vice President in 2004 and has served as our General Counsel and Corporate Secretary since 2003. From 2002 to 2003, she served as a consultant to various companies in the pharmaceutical industry. From 2000 to 2002, she served as General Counsel and Corporate Secretary of Aerogen, Inc., a biopharmaceutical company acquired by Nektar Therapeutics. From 1988 to 2000, she held various positions with ALZA Corporation, most recently as its Senior Vice President and Chief Corporate Counsel. She received a B.S. from Syracuse University and a J.D. from the University of California, Berkeley, Boalt Hall.

Janne L. T. Wissel has served as our Senior Vice President of Development since 2004. From 2003 to 2004, she served as our Vice President of Development. From 1981 to 2003, she held various positions at ALZA Corporation, most recently as its Senior Vice President, Operations, with responsibility for ALZA Corporation's global regulatory, quality, general operations and manufacturing activities. She has led the development, registration and launch of more than 20 pharmaceutical products in the neurology, pediatric psychiatry, endocrinology, urology and oncology areas. She received a B.S. from the University of California, Davis and an M.B.A. from the University of Phoenix.

Directors

Adam H. Clammer has served as a member of our board of directors since 2004. Since 1995, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is a Member of its general partner, KKR & Co. L.L.C. He serves on the boards of MedCath Corporation, a cardiovascular services company and several privately-held technology companies. He received a B.S. from the University of California and an M.B.A. from Harvard Business School.

Samuel D. Colella has served as a member of our board of directors since 2004. Since 1999, he has served as Managing Member of Versant Ventures, a venture capital firm, which he co-founded. He serves on the boards of Alexza Pharmaceuticals, Inc., a pharmaceutical company, Genomic Health Inc., a molecular diagnostics company, Symyx Technologies, Inc., a research technology company, Thermage, Inc., a aesthetic medicine company, and several privately-held companies. He received a B.S. from the University of Pittsburgh and an M.B.A. from the Stanford Graduate School of Business.

Bryan C. Cressey has served as a member of our board of directors since 2006. Since 1998, he has been a Partner of Thoma Cressey Bravo, Inc., a private equity firm, of which he is a founder. He serves on the boards of Belden CDT, Inc., a division of Belden Cable, a cable technology company, Select Medical Corporation, a healthcare services company, and several privately-held healthcare services companies. He received a B.A. from the University of Washington, a J.D. from Harvard Law School and an M.B.A. from Harvard Business School.

Michael W. Michelson has served as a member of our board of directors since 2004. Since 1981, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is a Member of its general partner, KKR & Co. L.L.C. and also serves on KKR's Investment and Operating committees. He serves on the boards of HCA Inc., a

healthcare services company, and Accellant Inc., a manufacturing and engineering services company. He received an A.B. from Harvard College and a J.D. from Harvard Law School.

James C. Momtazee has served as a member of our board of directors since 2004. Since 1996, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is a Director. He serves on the boards of HCA Inc., a healthcare services company, and Accellent Inc., a manufacturing and engineering services company. He received an A.B. from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

Kenneth W. O'Keefe has served as a member of our board of directors since 2004. Since 1997, he has been Managing Director of Beecken Petty O'Keefe & Company, a private equity firm, which he co-founded. He serves on the boards of several privately-held healthcare companies. He received a B.A. from Northwestern University and an M.B.A. from the University of Chicago.

Jaimin R. Patel has served as a member of our board of directors since 2007. Since June 2006, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is an Associate. From August 2004 to June 2006, Mr. Patel was an analyst with UBS Securities LLC. Prior to that, Mr. Patel was a full-time student at the University of Pennsylvania where he received a B.S. in 2004.

Alan M. Sebulsky has served as a member of our board of directors since 2004. Since 2003, he has served as a Managing Partner of Apothecary Capital LLC, an investment advisory firm. From 2002 to 2003, he was an independent investor. From 1994 to 2002, he held various positions, most recently as a Managing Director, at Lincoln Capital Management, a private investment management firm, where he was responsible for investments in the health care industry. He received a B.B.A. and an M.S. from the University of Wisconsin-Madison.

James B. Tananbaum, M.D. has served as a member of our board of directors since 2003. Since 2000, Dr. Tananbaum has been a Managing Member of Prospect Venture Partners, a venture capital firm he co-founded. He serves on the boards of Critical Therapeutics, Inc., a biopharmaceutical company, Infinity Pharmaceuticals, Inc., a drug discovery company, Novavax, Inc., a biotechnology company, and Vanda Pharmaceuticals Inc., a biopharmaceutical company, as well as several private companies. Dr. Tananbaum was also the founder of GelTex, Inc. and Theravance, Inc. He received a B.S.E.E. from Yale University, and an M.D. and an M.B.A. from Harvard University.

Board Composition

Our board of directors currently consists of ten members. Our board of directors has determined that all of our directors, other than Mr. Cozadd and Dr. Saks, are "independent" within the meaning of applicable NASDAQ listing standards.

Effective upon the completion of this offering, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of Dr. Tananbaum and Messrs. Clammer, Cressey and Patel, and whose term will expire at our annual meeting of stockholders to be held in 2008;
- Class II, which will consist of Dr. Saks and Messrs. Colella and Momtazee, and whose term will expire at our annual meeting of stockholders to be held in 2009; and
- Class III, which will consist of Messrs. Cozadd, Michelson, O'Keefe and Sebulsky, and whose term will expire at our annual meeting of stockholders to be held in 2010.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until their successors are duly elected and qualified at the third annual meeting following their election. The authorized number of directors may be changed only by resolution of the

board of directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Under Delaware law, our directors may be removed for cause by the affirmative vote of the holders of at least a majority of our voting stock.

Board Committees

Our board of directors currently has an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and primary responsibilities of each committee are described below.

Audit Committee. The members of our audit committee are Messrs. Momtazee, O'Keefe and Sebulsky. Mr. O'Keefe chairs the audit committee. Our board of directors has determined that Messrs. O'Keefe and Sebulsky meet the independence requirements of Rule 10A-3 of the Exchange Act and NASDAQ listing standards. Our board of directors has also determined that Mr. O'Keefe qualifies as an audit committee financial expert within the meaning of SEC regulations and the NASDAQ listing standards. In making this determination, our board of directors considered the nature and scope of experience Mr. O'Keefe has had with reporting companies and his employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our accounting, financial and other reporting and internal control practices and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- evaluating the performance of our independent registered public accounting firm and determining whether to retain or terminate their services;
- determining and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services, other than immaterial aggregate amounts of non-audit services as excepted under applicable laws and rules;
- reviewing and discussing with management and our independent registered public accounting firm, as appropriate, the results of the annual audit and the independent registered public accounting firm's review of our annual and quarterly financial statements and reports;
- reviewing with management and our independent registered public accounting firm significant issues that arise regarding accounting principles and financial statement presentation;
- conferring with management and our independent registered public accounting firm, as appropriate, regarding the scope, adequacy and effectiveness of our internal control over financial reporting; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal control or auditing matters.

Compensation Committee. The members of our compensation committee are Messrs. Colella and Michelson and Dr. Tananbaum. Mr. Michelson chairs the compensation committee. Each member of the compensation committee is independent within the meaning of applicable NASDAQ listing standards, is a "non-employee director" as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is an "outside director" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended. The purpose of our compensation committee is to discharge the responsibilities of our board of directors to oversee our compensation policies, plans and programs, and to review and determine the compensation to be paid to our executive officers and other senior management. Specific responsibilities of our compensation committee include:

- recommending to our board of directors for approval the compensation and other terms of employment of our Executive Chairman and our Chief Executive Officer;
- determining the compensation and other terms of employment of our other executive officers and senior management;

- reviewing and approving corporate performance goals and objectives relevant to the compensation of our executive officers and other senior management;
- evaluating and recommending to our board of directors for approval the compensation plans and programs advisable for us, and evaluating and recommending the modification or termination of existing plans and programs; and
- reviewing and approving the terms of any employment agreements, severance arrangements, change of control protections and any other compensatory arrangements for our executive officers and other senior management.

Nominating and Corporate Governance Committee. The members of our nominating and corporate governance committee are Messrs. Colella and Momtazee. Mr. Colella chairs the nominating and corporate governance committee. Each member of the nominating and corporate governance committee is independent within the meaning of applicable NASDAQ listing standards. The specific responsibilities of our nominating and corporate governance committee include:

- identifying, reviewing, evaluating and recommending for selection candidates for membership to our board of directors;
- reviewing, evaluating and considering the recommendation for nomination of incumbent members of our board of directors for reelection to our board of directors and monitoring the size of our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- reviewing, discussing and reporting to our board of directors an assessment of our board's performance;
- recommending director compensation; and
- determining adherence to our Code of Conduct.

Compensation Committee Interlocks and Insider Participation

In 2006, our compensation committee consisted of Messrs. Colella and Michelson and Dr. Tananbaum. David Mayer, one of our former directors, served on the compensation committee until his resignation from our board of directors in October 2006. None of the members of the compensation committee is currently or has been at any time one of our officers or employees. None of our officers currently serves, or has served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more officers serving as a member of our board of directors or compensation committee.

Executive Compensation

Compensation Discussion and Analysis

Overview

Our executive compensation program is designed to help us attract, as needed, talented individuals to manage and operate all aspects of our business, to reward those individuals fairly over time, and to retain those individuals who continue to meet our high expectations. The goals of our executive compensation program are to align our executive officers' compensation with our business objectives and the interests of our stockholders, to incentivize and reward our executive officers for our success, and to reflect the teamwork philosophy of our executive management team. Specifically, we have created an executive compensation program that combines short and long-term components, cash and equity, and fixed and contingent payments, in the proportions that we believe are the most appropriate to incentivize and reward our executive officers for achieving our objectives. Our executive compensation program is also intended to make us competitive in the San Francisco Bay Area, and

in the pharmaceutical and biotechnology industry, where there is significant competition for talented employees, and to be fair relative to other professionals within our organization. We believe that we must provide competitive compensation packages to attract and retain executive officers and to help our executive management function as a stable team over the longer term.

As discussed in further detail below, our executive compensation program consists of the following three principal components:

- *Base Salary*. Base salary for our executive officers is set each year, effective March 1. For 2006, our executive officers' base salaries were set by reviewing their then current salaries in light of 2005 company performance and individual performance, base salary benchmarking against comparable companies, and general economic factors. We also considered, as we have since our inception, compensation equity among our executive officers.
- *Bonus*. We have an annual cash bonus plan for our employees under which bonuses may be paid shortly after the end of each year, at the discretion of our board of directors, based on our performance in meeting our corporate objectives for the year and each individual's performance and contribution in meeting our corporate objectives.
- *Stock Option Grants*. Our employees and executive officers receive stock option grants as long-term incentives to ensure that a portion of compensation is linked to our long-term success.

The compensation committee does not have any formal policies for allocating compensation among salary, bonus and stock option grants. However, the compensation of our executive officers is based in part on the terms of employment agreements we entered into with each of our executive officers in February 2004 which set forth the initial base salaries for our executive officers as well as the target bonuses under our annual cash bonus plan (subject, in each case, to increases approved by our board of directors or compensation committee).

Role of the Compensation Committee in Setting Executive Compensation

The compensation committee determines the salary, annual cash bonus awards and stock option grants for our executive officers. The compensation committee considers recommendations from Samuel Saks, our Chief Executive Officer, and Bruce Cozadd, our Executive Chairman, in determining executive compensation. While Dr. Saks and Mr. Cozadd discuss their recommendations with the compensation committee, they do not participate in determining their own compensation or that of one another. In making their recommendations, Dr. Saks and Mr. Cozadd receive input from our Human Resources department and have access to various third party compensation surveys and compensation data of publicly-traded we obtained from SEC filings. This information is also available to our compensation committee. Carol Gamble, our General Counsel, participates in compensation committee meetings, but does not participate in any discussions of her own compensation. None of our other executive officers participates in the compensation committee's executive compensation discussions. The compensation committee does not delegate any of its functions to others in determining executive compensation.

The compensation committee has not historically engaged consultants with respect to executive compensation matters. However, the compensation committee engaged Compensia, Inc., a compensation consulting firm located in San Jose, California, to provide the compensation committee with certain benchmarking material to assist it in determining appropriate salary, bonus and long-term equity compensation for our executive officers for 2007. Compensia provided the compensation committee with compensation data for 17 publicly-traded companies in the pharmaceuticals and biotechnology industry, some smaller than our company, some of similar size, and some larger, including Alexza Pharmaceuticals, Inc., Alkermes, Inc., CV Therapeutics, Inc., Endo Pharmaceuticals Holdings, Inc., Indevus Pharmaceuticals, Inc., InterMune, Inc., Medicis Pharmaceutical Corporation and Theravance, Inc. The companies in the survey were chosen because they were generally similar to ours in terms of industry, capital structure, financial attributes, geographic location and/or competition for talent. However, because certain aspects of our business and management team are unique, the

compensation committee used the peer company data as one resource in determining executive compensation for 2007 and not as a stand-alone tool. The compensation committee reviewed the data from Compensia and discussed it, along with other publicly-available compensation data, with Compensia, Dr. Saks and Mr. Cozadd in determining compensation for our executive officers for 2007.

Executive Compensation Program

Our executive compensation program consists of three principal components: base salary, annual cash bonuses (if approved by our board of directors) and long-term incentive compensation in the form of stock options. Our executive officers are also eligible to participate, on the same basis as other employees, in our 401(k) plan and our other benefit programs generally available to all employees. Our executive officers do not receive any perquisites.

Base Salary. Each of our executive officers entered into an employment agreement with us in February 2004 that provides for an initial base salary, subject to annual increases determined by the compensation committee. We review company and individual performance annually, shortly after the end of each calendar year. As discussed above, Dr. Saks and Mr. Cozadd review the executive officers' salaries with the compensation committee in connection with that annual performance review. For 2006, our executive officers' base salaries were set by reviewing their then current salaries against company and individual performance, base salary benchmarking against comparable companies, as well as general economic factors. We also considered, as we have since our inception, compensation equity among our executive officers. Since our inception, we have reviewed the compensation of our executive officers as a group, and have minimized the differences among their salaries. One of the core values of our company is fostering the teamwork philosophy of our management team, which is reflected in our policy of providing compensation equity among our executive officers.

Our compensation committee targets our executives' base salaries as a group in the 75th percentile of salaries for executive officers in similar positions with similar responsibilities at companies of similar size in our industry that have both commercial products and significant product development activities. Our compensation committee believes this is appropriate for several reasons. We have a complex business model and are pursuing multiple commercial and product development opportunities simultaneously with a relatively small organization relative to our level of investment in research and development. We do not have laboratories or manufacturing facilities, and therefore we conduct our development, manufacturing and clinical activities through arrangements with third parties. As a result, our executives are required to manage both internal and significant external resources. Competition for executive talent is intense in our industry and in our geographic area. Our executives have many years of valuable experience in our industry, and their continued leadership is critical to our short-term and long-term success.

Cash Bonuses. We have an annual cash bonus plan under which cash bonuses may be paid annually to all of our employees, including our executive officers, shortly after the end of the calendar year. Target bonus levels under the plan are assigned based on various categories of employees and with respect to our executive officers, are based on the terms of the employment agreements we entered into with them. For 2006, the target bonus level for our Executive Chairman, Chief Executive Officer and Executive Vice President was 50% of base salary; for Senior Vice Presidents, the target was 40% of salary; for Vice Presidents, 20-35% of salary; and lower percentage ranges for directors, managers and others. The actual bonus awarded in any year, if any, may be more or less than the target, depending on individual performance and the achievement of our corporate objectives. Whether or not a bonus is paid for any year is within the discretion of our board of directors. Our compensation committee also determines the size of the total bonus pool under the plan, which is based in large part on our board of directors' determination of our success in achieving our corporate objectives for the plan year. The compensation committee determines the portion of the pool, if any, that will be allocated to the executive officers as a group and the bonuses for each of our executive officers and vice presidents. Dr. Saks and Mr. Cozadd provide input to the compensation committee with respect to bonuses for executive officers.

For 2006, our corporate objectives fell generally in the following categories: achieving certain sales targets, reaching certain development milestones, achieving certain financial targets (for example, spending and EBITDA), completing important milestones in employee training and development and achieving and sustaining company-wide ethical and compliant behavior. The bonus plan does not give a particular weight to any particular corporate objective, nor does it set any formula for determining bonuses. Each employee, including each executive officer, has individual objectives for the year which are designed to contribute to the achievement of our corporate objectives.

The compensation committee has not determined whether it would attempt to recover bonuses from our executive officers if the performance objectives that led to the bonus determination were to be restated, or found not to have been met to the extent originally believed by the compensation committee. However, as a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws, as a result of misconduct, our Chief Executive Officer and Chief Financial Officer may be legally required to reimburse us for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of Section 304 of the Sarbanes-Oxley Act of 2002.

We have not paid any significant signing or promotion bonuses to our executive officers, nor have we guaranteed any bonuses to our executive officers.

Long-term Equity Compensation. Our salary and bonus programs are intended to compensate our executive officers for short-term performance. We also have an equity incentive program intended to reward longer-term performance and to help align the interests of our executive officers with those of our stockholders. We believe that long-term performance is achieved through an ownership culture that rewards such performance by our executive officers through the use of equity incentives. Our current long-term incentives consist solely of stock option grants under our 2003 Equity Incentive Plan. However, our executive officers have also acquired equity in our company through direct investment in our common stock and in our prior preferred stock offerings. The common stock acquired directly by our executive officers is subject to our right of repurchase which lapses on a vesting schedule over a period of four years as described under "—Executive Employment Agreements—Unvested Share Repurchase Right" below. Vested shares are also subject to our repurchase right until February 2009 upon specified termination events as described under "—Executive Employment Agreements—Vested Share Repurchase Right; Executive Put Right" below. The compensation committee believes that the use of stock options offers the best approach to achieve our compensation goals with respect to long-term compensation and currently provides tax and other advantages to our employees relative to other forms of equity compensation. We believe that our stock option program is an important retention tool for our employees. With respect to determining the size of stock option grants, the compensation committee has approved target ranges of stock options for new vice presidents, directors, managers and others, and it reviews those ranges at least annually. The target ranges are intended to set appropriate stock option incentive levels for the various levels of responsibility.

Our executive officers were granted stock option options under our 2003 Equity Incentive Plan in February 2004, which will be fully vested in February 2008 (but any vested shares acquired upon exercise of the options are subject to our repurchase right until February 2009). In connection with its compensation review for 2007, the compensation committee granted additional stock options to our executive officers in February 2007 as described in more detail under "—Compensation Actions for our Executive Officers" below. These options vest as to one-third of the shares subject to the option in February 2010, and the remaining two-thirds of the shares subject to the option vest monthly over two years thereafter. The exercise price of the options is equal to the fair market value of our common stock as determined by the compensation committee on the date of grant. In the absence of a public trading market for our common stock, the compensation committee determined the fair market value of our common stock in good faith based upon consideration of a number of relevant factors including the status of our development and commercialization efforts, results of operations, market conditions and a contemporaneous valuation of our common stock as of December 31,

2006. In determining the number of stock options granted to the executive officers, the compensation committee took into account each executive officer's position, scope of responsibility, ability to affect stockholder value, the individual's historic and recent performance, and our policy of providing compensation equity among our executive officers.

In connection with this offering, our board of directors has adopted new equity benefit plans described under "—Employee Benefit Plans" below. The 2007 Equity Incentive Plan will replace our existing 2003 Equity Incentive Plan immediately upon the signing of the underwriting agreement for this offering. In connection with our transition to a publicly-traded company, the compensation committee intends to evaluate an annual stock option grant program for executive officers to continue aligning the interests of our executive officers with those of our stockholders. Participation in our 2007 Employee Stock Purchase Plan that we have adopted and that will become effective immediately upon the signing of the underwriting agreement for this offering will also be available to all executive officers following this offering on the same basis as our other employees.

Employment Agreements. Our executive officers, each of whom is a party to an employment agreement with us, will continue, following this offering, to be parties to these agreements in their current form until such time as our compensation committee agrees with the executive officers to revise the employment agreements, or until they expire in February 2009. The material terms of these employment agreements are described under "—Executive Employment Agreements" below.

Severance and Change of Control Benefits. Under their employment agreements, our executive officers are entitled to certain severance and change of control benefits, the terms of which are described in detail below under "Executive Employment Agreements—Severance and Change of Control Benefits." With respect to change of control benefits, we provide severance compensation if an executive officer is terminated in connection with a change of control transaction to further promote the ability of our executive officers to act in the best interests of our stockholders even though they could be terminated as a result of the transaction. We also believe that the other severance benefits are appropriate, particularly with respect to a termination by us without cause since in that scenario, we and the executive have a mutually-agreed-upon severance package that is in place prior to any termination event which provides us with more flexibility to make a change in executive management if such a change is in our stockholders' best interests.

Other Benefits. We have a 401(k) plan in which substantially all of our employees are entitled to participate. Employees contribute their own funds, as salary deductions, on a pre-tax basis. Contributions may be made up to plan limits, subject to government limitations. The plan permits us to make matching contributions if we choose; however, to date, we have not made any matching contributions. We provide health care, dental and vision benefits to all full-time employees, including our executive officers. We also have a flexible benefits healthcare plan and a flexible benefits childcare plan under which employees can set aside pre-tax funds to pay for qualified health care expenses and qualified childcare expenses not reimbursed by insurance. These benefits are available to all employees, subject to applicable laws.

Compensation Actions for Our Executive Officers

Samuel Saks, M.D.—Chief Executive Officer. Dr. Saks' base salary effective as March 1, 2006 was $410,000, or a 5% increase over his base salary for the prior 12-month period. After review of the data from Compensia and other publicly-available compensation data, including chief executive officer salaries of public companies in our industry and other companies in the San Francisco Bay Area, the compensation committee increased Dr. Saks' salary to $450,000 effective March 1, 2007. Dr. Saks received a bonus of $102,000 for 2006. In setting the bonus pool for 2006, our board of directors determined that we had met many of our important objectives, but not all of our 2006 objectives, and approved a bonus payout of 56% of the total target bonus pool. The compensation committee determined Dr. Saks' bonus to be approximately 50% of target based on his performance and contributions to meeting our objectives for 2006, as well as his leadership during key challenges, and, at his and Mr. Cozadd's suggestion, the allocation of a portion of the available bonus pool to

executives other than Dr. Saks and Mr. Cozadd that could have otherwise been awarded to Dr. Saks and Cozadd. In February 2007, the compensation committee granted Dr. Saks an option to purchase 40,662 shares of common stock with the vesting schedule described above. The option has an exercise price of $19.37 per share, the fair market value of our common stock determined by the compensation committee on the date of grant. As with all of our executive officers, this option was granted in part due to the fact that Dr. Saks had not received any stock option grants since February 2004, and Dr. Saks' option granted in 2004 will be fully vested in February 2008 (but any vested shares acquired upon exercise of the options are subject to our repurchase right until February 2009). The new stock option is intended to provide a strong retention incentive well into the future, and to help align Dr. Saks' long-term interests with those of our stockholders.

Bruce Cozadd—Executive Chairman. Mr. Cozadd's base salary effective March 1, 2006 was $310,000, or a 6% increase over his base salary for the prior 12-month period. Mr. Cozadd currently devotes 75% of his professional time to his role as our Executive Chairman. Since our inception in 2003, Mr. Cozadd and Dr. Saks have had approximately the same salary on a full-time equivalent basis. Mr. Cozadd's salary effective as of March 1, 2007 is $338,000 for 75% time. Mr. Cozadd's base salary was determined by the compensation committee as part of its compensation review described above, with reference to Dr. Saks' base salary. Mr. Cozadd's bonus for 2006 was $77,000, or approximately 50% of his target bonus. The bonus for Mr. Cozadd was determined by the compensation committee based on his performance, contributions and leadership in 2006 and, at his and Dr. Saks' suggestion, the allocation of a portion of the available bonus pool to executives other than Dr. Saks and Mr. Cozadd that could have otherwise been awarded to Dr. Saks and Cozadd. In February 2007, the compensation committee granted Mr. Cozadd an option to purchase 40,662 shares of common stock with the vesting schedule described above. The option has an exercise price of $19.37 per share, the fair market value of our common stock determined by the compensation committee on the date of grant.

Robert Myers—President. Mr. Myers' base salary effective March 1, 2006 was $410,000, or a 5% increase over his salary for the prior 12-month period. Mr. Myers received a 4% salary increase effective March 1, 2007. Mr. Myers' bonus for 2006 was $120,000, or approximately 60% of his target bonus. The bonus for Mr. Myers was determined by the compensation committee based on Mr. Myers' leadership of our commercial team through a number of key transactions during the year, the expansion of our sales and marketing activities and the significant achievements of our commercial organization during 2006. In February 2007, partly in recognition of his promotion from Executive Vice President and Chief Business Officer to President, the compensation committee granted Mr. Myers an option to purchase 31,625 shares of common stock with vesting schedule described above. The option has an exercise price of $19.37 per share, the fair market value of our common stock determined by the compensation committee on the date of grant.

Senior Vice Presidents. The base salary effective March 1, 2006 for each of our remaining executive officers was $330,000, or a 5.6% increase over their salaries for the prior 12-month period. They received a 4% salary increase effective March 1, 2007. The 2006 bonuses for these executive officers, as determined by the compensation committee and based on the recommendations of Dr. Saks and Mr. Cozadd, were $70,000 for Mr. Fust, $80,000 for Ms. Gamble and $66,000 for Ms. Wissel. With these bonuses, the Compensation Committee recognized the efforts of each of these executive officers in connection with our key corporate objectives for 2006. In February 2007, the compensation committee granted each of these executive officers an option to purchase 22,590 shares of common stock with the vesting schedule described above. The options have an exercise price of $19.37 per share, the fair market value of our common stock determined by the compensation committee on the date of grant.

Accounting and Tax Considerations

Effective January 1, 2006, we adopted the fair value provisions of Financial Accounting Standards Board Statement No. 123(R) (revised 2004), "Share-Based Payment," or SFAS 123R. Under SFAS 123R, we are required to estimate and record an expense for each award of equity compensation (including stock options) over the vesting period of the award. The compensation committee has determined to retain for the foreseeable future

our stock option program as the sole component of its long-term compensation program, and, therefore, to record this expense on an ongoing basis according to SFAS 123R. The compensation committee has considered, and may in the future consider, the grant of restricted stock to our executive officers in lieu of stock option grants in light of the accounting impact of SFAS 123R with respect to stock option grants and other considerations.

Section 162(m) of the Internal Revenue Code of 1986 limits our deduction for federal income tax purposes to not more than $1 million of compensation paid to certain executive officers in a calendar year. Compensation above $1 million may be deducted if it is "performance-based compensation." The compensation committee has not yet established a policy for determining which forms of incentive compensation awarded to our executive officers shall be designed to qualify as "performance-based compensation." To maintain flexibility in compensating our executive officers in a manner designed to promote our objectives, the compensation committee has not adopted a policy that requires all compensation to be deductible. However, the compensation committee intends to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and the compensation committee intends to provide future compensation in a manner consistent with our best interests and those of our stockholders.

Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by, or paid to our principal executive officer, principal financial officer and our four other highest paid executive officers for the year ended December 31, 2006. The officers listed in the table below are referred to in this prospectus as the "named executive officers."

2006 Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Bruce C. Cozadd(4) Executive Chairman	2006	307,236	605,818	77,000	234	990,288
Samuel R. Saks, M.D. Chief Executive Officer	2006	406,853	605,818	102,000	234	1,114,905
Robert M. Myers President	2006	406,853	605,818	120,000	234	1,132,905
Matthew K. Fust Senior Vice President and Chief Financial Officer	2006	327,159	231,268	70,000	234	628,661
Carol A. Gamble Senior Vice President, General Counsel and Corporate Secretary	2006	327,159	231,268	80,000	234	638,661
Janne L.T. Wissel Senior Vice President of Development	2006	327,159	231,268	66,000	234	624,661

(1) We did not grant any stock option awards to our named executive officers in 2006. The dollar amounts in this column represent the compensation cost for the year ended December 31, 2006 of stock option awards granted in prior years. These amounts have been calculated in accordance with FASB Statement No. 123 (revised), "Share-Based Payment," or SFAS No. 123R, using the Black-Scholes option-pricing model. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For a discussion of valuation assumptions, see Note 14 to our consolidated financial statements included elsewhere in this prospectus.
(2) See footnote (1) to the 2006 Grants of Plan-Based Awards Table below.
(3) Represents group term life insurance premiums paid by us.
(4) Mr. Cozadd currently devotes 75% of his professional time to his role as our Executive Chairman.

Grants of Plan-Based Awards in Fiscal 2006

The following table sets forth certain information regarding grants of plan-based awards to the named executive officers during the year ended December 31, 2006.

2006 Grants of Plan-Based Awards Table

Name	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards Target ($)(1)
Bruce C. Cozadd	153,618
Samuel R. Saks, M.D.	203,427
Robert M. Myers	203,427
Matthew K. Fust	130,864
Carol A. Gamble	130,864
Janne L.T. Wissel	130,864

(1) This column sets forth the target bonus amount for each named executive officer for the year ended December 31, 2006 under our annual cash bonus plan established by our board of directors, which for Dr. Saks and Messrs. Cozadd and Myers was 50% of their respective salaries earned for fiscal year ended December 31, 2006. The target bonus amount for Mr. Fust, Ms. Gamble and Ms. Wissel was 40% of their respective salaries earned for fiscal year ended December 31, 2006. The actual cash bonus award earned for the year ended December 31, 2006 for each named executive officer is set forth in the 2006 Summary Compensation Table above. As such, the amounts set forth in this column do not represent additional compensation earned by the named executive officers for the year ended December 31, 2006. For a description of our annual cash bonus plan, please see "—Compensation Discussion and Analysis—Executive Compensation Program—Cash Bonuses" above.

Executive Employment Agreements

General

In February 2004, we entered into employment agreements with each of our named executive officers. Each of the employment agreements provides for an initial annual base salary subject to annual increases approved by our board of directors. The employment agreements set forth an initial base salary of $375,000 for Mr. Cozadd, $375,000 for Dr. Saks, $375,000 for Mr. Myers and $300,000 for each of Mr. Fust, Ms. Gamble and Ms. Wissel. Mr. Cozadd's annual base salary is pro-rated based on full-time employment. Mr. Cozadd currently devotes 75% of his professional time to his role as our Executive Chairman. Dr. Saks and Messrs. Cozadd and Myers are each eligible to receive an annual performance bonus determined in accordance with our annual cash bonus plan and targeted at 50% of their respective annual base salaries, subject to increases approved by our board of directors. Mr. Fust, Ms. Gamble and Ms. Wissel are each eligible to receive an annual performance bonus determined in accordance with our annual cash bonus plan and targeted at 40% of their respective annual base salaries, subject to increases approved by our board of directors. Each of the named executive officers is also eligible to participate in our general employee benefits plans for executives or key management employees in accordance with the terms and conditions of these plans.

Term

Each employment agreement provides that the terms and conditions of the agreement will apply to the named executive officers' employment until the fifth anniversary of the date of the agreement. However, each employment agreement also provides that the employment of the named executive officer may be terminated at any time by us or by the named executive officer, subject to the named executive officer's right to receive certain severance and other benefits, and our right to repurchase shares of our common stock held by the named executive officer.

Unvested Share Repurchase Right

In the event a named executive officer's employment is terminated by us or the named executive officer, we have the right to repurchase at cost all or any portion of the shares of common stock that were held by the named executive officer on the date of the employment agreement, which we refer to in this prospectus as the "founder shares." Our right of repurchase with respect to the founder shares lapses on an equal monthly basis over a period of four years, subject to acceleration in certain termination scenarios as described under "—Severance and Change of Control Benefits" and subject to our right to repurchase vested shares as described under "—Vested Share Repurchase Right; Executive Put Right."

Vested Share Repurchase Right; Executive Put Right

In the event a named executive officer is terminated by us for "cause" or is terminated by the named executive officer without "good reason," as those terms are defined in the employment agreements, we have the right to repurchase any vested shares of common stock held by the named executive officer at the lesser of cost or fair market value. If the named executive officer's employment is terminated without cause or for good reason, we have the right to repurchase the named executive officer's vested shares at fair market value. Finally, if the named executive officer's employment is terminated because of death or disability, we have the right to repurchase, and the named executive officer (or his or her estate) has the right to require us to repurchase, the named executive officer's vested shares at fair market value. Our right to repurchase these vested shares terminates in February 2009, or earlier upon the completion of a change of control event; however, our vested share repurchase rights terminate on the date one year after our initial public offering as to 20% of the vested shares then held by each named executive officer.

Severance and Change of Control Benefits

Cash Severance Payments. In the event a named executive officer is terminated by us without cause or is terminated by the named executive officer for good reason, the named executive officer is entitled, subject to our receipt of an effective waiver and release of claims executed by the named executive officer, to the following cash severance payments:

- an amount, payable in accordance with our customary payroll practices, equal to $1/12^{th}$ of the named executive officer's base salary at the time of termination for each month in a severance period of up to 24 months;
- COBRA premiums for the number of months in a severance period of up to 24 months, payable on a monthly basis;
- an amount, payable when bonus payments for the year of termination are paid to other employees, equal to the sum of:
  - the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days remaining in the year of termination after the date of termination) multiplied by the lesser of (a) the named executive officer's historical bonus rate (based on the average ratio of bonus paid to salary paid) or (b) the named executive officer's target bonus rate for the year of termination (which may be reduced based on the ratio of bonuses paid to target bonuses for the remaining named executive officers in the year of termination), which lesser amount we refer to in this prospectus as the "severance bonus rate", plus
  - the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days elapsed in the year of termination including the date of termination) multiplied by one-half of the severance bonus rate; and
- an amount, payable when bonus payments for the year following the year of termination are paid to other employees, equal to the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days elapsed in the year of termination including the date

of termination) multiplied by the lesser of (a) the named executive officer's historical bonus rate or (b) the named executive officer's target bonus rate for the year of following termination (which may be reduced based on the ratio of bonuses paid to target bonuses for the remaining named executive officers in the year following termination).

The employment agreements also provide for the payment of the cash severance payments described above if a named executive officer voluntarily terminates his or her employment within one year after the effective date of (a) a change of control event or (b) in the case of the named executive officers other than Dr. Saks, a significant transaction, such as our acquisition of another entity, where the members of our board of directors prior to the significant transaction constitute a majority of the board of directors after the transaction and the employment of 50% or more of the existing members of our executive management team, including our Chief Executive Officer, is terminated in connection with the significant transaction.

The following table estimates the amount of compensation payable to each named executive officer in the event of a termination described above, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual amounts that would be paid out in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

Name	Salary Continuation ($)	COBRA Premiums ($)	Bonus Payment for the Year of Termination ($)	Bonus Payment for the Year Following Termination ($)(1)
Bruce C. Cozadd	465,000	21,320	24,823	49,104
Samuel R. Saks, M.D.	615,000	33,049	30,735	60,801
Robert M. Myers	615,000	25,485	44,323	87,679
Matthew K. Fust	495,000	6,043	29,676	58,706
Carol A. Gamble	495,000	21,228	22,926	45,352
Janne L.T. Wissel	467,500	12,493	22,926	45,352

(1) For purposes of calculating the amounts set forth in this column, applicable bonus rates in the year of termination and the year following termination are assumed to be the same.

The employment agreements further provide that if a named executive officer's employment is terminated (a) by the named executive officer due to a relocation of our executive office of more than 20 miles from our current executive office, (b) without cause by us or for good reason by the named executive officer in connection with a change of control or a significant transaction, or (c) in the case of the named executive officers other than Dr. Saks, without cause by us or for good reason by the named executive officer prior to the first anniversary of the effective date of a significant transaction in connection with which the employment of 50% or more of the existing members of our executive management team, including our Chief Executive Officer, is terminated, then, and in each such case, the named executive officer is entitled, subject to our receipt of an effective waiver and release of claims executed by the named executive officer, to the following cash severance payments:

- a single lump sum payment equal to $1/12^{th}$ of the named executive officer's base salary at the time of termination for each month in a severance period of up to 24 months;
- a single lump sum payment equal to the product of the named executive officer's base salary at the time of termination (prorated to reflect the number of days elapsed in the year of termination including the date of termination) multiplied by the named executive officer's historical bonus rate;
- a single lump sum payment equal to the product of (a) $1/12^{th}$ of the named executive officer's base salary at the time of termination multiplied by (b) the named executive officer's historical bonus rate multiplied by (c) the number of months in a severance period of up to 24 months; and
- COBRA premiums for the number of months in a severance period of up to 24 months, payable on a monthly basis.

The following table estimates the amount of compensation payable to each named executive officer in the event of a termination described above, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual amounts that would be paid out in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

Name	Lump Sum Salary Payment ($)	COBRA Premiums ($)	Lump Sum Bonus Payment ($)
Bruce C. Cozadd	465,000	21,320	123,167
Samuel R. Saks, M.D.	615,000	33,049	152,505
Robert M. Myers	615,000	25,485	219,922
Matthew K. Fust	495,000	6,043	147,249
Carol A. Gamble	495,000	21,228	113,754
Janne L.T. Wissel	467,500	12,493	109,954

In the event a named executive officer's employment is terminated by reason of death or disability, the named executive officer will be entitled to a cash payment equal to the named executive officer's accrued bonus (if any) at the rate in effect at the time of termination. As described above, each of named executive officer (or his or her estate) would also be entitled to require us to repurchase the named executive officer's vested shares at fair market value. The following table estimates the amount of compensation payable to each named executive officer in the event of a termination by reason of death or disability, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual amounts that would be paid out in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

Name	Accrued Bonus ($)	Executive Put Right ($)(1)
Bruce C. Cozadd	76,578	3,362,000
Samuel R. Saks, M.D.	101,441	4,482,674
Robert M. Myers	119,342	1,706,851
Matthew K. Fust	69,616	547,596
Carol A. Gamble	79,562	509,384
Janne L.T. Wissel	65,638	496,654

(1) The value of the put right is calculated assuming a price per share of $20.50 which is the mid-point of the range reflected on the cover page of this prospectus, with respect to vested shares of common stock.

Vesting Acceleration. The employment agreements provide that if the named executive officer's employment is terminated (a) without cause by us or for good reason by the named executive officer in connection with change of control or significant transaction, or within 12 months following a change of control, or (b) in the case of the named executive officers other than Dr. Saks, without cause by us or for good reason by the named executive officer prior to the first anniversary of the effective date of a significant transaction in connection with which the employment of 50% or more of the existing members of our executive management team, including our Chief Executive Officer, is terminated, then all unvested founder shares will immediately vest and our unvested share repurchase right will immediately lapse with respect to those shares. These provisions also govern the terms of the stock options granted to our named executive officers under our 2003 Equity Incentive Plan such that in the event of one of these termination scenarios, the options granted to our named executive officers under our 2003 Equity Incentive Plan would immediately vest and become exercisable and would no longer be subject to our unvested share repurchase right.

In addition, the employment agreements provide that if the named executive officer's employment is terminated without cause by us or for good reason by the named executive officer prior to and not in connection

with or more than 12 months following, a change in control, then 1/4th of the founder shares (or the actual number of unvested founder shares immediately prior to the termination, if less) will immediately vest and our unvested share repurchase right will immediately lapse with respect to those shares. These provisions are not applicable to the stock options granted to our named executive officers under our 2003 Equity Incentive Plan.

The following table estimates the value of the vesting acceleration provisions described above with respect to each named executive officer in the event of a termination described above, in each case as if the named executive officer's employment had terminated on December 29, 2006, the last business day of our prior fiscal year. The actual value of vesting acceleration in any termination event can only be determined at the time of the termination of the named executive officer's employment with us.

	Full Vesting Acceleration		Partial Vesting Acceleration	
Name	Founder Share Acceleration ($)(1)	Option Acceleration ($)(2)	Founder Share Acceleration ($)(1)	Option Acceleration ($)
Bruce C. Cozadd	305,655	208,811	76,414	—
Samuel R. Saks, M.D.	407,520	208,811	101,880	—
Robert M. Myers	233,475	208,811	58,369	—
Matthew K. Fust	63,673	79,710	15,918	—
Carol A. Gamble	46,310	79,710	11,577	—
Janne L.T. Wissel	114,616	79,710	28,654	—

(1) The value of vesting acceleration is calculated assuming a price per share of $20.50, which is the mid-point of the range reflected on the cover page of this prospectus, with respect to unvested founder shares subject to acceleration.
(2) The value of vesting acceleration is calculated assuming a price per share of $20.50, which is the mid-point of the range reflected on the cover page of this prospectus, with respect to unvested option shares subject to acceleration minus the exercise price of these unvested option shares.

Employee Benefit Plans

2003 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved, the 2003 Equity Incentive Plan, or 2003 plan, in March 2003. An aggregate of 2,125,042 shares of our common stock is reserved for issuance under the 2003 plan. The 2003 plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, stock issuances and cash awards. As of March 31, 2007, options to purchase 1,862,530 shares of our common stock at a weighted average exercise price per share of $21.34 remained outstanding under the 2003 plan. No stock appreciation rights, stock issuances, or cash awards have been granted under the 2003 plan. As of March 31, 2007, 215,792 shares of our common stock remained available for future issuance under the 2003 plan.

Our board of directors has the authority to administer the 2003 plan and the awards granted under it. Upon the signing of the underwriting agreement for this offering, the 2003 plan will terminate so that no further awards may be granted under the 2003 plan. Although the 2003 plan will terminate, all outstanding awards will continue to be governed by their existing terms.

Stock Options. The 2003 plan provides for the grant of incentive stock options under the federal tax laws or nonstatutory stock options. Incentive stock options may be granted only to employees. Nonstatutory stock options may be granted to employees, non-employee directors and consultants. The exercise price of incentive stock options may not be less than 100% of the fair market value of our common stock on the date of grant. The exercise price of nonstatutory stock options may not be less than 85% of the fair market value of our common stock on the date of grant. Shares subject to options under the 2003 plan generally vest in a series of installments over an optionee's period of service, with a minimum vesting rate as to non-executive employees of at least 20% per year over five years from the date of grant.

In general, the maximum term of options granted under the 2003 plan is ten years. Unless the terms of an optionee's stock option agreement provide otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases for any reason other than for cause, disability or death, the optionee may exercise the vested portion of any option for three months after the date of such termination. If an optionee's service relationship with us, or any of our affiliates, terminates by reason of disability or death, the optionee or a personal representative may exercise the vested portion of any option for 12 months after the date of such termination. In no event, however, may an option be exercised beyond the expiration of its term.

Corporate Transactions. In the event of certain significant corporate transactions, our board of directors has the discretion to take one or more of the following actions: (a) arrange for the assumption or substitution of outstanding awards, (b) accelerate the vesting and termination of outstanding awards in whole or in part, (c) cancel or arrange for the cancellation of awards in exchange for cash payments and (d) arrange for any repurchase rights applicable to award shares to apply to any substituted securities issued in the transaction. Our board of directors need not take the same action for each award.

Changes in Control. In general, the vesting and exercisability of options granted to non-executive employees under the 2003 plan will accelerate with respect to an additional 25% of the option shares if (a) a change in control occurs and (b) the individual's employment is terminated by us without cause within 12 months thereafter. In addition, pursuant to our Executive Change in Control and Severance Benefit Plan, in which our non-executive officer vice presidents are participants, if a participant's employment with us terminates due to an involuntary termination without cause or a constructive termination, in each case within 12 months following a change in control, the vesting and exercisability of all options held by the participant will accelerate in full. In general, under our employment agreements with our executive officers, the vesting and exercisability of options granted to executive officers under the 2003 plan will accelerate in full (a) if a change in control or significant transaction occurs and the officer's employment is terminated by us without cause or the officer resigns for good reason in connection therewith or within 12 months thereafter or (b) if the employment of the officer (other than Dr. Saks) is terminated by us without cause or the officer (other than Dr. Saks) resigns for good reason within one year of a significant transaction where the employment of 50% or more of the members of our executive management team, including the employment of Dr. Saks, are terminated in connection with such significant transaction. See "—Executive Employment Agreements—Severance and Change of Control Benefits."

2007 Equity Incentive Plan

Our board of directors adopted the 2007 Equity Incentive Plan, or 2007 incentive plan, in May 2007, and our stockholders approved the 2007 incentive plan in May 2007. The 2007 incentive plan will become effective immediately upon the signing of the underwriting agreement for this offering. The 2007 incentive plan will terminate on April 30, 2017, unless sooner terminated by our board of directors.

Stock Awards. The 2007 incentive plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation, which may be granted to employees, including officers, non-employee directors, and consultants.

Share Reserve. Following this offering, the aggregate number of shares of our common stock that may be issued initially pursuant to stock awards under the 2007 incentive plan is 4,625,042 shares. The share reserve consists of (i) the 2,125,042 shares reserved for issuance under the 2003 plan, plus (ii) an additional 2,500,000 shares reserved for issuance under the 2007 incentive plan. The aggregate reserve number will be reduced by any unused shares of our common stock remaining available for the future grant of stock awards under the 2003 plan on the effective date of the 2007 incentive plan. The number of shares of our common stock reserved for issuance will automatically increase on January 1st, from January 1, 2008 through January 1, 2017, by the lesser of (a) 4.5% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year and (b) 3,000,000 shares. The maximum number of shares that may be issued pursuant

to the exercise of incentive stock options under the 2007 incentive plan is equal to the total share reserve, as increased from time to time pursuant to annual increases and shares subject to options granted under the 2003 plan that expire without being exercised in full.

No person may be granted awards covering more than 2,000,000 shares of our common stock under the 2007 incentive plan during any calendar year pursuant to an appreciation-only stock award. An appreciation-only stock award is a stock award whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value of our common stock on the date of grant. A stock option with an exercise price equal to the value of the stock on the date of grant is an example of an appreciation-only award. Such limitation is designed to help assure that any deductions to which we would otherwise be entitled upon the exercise of an appreciation-only stock award or upon the subsequent sale of shares purchased under such an award, will not be subject to the $1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Internal Revenue Code.

If a stock award granted under the 2007 incentive plan expires or otherwise terminates without being exercised in full, the shares of our common stock not acquired pursuant to the stock award again become available for subsequent issuance under the 2007 incentive plan. In addition, the following types of shares under the 2007 incentive plan will become available for the grant of new stock awards under the 2007 incentive plan: (a) shares that are forfeited to or repurchased by us prior to becoming fully vested, (b) shares withheld to satisfy income and employment withholding taxes, (c) shares used to pay the exercise price of an option in a net exercise arrangement, (d) shares tendered to us to pay the exercise price of an option and (e) shares that are cancelled pursuant to an exchange or repricing program. Shares issued under the 2007 incentive plan may be previously unissued shares or reacquired shares bought on the open market. As of the date hereof, no shares of our common stock have been issued under the 2007 incentive plan.

Administration. Our board of directors has delegated its authority to administer the 2007 incentive plan to our compensation committee. Subject to the terms of the 2007 incentive plan, our board of directors or an authorized committee, referred to as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted, and the terms and conditions of the stock awards, including the period of their exercisability and vesting. Subject to the limitations set forth below, the plan administrator will also determine the exercise price of options granted, the consideration to be paid for restricted stock awards, and the strike price of stock appreciation rights.

The plan administrator has the authority to:

- reduce the exercise price of any outstanding option or the strike price of any outstanding stock appreciation right;
- cancel any outstanding option or stock appreciation right and to grant in exchange one or more of the following:
  - new options or stock appreciation rights covering the same or a different number of shares of common stock,
  - new stock awards,
  - cash, and/or
  - other valuable consideration; or
- engage in any action that is treated as a repricing under generally accepted accounting principles.

Stock Options. Incentive and nonstatutory stock options are granted pursuant to incentive and nonstatutory stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option provided that the exercise price of an incentive stock option and nonstatutory stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2007 incentive plan vest at the rate specified by the plan administrator.

Generally, the plan administrator determines the term of stock options granted under the 2007 incentive plan, up to a maximum of ten years (except in the case of certain incentive stock options, as described below). Unless the terms of an optionee's stock option agreement provide otherwise, if an optionee's relationship with us, or any of our affiliates, ceases for any reason other than disability or death, the optionee may exercise any vested options for a period of three months following the cessation of service. If an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death (or an optionee dies within a certain period following cessation of service), the optionee or a beneficiary may exercise any vested options for a period of 12 months in the event of disability, and 18 months in the event of death. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (a) cash or check, (b) a broker-assisted cashless exercise, (c) the tender of common stock previously owned by the optionee, (d) a net exercise of the option and (e) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionee may designate a beneficiary, however, who may exercise the option following the optionee's death.

Tax Limitations on Incentive Stock Options. Incentive stock options may be granted only to our employees. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year under all of our stock plans may not exceed $100,000. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (a) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (b) the term of the incentive stock option does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (a) cash or check, (b) past or future services rendered to us or our affiliates or (c) any other form of legal consideration. Shares of common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect to shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation rights agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right which cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (a) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (b) the number of shares of common stock with respect to which the stock appreciation right

is exercised. A stock appreciation right granted under the 2007 incentive plan vests at the rate specified by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2007 incentive plan, up to a maximum of ten years. If a participant's service relationship with us, or any of our affiliates, ceases, then the participant, or the participant's beneficiary, may exercise any vested stock appreciation right for three months (or such longer or shorter period specified in the stock appreciation right agreement) after the date such service relationship ends. In no event, however, may a stock appreciation right be exercised beyond the expiration of its term.

Performance Stock Awards. The 2007 incentive plan permits the grant of performance stock awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Internal Revenue Code. To assure that the compensation attributable to one or more performance stock awards will so qualify, our compensation committee can structure one or more such awards so that stock will be issued or paid pursuant to such award only upon the achievement of certain pre-established performance goals during a designated performance period. The maximum benefit to be received by a participant in any calendar year attributable to performance stock awards may not exceed 2,000,000 shares of our common stock.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split, appropriate adjustments will be made to (a) the number of shares reserved under the 2007 incentive plan, (b) the maximum number of shares by which the share reserve may increase automatically each year, (c) the maximum number of appreciation-only stock awards and performance stock awards that can be granted in a calendar year and (d) the number of shares and exercise price or strike price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain significant corporate transactions, our board of directors has the discretion to take one or more of the following actions with respect to outstanding stock awards:

- arrange for assumption, continuation, or substitution of a stock award by a surviving or acquiring entity (or its parent company);
- arrange for the assignment of any reacquisition or repurchase rights applicable to any shares of our common stock issued pursuant to a stock award to the surviving or acquiring corporation (or its parent company);
- accelerate the vesting and exercisability of a stock award followed by the termination of the stock award;
- arrange for the lapse of any reacquisition or repurchase rights applicable to any shares of our common stock issued pursuant to a stock award;
- cancel or arrange for the cancellation of a stock award, to the extent not vested or not exercised, in exchange for appropriate cash consideration; and
- arrange for the surrender of a stock award in exchange for a payment equal to the excess of (a) the value of the property the holder of the stock award would have received upon the exercise of the stock award, over (b) any exercise price payable by such holder in connection with such exercise.

Our board of directors need not take the same action for each stock award.

Changes in Control. The form of option agreement adopted by our board under the 2007 incentive plan provides that in the event an optionee's service relationship with us or a successor entity is terminated, actually without cause or constructively, within 12 months following, or one month prior to, the effective date of certain specified change in control transactions, the vesting and exercisability of the option will accelerate in full. Our board of directors has the discretion to provide additional acceleration of vesting and exercisability upon or after a change in control transaction as may be provided in a stock award agreement or any other written agreement between us or any of our affiliates and a participant.

2007 Employee Stock Purchase Plan

Our board of directors adopted our 2007 Employee Stock Purchase Plan, or 2007 purchase plan, in May 2007 and our stockholders approved the 2007 purchase plan in May 2007. The 2007 purchase plan will become effective immediately upon the signing of the underwriting agreement for this offering.

Share Reserve. Following this offering, the 2007 purchase plan authorizes the issuance of 350,000 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1st, from January 1, 2008 through January 1, 2017, by the lesser of (a) 1.5% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year or (b) 350,000 shares. The 2007 purchase plan is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. As of the date hereof, no shares of our common stock have been purchased under the 2007 purchase plan.

Administration. Our board of directors has delegated its authority to administer the 2007 purchase plan to our compensation committee. The 2007 purchase plan is implemented through a series of offerings of purchase rights to eligible employees. Under the 2007 purchase plan, we may specify offerings with a duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our affiliates may participate in the 2007 purchase plan and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the 2007 purchase plan. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the 2007 purchase plan at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

Reset Feature. Our board of directors may specify that if the fair market value of a share of our common stock on any purchase date within a particular offering period is less than the fair market value on the start date of that offering period, then the employees in that offering period will automatically be transferred and enrolled in a new offering period which will begin on the next day following such a purchase date.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the 2007 purchase plan, as determined by our board of directors: (a) customarily employed for more than 20 hours per week, (b) customarily employed for more than five months per calendar year or (c) continuous employment with us or one of our affiliates for a period of time not to exceed two years. No employee may purchase shares under the 2007 purchase plan at a rate in excess of $25,000 worth of our common stock valued based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the 2007 purchase plan if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split, appropriate adjustments will be made to (a) the number of shares reserved under the 2007 purchase plan, (b) the maximum number of shares by which the share reserve may increase automatically each year, and (c) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, any then-outstanding rights to purchase our stock under the 2007 purchase plan will be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately thereafter.

Cash Bonus Plan

We maintain an annual cash bonus plan to reward executive officers and other employees for successful achievement of company-wide and individual performance objectives. For more information regarding our annual cash bonus plan, please see "—Compensation Discussion and Analysis—Executive Compensation Program—Cash Bonuses."

401(k) Plan

Our employees are eligible to participate in our 401(k) plan. Our 401(k) plan is intended to qualify as a tax qualified plan under Section 401 of the Code. Our 401(k) plan provides that each participant may contribute a portion of his or her pretax compensation, up to a statutory limit, which for most employees is $15,500 in 2007 (with a larger "catch up" limit for older employees). Employee contributions are held and invested by the plan's trustee. Our 401(k) plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. To date, we have not made any contributions to the plan on behalf of participating employees.

Outstanding Equity Awards at Fiscal Year-End

The following table shows, for the fiscal year ended December 31, 2006, certain information regarding outstanding equity awards at fiscal year end for our named executive officers.

2006 Outstanding Equity Awards at Fiscal Year-End Table

	Option Awards(1)				Stock Awards(2)	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(3)
Bruce C. Cozadd	116,254	47,866	15.09	02/18/14	—	—
	38,753	15,954	30.18	02/18/14	—	—
	38,753	15,954	45.27	02/18/14	—	—
	—	—	—	—	14,910	305,655
Samuel R. Saks, M.D.	116,254	47,866	15.09	02/18/14	—	—
	38,753	15,954	30.18	02/18/14	—	—
	38,753	15,954	45.27	02/18/14	—	—
	—	—	—	—	19,879	407,520
Robert M. Myers	116,254	47,866	15.09	02/18/14	—	—
	38,753	15,954	30.18	02/18/14	—	—
	38,753	15,954	45.27	02/18/14	—	—
	—	—	—	—	11,389	233,475
Matthew K. Fust	44,380	18,272	15.09	02/18/14	—	—
	14,794	6,090	30.18	02/18/14	—	—
	14,794	6,090	45.27	02/18/14	—	—
	—	—	—	—	2,485	50,943
Carol A. Gamble	44,380	18,272	15.09	02/18/14	—	—
	14,794	6,090	30.18	02/18/14	—	—
	14,794	6,090	45.27	02/18/14	—	—
	—	—	—	—	2,259	46,310
Janne L.T. Wissel	44,380	18,272	15.09	02/18/14	—	—
	14,794	6,090	30.18	02/18/14	—	—
	14,794	6,090	45.27	02/18/14	—	—
	—	—	—	—	5,591	114,616

(1) For each named executive officer, the shares listed in the table above under “Option Awards” are subject to a single stock option award carrying the varying exercise prices as set forth in the table above. The shares subject to each stock option vest over a four year period, with 25% of the shares subject to the option vesting after one year, an additional 12.5% vesting six months thereafter, and the remaining shares subject to the stock option vesting on an equal monthly basis over the following 30 months. On each vesting date, the number of shares subject to each stock option award vest proportionately based on the exercise price associated with the shares, such that 60% of the shares vesting on each vesting date carry an exercise price equal to $15.09 per share, 20% carry an exercise price equal to $30.18 per share, and 20% carry an exercise price equal to $45.27 per share. All shares of common stock that are issued to a named executive officer pursuant to the exercise of his or her stock option award are subject to a right of repurchase, on the same terms as “vested shares” as described under “—Executive Employment Agreements.”

(2) For each named executive officer, our right to repurchase the unvested shares listed in the table above under “Stock Awards” lapses on a monthly basis at the rate of 2.08% per month.

(3) The market value of the unvested shares has been calculated assuming a price per share of $20.50, which is the mid-point of the range reflected on the cover page of this prospectus, multiplied by the number of unvested shares.

Option Exercises and Stock Vested

Our named executive officers did not exercise any stock options during the year ended December 31, 2006. The following table shows certain information regarding stock vested during the year ended December 31, 2006 for our named executive officers.

2006 Option Exercises and Stock Vested Table

	Stock Awards	
Name	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)(1)
Bruce C. Cozadd	44,727	916,904
Samuel R. Saks, M.D.	59,637	1,222,559
Robert M. Myers	23,663	485,092
Matthew K. Fust	7,455	152,828
Carol A. Gamble	6,777	138,929
Janne L.T. Wissel	7,455	152,828

(1) The value realized on vesting has been calculated assuming a price per share of $20.50, which is the mid-point of the range reflected on the cover page of this prospectus, multiplied by the number of shares vested.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the year ended December 31, 2006.

Nonqualified Deferred Compensation

During the year ended December 31, 2006, our named executive officers did not contribute to, or earn any amounts with respect to, any defined contribution or other plan sponsored by us that provides for the deferral of compensation on a basis that is not tax-qualified.

Non-Employee Director Compensation

Cash Compensation Arrangements

The non-employee members of our board of directors are reimbursed for travel and other reasonable expenses incurred in attending board or committee meetings. Other than respect to Mr. Sebulsky, members of our board of directors do not currently receive cash compensation for attending board or committee meetings. Mr. Sebulsky currently receives $1,500 for each board meeting he attends and $500 for each committee meeting he attends.

After this offering, we will continue to reimburse our non-employee directors for their travel and other reasonable expenses incurred in attending board or committee meetings. In addition, each non-employee director will receive an annual retainer of $30,000. The chair of the audit committee will receive a supplemental annual retainer of $15,000, the chair of the compensation committee will receive a supplemental annual retainer of $10,000, and the chair of each other committee of the board will receive a supplement annual retainer of $5,000.

Directors Deferred Compensation Plan

Our board of directors adopted the Directors Deferred Compensation Plan, or deferred plan, in May 2007. The deferred plan allows each non-employee director to elect to defer receipt of all or a portion of his or her

annual retainer fees to a future date or dates. Any amounts deferred under the deferred plan are credited to a phantom stock account. The number of phantom shares of our common stock credited to each director's phantom stock account each year will be determined based on the amount of the compensation deferred during any given year, divided by the fair market value of our common stock on the date the retainer fees are due to be paid. Upon a separation from our board of directors or the occurrence of a change in control, each non-employee director will receive (or commence receiving, depending upon whether the director has elected to receive distributions from his or her phantom stock account in a lump sum or in installments over time) a distribution of his or her phantom stock account, in either cash or shares of our common stock (subject to the prior election of each such director). Any distributions in shares of our common stock will be paid with shares reserved under our 2007 Non-Employee Directors Stock Option Plan, which is described below. The deferred plan may be amended or terminated at any time by our board of directors, and in form and operation is intended to be compliant with Section 409A of the Internal Revenue Code of 1986, as amended.

2007 Non-Employee Directors Stock Option Plan

Our board of directors adopted our 2007 Non-Employee Directors Stock Option Plan, or 2007 directors plan, in May 2007, and our stockholders approved the 2007 directors plan in May 2007. The 2007 directors plan will become effective immediately upon the signing of the underwriting agreement for this offering. The 2007 directors plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to our non-employee directors over their period of service on our board. In addition, the 2007 directors plan provides a source of shares to fund distributions under the deferred plan.

Share Reserve. Following this offering, the aggregate number of shares of common stock that may be issued initially under the 2007 directors plan is 200,000 shares. The number of shares of common stock reserved for issuance will automatically increase on January 1st, from January 1, 2008 through January 1, 2017, by the sum of (a) the excess of (i) the number of shares of common stock subject to options granted during the preceding calendar year, over (ii) the number of shares added back to the share reserve during the preceding calendar year and (b) the aggregate number of shares credited to our non-employee directors' stock accounts under the deferred plan. In no event may the amount of such annual increase exceed 200,000 shares.

If any option expires or terminates for any reason, in whole or in part, without having been exercised in full, the shares of common stock not acquired under such option will become available for future issuance under the 2007 directors plan. The following types of shares issued under the 2007 directors plan may again become available for the grant of new options: (a) any shares withheld to satisfy withholding taxes, (b) any shares used to pay the exercise price of an option in a net exercise arrangement and (c) shares tendered to us to pay the exercise price of an option. As of the date hereof, no shares of common stock have been issued under the 2007 directors plan.

Administration. All options granted under the 2007 directors plan are made in strict compliance with its express provisions. Subject to the provisions of the 2007 directors plan, our board of directors has the authority to construe and interpret the 2007 directors plan and the stock options granted under it, and to establish rules for its administration.

Initial Option. Pursuant to the terms of the 2007 directors plan, any individual who first becomes a non-employee director after the completion of this offering will automatically be granted an option to purchase 30,000 shares of our common stock. Each initial option will vest with respect to one-third of the shares on the first anniversary of the date of grant, and the balance in a series of 24 successive equal monthly installments thereafter.

Annual Option. Pursuant to the terms of the 2007 directors plan, each individual who is serving as a non-employee director on the first trading day on or after August 15 of each year, commencing on August 15, 2007, will automatically be granted an option to purchase 10,000 shares of our common stock on such date.

The shares subject to each such annual option vest in a series of 12 successive equal monthly installments measured from the date of grant.

Terms of All Options. The exercise price of each option granted under the 2007 directors plan is equal to 100% of the fair market value of our common stock on the date of grant. The maximum term of options granted under the 2007 directors plan is ten years. If a non-employee director's service relationship with us, or any of our affiliates, whether as a non-employee director or subsequently as an employee, director or consultant of ours or an affiliate, ceases for any reason other than disability or death, or after any 12-month period following a change in control, the optionee may exercise any vested options for a period of three months following the cessation of service. If such an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death (or an optionee dies within a certain period following cessation of service), the optionee or a beneficiary may exercise the option for a period of 12 months in the event of disability, and 18 months in the event of death. If such an optionee's service terminates within 12 months following a specified change in control transaction, the optionee may exercise the option for a period of 12 months following the effective date of such a transaction. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term.

Transferability of Options. Options granted under the 2007 directors plan are generally not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. However, an option may be transferred for no consideration upon written consent of our board of directors if (a) at the time of transfer, a Form S-8 registration statement under the Securities Act is available for the issuance of shares upon the exercise of such transferred option or (b) the transfer is to the optionee's employer or its affiliate at the time of transfer.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split, appropriate adjustments will be made to (a) the number of shares reserved under the 2007 directors plan, (b) the maximum number of shares by which the share reserve may increase automatically each year, (c) the number of shares for which options are to be subsequently made to new and continuing non-employee directors and (d) the number of shares and exercise price of all outstanding options.

Corporate Transactions. In the event of certain significant corporate transactions, all outstanding options under the 2007 directors plan may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such options, then (a) with respect to any such options that are held by optionees then performing services for us or our affiliates, the vesting and exercisability of such options will be accelerated in full and such options will be terminated if not exercised prior to the effective date of the corporate transaction and (b) all other outstanding options will terminate if not exercised prior to the effective date of the corporate transaction. Our board of directors may also provide that the holder of an outstanding option not assumed in the corporate transaction will surrender such option in exchange for a payment equal to the excess of (a) the value of the property that the optionee would have received upon exercise of the option, over (b) the exercise price otherwise payable in connection with the option.

Changes in Control. The vesting and exercisability of options held by non-employee directors who are either (a) required to resign their position in connection with a specified change in control transaction or (b) removed from their position in connection with such a change in control will be accelerated in full.

Director Compensation Table

The following table shows for the fiscal year ended December 31, 2006 certain information with respect to the compensation of all of our non-employee directors.

2006 Director Compensation Table

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(2)(3)	Total ($)
Adam H. Clammer	—	—	—
Samuel D. Colella	—	—	—
Bryan C. Cressey(1)	—	—	—
David Mayer(1)	—	—	—
Michael W. Michelson	—	—	—
James C. Momtazee	—	—	—
Kenneth W. O'Keefe	—	—	—
Jaimin R. Patel(4)	—	—	—
Alan M. Sebulsky	9,500(5)	22,475	31,975
James B. Tananbaum, M.D.	—	—	—

(1) Mr. Cressey joined our board of directors in October 2006 following the resignation of Mr. Mayer.
(2) We did not grant any stock option awards to our directors in 2006. The dollar amount in this column represents the compensation cost for the year ended December 31, 2006 of a stock option award granted in 2004. This amount has been calculated in accordance with SFAS No. 123R using the Black-Scholes option-pricing model. Pursuant to SEC rules, the amount shown excludes the impact of estimated forfeiture related to service-based vesting conditions. For a discussion of valuation assumptions, see Note 14 to our consolidated financial statements included elsewhere in this prospectus.
(3) At December 31, 2006, Mr. Sebulsky held a stock option exercisable for 9,036 shares of our common stock carrying an exercise price of $15.09 per share, 4,518 shares of which were vested and exercisable at December 31, 2006. In addition, on May 1, 2007, the board approved the grant of a stock option to Mr. Sebulsky to purchase 17,500 shares of our common stock, such option to be granted on the date of the signing of the underwriting agreement for this offering and to have an exercise price equal to the initial public offering price. The stock option vests as to one-third of the shares on the first anniversary of the date of the signing of the underwriting agreement for this offering, and the balance in series of 24 successive equal monthly installments thereafter. None of the other directors listed in the table above held any outstanding stock options at December 31, 2006.
(4) Mr. Patel joined our board of directors in May 2007.
(5) Consists of fees earned for board and committee meeting attendance.

Limitation of Liability and Indemnification

Our fourth amended and restated certificate of incorporation and amended and restated bylaws to be in effect upon the closing of this offering limit the liability of our directors, officers, employees and other agents to the fullest extent permitted by Delaware law; provided, however, that we indemnify any such person in connection with a proceeding initiated by such person only if such indemnification is expressly required by law, the proceeding was authorized by our board of directors, the indemnification is provided by us, in our sole discretion, pursuant to the Delaware General Corporation Law or other applicable law or is otherwise expressly required by our amended and restated bylaws. Section 145 of the Delaware General Corporation Law permits indemnification of officers, directors and other agents under certain circumstances and subject to certain limitations. Delaware law also permits a corporation to not hold its directors personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for: (1) breach of their duty of loyalty to the corporation or its stockholders, (2) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) unlawful payments of dividends or unlawful stock repurchases or redemptions and (4) any transaction from which the director derived an improper personal benefit. This limitation of liability does not apply to liabilities arising under the federal or state securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity. We have obtained directors and officers' liability insurance to cover certain liabilities described above. Messrs. Clammer, Michelson, Momtazee and Patel are further insured by liability insurance that has been purchased by Kohlberg Kravis Roberts & Co. L.P. on their behalf for any excess liabilities that are not covered by our liability insurance. Mr. Colella is insured by liability insurance purchased on his behalf by, and indemnified pursuant to the governing agreements of, Versant Ventures for his service on our board of directors.

We have entered into indemnity agreements with each of our directors and executive officers that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding or alternative dispute resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of us or any of our affiliated enterprises, provided that such person's conduct did not constitute a breach of his or her duty of loyalty to us or our stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnity agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. We believe that these provisions and agreements are necessary to attract and retain qualified persons as officers and directors of our company.

At present, there is no pending litigation or proceeding involving a director or officer of our company for which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted by directors, executive officers or persons controlling us, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since our inception to which we have been a party in which the amount involved exceeded $120,000 and in which any of our executive officers, directors or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus entitled “Management—Executive Compensation.”

Related Party Transaction Policy

In 2007, we adopted a Related Party Transaction Policy that sets forth our procedures for the identification, review, consideration and approval or ratification of “related-person transactions.” The policy will become effective immediately upon the signing of the underwriting agreement for this offering. For purposes of our policy only, a “related-person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are, were or will be participants in which the amount involves exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A “related person” is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related-person transaction (including any transaction that was not a related-person transaction when originally consummated or any transaction that was not initially identified as a related-person transaction prior to consummation), our management must present information regarding the related-person transaction to our audit committee (or, if audit committee approval would be inappropriate, to another independent body of our board of directors) for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will, on an annual basis, collect information that our general counsel deems reasonably necessary from each director, executive officer and (to the extent feasible) significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest to our general counsel, or, if the employee is an executive officer, to our board of directors. In considering related-person transactions, our audit committee (or other independent body of our board of directors) will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related-person transaction, our audit committee (or other independent body of our board of directors) must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee (or other independent body of our board of directors) determines in the good faith exercise of its discretion. All of the transactions described below were entered into prior to the adoption of the policy and were approved by our board of directors.

Sales of Securities

The shares of common stock set forth in the table below were purchased by our executive officers and directors in March 2003 at a per share price of $.03, in April 2003 at per share prices of $.06 and $.11, in October 2003 at a per share price of $1.11, in January 2004 at a per share price of $1.11 and in September 2004 at a per share price of $15.09, for aggregate consideration of $338,033.

During the period from April 2003 through January 2004, we issued and sold an aggregate of 1,355,377 shares of our Series A preferred stock at a per share price of $11.07 for aggregate consideration of $15.0 million. During the period from February 2004 through December 2006, we issued and sold an aggregate of 7,951,755 shares of our Series B preferred stock at a per share price of $15.09 for aggregate consideration of approximately $120.0 million. During the period from February 2004 through December 2006, we also issued and sold an aggregate of 8,614,419 shares of our Series B Prime preferred stock at a per share price of $15.09 for aggregate consideration of approximately $130.0 million.

In June 2005, we issued warrants to purchase an aggregate of 785,728 shares of our Series BB preferred stock in connection with the issuance of senior secured notes in the aggregate principal amount of $80.0 million. The warrants have an exercise price of $20.36 per share. In connection with the conversion of all our outstanding shares of preferred stock into common stock immediately prior to the closing of this offering, the warrants will automatically become exercisable for shares of common stock. These warrants will terminate on June 24, 2012, unless exercised earlier.

We believe that the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

Purchaser	Common Stock	Series A Preferred Stock	Series B Preferred Stock	Series B Prime Preferred Stock	Series BB Preferred Stock Warrants
Executive Officers and Directors					
Bruce C. Cozadd(1)	178,910	—	66,264	—	—
Samuel R. Saks, M.D.(2)	238,546	13,553	66,264	—	—
Robert M. Myers(3)	94,650	—	46,385	—	—
Matthew K. Fust(4)	29,818	—	19,879	—	—
Carol A. Gamble(5)	27,107	—	—	—	—
Janne L.T. Wissel(6)	29,818	—	66,264	—	—
Alan M. Sebulsky(7)	13,252	—	—	—	—
Principal Stockholders(8)					
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.(9)	—	—	—	8,614,419	245,540
Entities affiliated with Thoma Cressey Bravo, Inc.(10)	—	—	1,987,942	—	—
Entities affiliated with Beecken Petty O'Keefe & Company(11)	—	—	1,325,295	—	—
Entities affiliated with Prospect Venture Partners(12)	—	670,912	563,249	—	—
Entities affiliated with Versant Ventures(13)	—	670,912	563,249	—	—
Entities affiliated with Golden Gate Capital(14)	—	—	993,969	—	—
Entities affiliated with Lehman Brothers Holdings Inc.(15)	—	—	662,645	—	304,469

(1) Includes 3,728 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapsed in full on April 1, 2007.

(2) Includes 4,970 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapsed in full on April 1, 2007.
(3) Includes 5,474 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapses in full on December 18, 2007.
(4) Includes 622 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapses in full on April 30, 2007.
(5) Includes 565 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapsed in full on April 18, 2007.
(6) Includes 3,728 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapses in full on September 3, 2007.
(7) Includes 4,418 shares of common stock that are subject to our right of repurchase as of March 31, 2007, which such right of repurchase lapses in full on July 13, 2008.
(8) Certain of our directors are associated with our principal stockholders as indicated in the table below:

Director	Principal Stockholder
Adam H. Clammer	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
Samuel D. Colella	Entities affiliated with Versant Ventures
Bryan C. Cressey	Entities affiliated with Thoma Cressey Bravo
Michael W. Michelson	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
James C. Momtazee	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
Kenneth W. O'Keefe	Entities affiliated with Beecken Petty O'Keefe & Company
Jaimin R. Patel	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
James B. Tananbaum, M.D.	Entities affiliated with Prospect Venture Partners

(9) Consists of 8,577,974 shares of Series B Prime preferred stock held by KKR JP LLC, 36,445 shares of Series B Prime preferred stock held by KKR JP III LLC and warrants to purchase 245,540 shares of Series BB preferred stock held by KKR Financial Holdings III, LLC.
(10) Consists of 1,957,380 shares of Series B preferred stock held by Thoma Cressey Fund VII, LP and 30,562 shares of Series B preferred stock held by Thoma Cressey Friends Fund VII, LP.
(11) Consists of 1,325,295 shares of Series B preferred stock held by Jazz Investors LLC.
(12) Consists of 660,849 shares of Series A preferred stock and 554,801 shares of Series B preferred stock held by Prospect Venture Partners II, L.P. and 10,063 shares of Series A preferred stock and 8,448 shares of Series B preferred stock held by Prospect Associates II, L.P.
(13) Consists of 652,693 shares of Series A preferred stock and 547,954 shares of Series B preferred stock held by Versant Venture Capital II, L.P., 12,386 shares of Series A preferred stock and 10,398 shares of Series B preferred stock held by Versant Affiliates Fund II-A, L.P., and 5,833 shares of Series A preferred stock and 4,897 shares of Series B preferred stock held by Versant Side Fund II, L.P.
(14) Consists of 860,336 shares of Series B preferred stock held by CCG Investment Fund, LP, 43,461 shares of Series B preferred stock held by CCG AV, LLC-Series C, 47,269 shares of Series B preferred stock held by CCG Associates-QP, LLC, 11,499 shares of Series B preferred stock held by CCG AV, LLC-Series A, 11,525 shares of Series B preferred stock held by CCG Investment Fund-AI, LP, and 19,879 shares of Series B preferred stock held by CCG CI, LLC.
(15) Consists of 165,661 shares of Series B preferred stock held by Lehman Brothers HealthCare Venture Capital LP, 317,076 shares of Series B preferred stock held by Lehman Brothers PA LLC, 142,858 shares of Series B preferred stock held by Lehman Brothers Partnership Account 2000/2001, LP, 37,050 shares of Series B preferred stock held by Lehman Brothers Offshore Partnership Account 2000/2001 LP, and warrants to purchase 304,469 shares of Series BB Preferred Stock held by LB I Group Inc. Lehman Brothers Holdings Inc. is affiliated with Lehman Brothers Inc., which is acting as a representative of the underwriters of this offering.

Senior Secured Notes

In June 2005, we issued senior secured notes in the aggregate principal amount of $80.0 million with interest payable on the notes at the rate of 15% per year, payable quarterly in arrears. The notes are due and payable on June 24, 2011. As of March 31, 2007, KKR TRS Holdings, Inc., an entity affiliated with Kohlberg Kravis Roberts & Co. L.P., and LB I Group, an entity affiliated with Lehman Brothers Holdings Inc., both of which are significant stockholders, held $25.0 million and $31.0 million, respectively, in principal amount of these senior secured notes which represented the largest aggregate amount of principal balance outstanding to date for each of these note holders. The interest payments made to KKR TRS Holdings, Inc. during the fiscal years ended December 31, 2005 and 2006 and the three months ended March 31, 2007 were approximately $1.9 million, $3.8 million and $.9 million, respectively. The interest payments made to LB I Group during the fiscal years ended December 31, 2005 and 2006 and the three months ended March 31, 2007 were approximately $2.3 million, $4.6 million and $1.2 million, respectively. There were no payments of principal made in either of these periods. Lehman Brothers Inc., one of the representatives of the underwriters of this offering, is affiliated with Lehman Brothers Holdings Inc. In connection with the issuance of the senior secured notes, we issued warrants

to purchase 245,540 and 304,469 shares of our Series BB preferred stock to KKR TRS Holdings, Inc. and LB I Group, respectively. In May 2007, KKR TRS Holdings, Inc. transferred its interest in both the senior secured notes and the warrants to purchase 245,540 shares of our Series BB preferred stock to KKR Financial Holdings III, LLC, an entity affiliated with Kohlberg Kravis Roberts & Co. L.P.

Third Amended and Restated Investor Rights Agreement

We entered into an investor rights agreement with certain purchasers of our common stock, preferred stock and warrants to purchase our Series BB preferred stock, including our principal stockholders with which certain of our directors are affiliated. As of March 31, 2007, the holders of 19,306,128 shares of our common stock, including the shares of common stock issuable upon the conversion of our preferred stock and exercise of outstanding warrants, are entitled to rights with respect to the registration of their shares under the Securities Act. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights with respect to registration of the shares of common stock acquired upon exercise. For a description of these registration rights, see “Description of Capital Stock—Registration Rights.”

Second Amended and Restated Voting Agreement

The election of the members of our board of directors is governed by a voting agreement with certain of the purchasers of our outstanding common stock, preferred stock and warrants to purchase our Series BB preferred stock, including our principal stockholders with which certain of our directors are affiliated, and by related provisions of our second amended and restated certificate of incorporation. The parties to the voting agreement have agreed, subject to certain conditions, to vote their shares so as to elect as directors the nominees designated by certain of our investors, including KKR JP LLC and its affiliated funds, Thoma Cressey Fund VII, L.P. and its affiliated funds, Jazz Investors LLC, Versant Venture Capital II, L.P. and its affiliated funds, and Prospect Venture Partners II, L.P. and its affiliated funds. In addition, so long as Mr. Cozadd and Dr. Saks are employed by us, the parties to the voting agreement have agreed to vote their shares so as to elect each of Mr. Cozadd and Dr. Saks to our board of directors. The parties further agreed to vote their shares so as to elect up to three persons who are not affiliates of us or any of our stockholders, and which nominees are nominated by at least two-thirds of our board of directors. Upon the signing of the underwriting agreement for this offering, the obligations of the parties to the voting agreement to vote their shares so as to elect as these nominees will terminate and none of our stockholders will have any special rights regarding the nomination, election or designation of members of our board of directors.

Other Transactions

We have entered into employment agreements with our executive officers that, among other things, provide for certain severance and change of control benefits. For a description of these agreements, see “Management—Executive Compensation—Executive Employment Agreements.”

We have granted stock options to our executive officers and to one of our directors. For a description of these options, see “Management—Non-Employee Director Compensation” and “—Executive Compensation.”

We have entered into indemnity agreements with our directors and executive officers. For a description of these agreements, see “Management—Limitation of Liability and Indemnification.”

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of March 31, 2007 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of the named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information shown in the table is based upon 18,550,554 shares outstanding as of March 31, 2007, assuming the conversion of all outstanding shares of our preferred stock as of March 31, 2007, and the issuance of 6,000,000 shares of common stock in this offering. The percentage ownership information assumes no exercise of the underwriters' overallotment option.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before May 30, 2007, which is 60 days after March 31, 2007. These shares are deemed to be outstanding and beneficially owned by the person holding those options or a warrant for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for person or entity listed in the table is c/o Jazz Pharmaceuticals, Inc., 3180 Porter Drive, Palo Alto, California 94304.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% Stockholders			
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.			
KKR JP, LLC(1)	8,577,974	46.24%	34.94%
KKR JP III LLC(1)	36,445	*	*
KKR TRS Holdings, Inc.(2)	245,540	1.31	*
Entities affiliated with Thoma Cressey Bravo, Inc.(3)	1,987,942	10.72	8.10
Entities affiliated with Beecken Petty O'Keefe & Company(4)	1,325,295	7.14	5.40
Entities affiliated with Prospect Venture Partners(5)	1,234,161	6.65	5.03
Entities affiliated with Versant Ventures(6)	1,234,161	6.65	5.03
Entities affiliated with Golden Gate Capital(7)	993,969	5.36	4.05
Entities affiliated with Lehman Brothers Holdings Inc.(8)	967,114	5.13	3.89
Named Executive Officers and Directors			
Bruce C. Cozadd(9)	467,425	2.49	1.89
Samuel R. Saks, M.D.(10)	540,614	2.88	2.18
Robert M. Myers(11)	363,286	1.94	1.47
Matthew K. Fust(12)	134,538	*	*
Janne L.T. Wissel(13)	180,923	*	*
Carol A. Gamble(14)	111,948	*	*
Adam H. Clammer(15)	—	—	—
Samuel D. Colella(16)	1,234,161	6.65	5.03
Bryan C. Cressey(17)	1,987,942	10.72	8.10
Michael W. Michelson(18)	8,859,959	47.14	35.73
James C. Momtazee(19)	—	—	—
Kenneth W. O'Keefe(20)	1,325,295	7.14	5.40
Jaimin R. Patel(21)	—	—	—
Alan M. Sebulsky(22)	17,770	*	*
James B. Tananbaum, M.D.(23)	1,234,161	6.65	5.03
All directors and executive officers as a group (15 persons)(24)	16,458,022	83.45%	63.98%

* Represents beneficial ownership of less than 1%.

(1) All of the outstanding equity interests of KKR JP LLC are owned directly by KKR Millennium Fund L.P. KKR Millennium GP LLC is the general partner of KKR Associates Millennium L.P., which is the general partner of KKR Millennium Fund L.P. All of the outstanding equity interests of KKR JP III LLC are owned directly by KKR Partners III, L.P. KKR III GP LLC is the general partner of KKR Partners III, L.P. The entities named in this footnote (1) are sometimes referred to as the KKR Funds. KKR Millennium GP LLC and KKR III GP LLC are limited liability companies, the managing members of which are Messrs. Henry R. Kravis and George R. Roberts, and the other members of which are James H. Greene, Jr., Paul E. Raether, Mr. Michelson, Perry Golkin, Johannes P. Huth, Todd A. Fisher, Alexander Navab, Marc Lipschultz, Jacques Garaialde, Reinhard Gorenflos, Michael M. Calbert and Scott C. Nuttall. Mr. Michelson is a member of our board of directors. Each of such individuals may be deemed to share beneficial ownership of any shares beneficially owned by KKR Millennium GP LLC and KKR III GP LLC, but disclaim beneficial ownership of such shares. Mr. Clammer is a member of our board of directors and is a member of KKR & Co. L.L.C. which is the general partner of Kohlberg Kravis Roberts & Co. L.P., which is an affiliate of the KKR Funds. Mr. Momtazee is a member of our board of directors and is an executive of Kohlberg Kravis Roberts & Co. L.P. Mr. Patel is a member of our board of directors and is an associate of Kohlberg Kravis Roberts & Co. L.P. Each of Messrs. Clammer, Momtazee and Patel disclaim beneficial ownership of any shares beneficially owned by the KKR Funds. The address of the KKR Funds and Messrs. Kravis, Raether, Golkin, Navab, Lipschultz and Nuttall is c/o Kohlberg Kravis Roberts & Co. L.P., 9 West 57th Street, New York, NY 10019. The address of Messrs. Roberts, Michelson, Greene, Calbert, Clammer, Momtazee and Patel is 2800 Sand Hill Road, Suite 200, Menlo Park, CA 94025. The address of Messrs. Fisher, Huth, Gorenflos and Garaialde is c/o Kohlberg Kravis Roberts & Co. Ltd., Stirling Square, 7 Carlton Garden, London SW1Y 5AD, England.

(2) Consists of 245,540 shares that KKR TRS Holdings, Inc. has the right to acquire within 60 days of March 31, 2007 through the exercise of a warrant. All of the outstanding equity interests of KKR TRS Holdings, Inc. are owned by KKR Financial Holdings LLC. KKR Financial Advisors LLC is the manager of KKR Financial Holdings LLC. KKR Financial LLC is the sole member of KKR Financial Advisors LLC. Kohlberg Kravis Roberts & Co. L.P. owns a majority of the outstanding equity interests of KKR Financial LLC. KKR & Co. L.L.C. is the general partner of Kohlberg Kravis Roberts & Co. L.P. The investment committee of KKR Financial Advisors LLC reviews the investments held by KKR Financial Holdings LLC. Mr. Nuttall is one of four members of the investment committee, and Messrs. Kravis and Roberts are ad hoc members of the investment committee. The members of KKR & Co. L.L.C. consist of the individuals named in footnote (1) above (other than Messrs. Momtazee and Patel) and other executives of Kohlberg Kravis Roberts & Co. L.P. Messrs. Kravis and Roberts, as managing members of KKR & Co. L.L.C., may be deemed to share beneficial ownership of any shares beneficially owned by KKR & Co. L.L.C., but disclaim beneficial ownership of such shares. The address of KKR TRS Holdings, Inc., KKR Financial Holdings LLC, KKR Financial Advisors LLC and KKR Financial LLC is 555 California Street, 50th Floor, San Francisco, CA 94104. In May 2007, KKR TRS Holdings, Inc. transferred its interest in the warrants to purchase 245,540 shares of our Series BB preferred stock to KKR Financial Holdings III, LLC, a wholly-owned subsidiary of KKR Financial Holdings LLC.

(3) Consists 1,957,380 shares held by Thoma Cressey Fund VII, LP and 30,562 shares held by Thoma Cressey Friends Fund VII, LP. Mr. Cressey, Orlando Bravo, Lee Mitchell and Carl Thoma are partners of Thoma Cressey Bravo, Inc., which is the general partner of each of Thoma Cressey Fund VII, LP and Thoma Cressey Friends Fund VII, LP., or the Thoma Cressey Funds, and are deemed to have shared voting and investment power over the shares held by the Thoma Cressey Funds. Each of Messrs. Cressey, Bravo, Mitchell and Thoma disclaim beneficial ownership of the shares held by the Thoma Cressey Funds, except to the extent of each of their pecuniary interest therein. The address for all entities and individuals affiliated with Thoma Cressey Bravo is Sears Tower, 92nd Floor, 22 South Wacker Drive, Chicago, IL 60606.

(4) Consists of 1,325,295 shares held by Jazz Investors LLC. Mr. O'Keefe, David K. Beecken, William G. Petty, Jr., Thomas A. Schlesinger, David J. Cooney, Gregory A. Moerschel and John W. Kneen are partners of Beecken Petty O'Keefe & Company, which is the general partner of Jazz Investors LLC, and are deemed to have shared voting and investment power over the shares held by Jazz Investors LLC. Each of Messrs. O'Keefe, Beecken, Petty, Schlesinger, Cooney, Moerschel and Kneen disclaim beneficial ownership of the shares held by Jazz Investors LLC, except to the extent of each of their pecuniary interest therein. The address for all entities and individuals affiliated with Beecken Petty O'Keefe & Company is 131 South Dearborn Street, Ste. 2800, Chicago, IL 60603.

(5) Consists of 1,215,650 shares held by Prospect Venture Partners II, L.P. and 18,511 shares held by Prospect Associates II, L.P. Dr. Tananbaum is a managing member of Prospect Management Co. II, L.L.C., which is the general partner of each of Prospect Venture Partners II, L.P. and Prospect Associates II, L.P., or the Prospect Funds. The managing members of Prospect Management Co. II, L.L.C. are deemed to have shared voting and investment power over the shares held by the Prospect Funds. Dr. Tananbaum disclaims beneficial ownership of the shares held by the Prospect Funds, except to the extent of his pecuniary interest therein. The address for all entities and individuals affiliated with Prospect Venture Partners is 435 Tasso Street, Suite 200, Palo Alto, CA 94301.

(6) Consists of 1,200,647 shares held by Versant Venture Capital II, L.P., 22,784 shares held by Versant Affiliates Fund II-A, L.P. and 10,730 shares held by Versant Side Fund II, L.P. Mr. Colella is a managing member of Versant Ventures II, LLC, which is the general partner of each of Versant Venture Capital II, L.P., Versant Affiliates Fund II-A, L.P. and Versant Side Fund II, L.P., or the Versant Funds, and is deemed to have shared voting and investment power over the shares held by the Versant Funds. Mr. Colella disclaims beneficial ownership of the shares held by the Versant Funds, except to the extent of his pecuniary interest therein. The address for all entities and individuals affiliated with Versant Ventures II LLC is 3000 Sand Hill Road, Building 4, Ste. 210, Menlo Park, CA 94025.

(7) Consists of 47,269 shares held by CCG Associates-QP, LLC, 11,499 shares held by CCG AV, LLC-Series A, 43,461 shares held by CCG AV, LLC-Series C, 19,879 shares held by CCG CI, LLC, 860,336 shares held by CCG Investment Fund, LP and 11,525 shares held by CCG Investment Fund-AI, LP. Golden Gate Capital Management, L.L.C. is the general partner or managing member of CCG Associates-QP, LLC, CCG AV, LLC-Series A, CCG AV, LLC-Series C, CCG CI, LLC, CCG Investment Fund, LP and CCG Investment Fund–AI, LP, or the CCG Funds. Messrs. David C. Dominik and Jesse T. Rogers, as principal managing members of Golden Gate Capital Management, L.L.C., are deemed to have shared voting and investment power over the shares held by the CCG Funds. Each of Messrs. Dominik and Rogers disclaim beneficial ownership of the shares held by the CCG Funds, except to the extent of each of their pecuniary interest therein. The address for all entities and individuals affiliated with Golden Gate Capital is One Embarcadero Center, 33rd Floor, San Francisco, CA 94111.

(8) Consists of 165,661 shares held by Lehman Brothers HealthCare Venture Capital LP, 317,076 shares held by Lehman Brothers PA LLC, 142,858 shares held by Lehman Brothers Partnership Account 2000/2001, LP, 37,050 shares held by Lehman Brothers Offshore Partnership Account 2000/2001 LP, and warrants to purchase 304,469 shares held by LB I Group Inc. Each of the foregoing entities is managed by a subsidiary of Lehman Brothers Holdings Inc. The address for all entities and individuals affiliated with Lehman Brothers Holdings Inc. is 399 Park Avenue, New York, NY 10022. Lehman Brothers Holdings Inc. is affiliated with Lehman Brothers Inc., which is acting as a representative of the underwriters of this offering.

(9) Includes 222,251 shares Mr. Cozadd has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(10) Includes 222,251 shares Dr. Saks has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(11) Includes 222,251 shares Mr. Myers has the right to acquire within 60 days of March 31, 2007 through the exercise of options, and 3,064 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.

(12) Includes 84,841 shares Mr. Fust has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(13) Includes 84,841 shares Ms. Wissel has the right to acquire within 60 days of March 31, 2007 through the exercise of options, and 2,485 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.

(14) Includes 84,841 shares Ms. Gamble has the right to acquire within 60 days of March 31, 2007 through the exercise of options.

(15) See Notes (1) and (2) above.
(16) Consists solely of the shares described in Note (6) above. Mr. Colella disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
(17) Consists solely of the shares described in Note (3) above. Mr. Cressey disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
(18) Consists solely of the shares described in Notes (1) and (2) above. Mr. Michelson disclaims beneficial ownership of these shares.
(19) See Notes (1) and (2) above.
(20) Consists solely of the shares described in Note (4) above. Mr. O'Keefe disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
(21) See Notes (1) and (2) above.
(22) Includes 4,518 shares Mr. Sebulsky has the right to acquire within 60 days of March 31, 2007 through the exercise of options, and 3,865 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.
(23) Consists solely of the shares described in Note (5) above. Dr. Tananbaum disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein.
(24) Includes 14,641,518 shares held by entities affiliated with certain of our directors, 925,794 shares that certain of our executive officers and directors have the right to acquire within 60 days of March 31, 2007 through the exercise of options and 9,414 shares subject to our unvested share repurchase right within 60 days of March 31, 2007.

DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering and the filing of our fourth amended and restated certificate of incorporation, our authorized capital stock will consist of 150,000,000 shares of common stock, par value $.0001 per share, and 20,000,000 shares of preferred stock, par value $.0001 per share.

The following is a summary of the rights of our common stock and preferred stock. This summary is not complete. For more detailed information, please see our fourth amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.

Common Stock

Outstanding Shares

Based on 629,003 shares of common stock outstanding as of March 31, 2007, the conversion of outstanding preferred stock as of March 31, 2007 into 17,921,551 shares of common stock upon the completion of this offering, the issuance of 6,000,000 shares of common stock in this offering, and no exercise of options or warrants, there will be 24,550,554 shares of common stock outstanding upon the closing of this offering. As of March 31, 2007, assuming the conversion of all outstanding preferred stock into common stock upon the closing of this offering, we had approximately 47 record holders of our common stock.

As of March 31, 2007, there were 785,728 shares of common stock subject to outstanding warrants, assuming the conversion of all outstanding preferred stock into common stock upon the closing of this offering, and 1,862,530 shares of common stock subject to outstanding options.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our fourth amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued pursuant to this offering will be, fully paid and nonassessable.

Preferred Stock

Upon the closing of this offering, all outstanding shares of preferred stock will have been converted into shares of common stock. See Note 12 to our consolidated financial statements for a description of the currently outstanding preferred stock. Following this offering, our fourth amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Under our fourth amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 20,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series (but not below the number of shares of such series then outstanding).

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Warrants

As of March 31, 2007, warrants exercisable for 785,728 shares of our Series BB preferred stock at an exercise price of $20.36 per share were outstanding. These warrants were issued in June 2005 under a senior secured note and warrant purchase agreement entered into in connection with our acquisition of Orphan Medical. In connection with the conversion of all our outstanding shares of preferred stock into common stock immediately prior to the closing of this offering, the warrants will automatically become exercisable for shares of common stock. The warrants have a net exercise provision under which their holders may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our stock at the time of exercise of the warrants after deduction of the aggregate exercise price. The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrants will terminate on June 24, 2012 if not exercised earlier.

Registration Rights

Under our investor rights agreement, following the closing of this offering, the holders of approximately 19,306,128 shares of common stock, including warrants to purchase 785,728 shares of common stock, or their transferees, have the right to require us to register their shares with the SEC so that those shares may be publicly resold, or to include their shares in any registration statement we file, in each case as described below. If our executive officers exercise outstanding stock options, the shares of common stock acquired on exercise would have the registration rights described below.

Demand Registration Rights

At any time after six months following the effective date of the registration statement for this offering, the holders of at least 40% of the shares having registration rights (or a lesser number if the anticipated aggregate amount of shares to be sold is expected to not be less than $25.0 million), and each holder who was an original

purchaser of at least 4,517,932 shares of our Series B preferred stock and/or Series B Prime preferred stock, each have the right to demand that we file one registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, the holders of at least 20% of the shares having registration rights and each holder who is an original purchaser of $40.0 million in original issue price of shares having registration rights, each have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of shares to be sold under the registration statement on Form S-3 is at least $25.0 million. A holder who was an original purchaser of $40.0 million in original issue price of our shares having registration rights has the right to demand one registration statement for each $40.0 million in original issue price of such shares having registration rights that the holder purchased. We are only obligated to file up to two registration statement on Form S-3 in any 12 month period. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

Piggyback Registration Rights

At any time after the closing of this offering, if we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, a stockholder with registration rights will have the right, subject to certain exceptions, to include their shares of common stock in the registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances, but not below 30% of the total number of shares included in the registration statement.

Expenses of Registration

We will pay all expenses relating to any demand registrations, Form S-3 registrations and piggyback registrations, other than underwriting discounts and commissions.

Termination

The registration rights and our obligations terminate upon the earlier of either February 18, 2016, or as to a given holder of registration rights, when such holder of registration rights can sell all of such holder’s registrable securities in a three month period pursuant to Rule 144 promulgated under the Securities Act.

Delaware Anti-Takeover Law and Certain Provisions of Our Fourth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares

outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Fourth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our fourth amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our fourth amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;

- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

The amendment of any of these provisions would require approval by the holders of at least 66 2/3% of our then outstanding common stock, voting as a single class.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, MA 02021.

NASDAQ Global Market Listing

We have applied for quotation of our common stock on the NASDAQ Global Market under the trading symbol "JAZZ."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of March 31, 2007, upon completion of this offering, 24,550,554 shares of common stock will be outstanding, assuming no exercise of the underwriters' over-allotment option and no exercise of options or warrants. All of the shares sold in this offering will be freely tradable unless purchased by our affiliates. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

- no restricted shares will be eligible for immediate sale upon the closing of this offering;
- approximately 14,219,877 shares, less shares subject to a repurchase option in our favor tied to the holders' continued service to us (which will be eligible for sale upon lapse of the repurchase option), will be eligible for sale upon expiration of lock-up agreements 180 days after the date of this prospectus; and
- the remainder of the restricted shares will be eligible for sale from time to time thereafter upon expiration of their respective one-year holding periods, but could be sold earlier if the holders exercise any available registration rights.

Rule 144

In general, under Rule 144 under the Securities Act of 1933, as in effect on the date of this prospectus, a person who has beneficially owned shares of our common stock for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 245,506 shares immediately after this offering; or
- the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 144(k)

Under Rule 144(k) of the Securities Act as in effect on the date of this prospectus, a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate, is entitled to sell the shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144. Approximately 1,954,058 shares of our common stock will qualify for resale under Rule 144(k) within 180 days of the date of this prospectus.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written

compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under “Underwriters” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-up Agreements

We, along with our directors, executive officers and substantially all of our other stockholders, optionholders and warrantholders have agreed with the underwriters that for a period of 180 days following the date of this prospectus, we or they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of common stock, subject to specified exceptions. Morgan Stanley & Co. Incorporated and Lehman Brothers Inc. may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us is publicly announced; or
- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the release or the occurrence of the material news or material event, except in no event will the restrictions extend past 214 days after the date of this prospectus.

Registration Rights

Upon the closing of this offering, the holders of approximately 19,306,128 shares of our common stock, including warrants exercisable for shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up arrangement described above. Shares acquired upon exercise of outstanding options by our executive officers would have these registration rights. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act (except for shares held by affiliates) immediately upon the effectiveness of this registration. Any sales of securities by these stockholders could adversely effect on the trading price of our common stock. See “Description of Capital Stock—Registration Rights.”

Equity Incentive Plans

We intend to file with the SEC a registration statement under the Securities Act covering the shares of common stock subject to outstanding stock options granted under our 2003 Equity Incentive Plan, as well as the shares of common stock reserved for issuance under our 2007 Equity Incentive Plan, 2007 Non-Employee Directors Stock Option Plan and 2007 Employee Stock Purchase Plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations applicable to our affiliates and the lock-up agreements described above.

MATERIAL U.S. TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a general discussion of the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, you are a "non-U.S. holder" if you are a beneficial owner of our common stock and you are not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, or of any political subdivision of the United States;
- an estate whose income is subject to U.S. federal income taxation regardless of its source; or
- a trust, in general, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has made a valid election to be treated as a U.S. person under applicable U.S. Treasury regulations.

If you are an individual, you may be treated as a resident of the United States in any calendar year for U.S. federal income tax purposes, instead of a nonresident, by, among other ways, being present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. For purposes of this calculation, you would count all of the days present in the current year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year. Residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens. If a partnership or other flow-through entity is a beneficial owner of our common stock, the tax treatment of a partner in the partnership or owner of the entity will generally depend on the status of the partner or owner and the activities of the partnership or entity. Such holders and their partners or owners should consult their own tax advisors regarding U.S. federal, state, local and non-U.S. income and other tax consequences of acquiring, holding and disposing of shares of our common stock.

This discussion does not purport to address all aspects of U.S. federal income and estate taxes or specific facts and circumstances that may be relevant to a particular non-U.S. holder's tax position, including:

- U.S. state or local or any non-U.S. tax consequences;
- the tax consequences for the stockholders, partners or beneficiaries of a non-U.S. holder;
- special tax rules that may apply to particular non-U.S. holders, such as financial institutions, insurance companies, tax-exempt organizations, U.S. expatriates, broker-dealers and traders in securities; and special tax rules that may apply to a non-U.S. holder that holds our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment.

The following discussion is based on provisions of the U.S. Internal Revenue Code of 1986, as amended, existing and proposed U.S. Treasury regulations and administrative and judicial interpretations, all as of the date of this prospectus, and all of which are subject to change, possibly with retroactive effect. The following summary assumes that you hold our common stock as a capital asset. **Each non-U.S. holder should consult a tax advisor regarding the U.S. federal, state, local and non-U.S. income and other tax consequences of acquiring, holding and disposing of shares of our common stock.**

Dividends

We do not anticipate paying cash dividends on our common stock in the foreseeable future. See "Dividend Policy." In the event, however, that we pay dividends on our common stock, we will have to withhold a

U.S. federal withholding tax at a rate of 30%, or a lower rate under an applicable income tax treaty, from the gross amount of the dividends paid to you. You should consult your tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in order for us to withhold tax at a lower treaty rate, you must provide us with a properly executed Form W-8BEN certifying your eligibility for the lower treaty rate. However:

- in the case of common stock held by a foreign partnership, the certification requirement will generally be applied to partners and the partnership will be required to provide certain information;
- in the case of common stock held by a foreign trust, the certification requirement will generally be applied to the trust or the beneficial owners of the trust, depending on whether the trust is a "foreign complex trust," "foreign simple trust" or "foreign grantor trust" as defined in the U.S. Treasury regulations; and
- look-through rules apply for tiered partnerships, foreign simple trusts and foreign grantor trusts.

A non-U.S. holder that is a foreign partnership or a foreign trust is urged to consult its tax advisor regarding its status under these U.S. Treasury regulations and the certification requirements applicable to it.

If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the U.S. Internal Revenue Service.

If the dividend is effectively connected with your conduct of a trade or business in the United States and, if an income tax treaty applies, is attributable to a permanent establishment that you maintain in the United States, the dividend will generally be exempt from the U.S. federal withholding tax, provided that you supply us with a properly executed Form W-8ECI. In this case, the dividend will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons and, if you are a foreign corporation, you may be subject to an additional branch profits tax at a rate of 30% or a lower rate as may be specified by an applicable income tax treaty.

Gain on Dispositions of Common Stock

You generally will not be subject to U.S. federal income tax on gain recognized on a disposition of our common stock unless:

- the gain is effectively connected with your conduct of a trade or business in the United States and, if an income tax treaty applies, the gain is attributable to a permanent establishment maintained by you in the United States; in this case, the gain will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons and, if you are a foreign corporation, you may be subject to an additional branch profits tax at a rate of 30% or a lower rate as may be specified by an applicable income tax treaty;
- you are an individual who is present in the United States for 183 days or more in the taxable year of the disposition and meets other requirements; or
- we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that you held our common stock; in this case, subject to the discussion below, the gain will be taxed on a net income basis in the manner described in the first bullet paragraph above.

Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. The tax relating to stock in a "U.S. real property holding corporation" generally will not apply to a non-U.S. holder whose holdings, direct and

indirect, at all times during the applicable period, constituted 5% or less of our common stock, provided that our common stock was regularly traded on an established securities market. We believe that we are not currently, and we do not anticipate becoming in the future, a "U.S. real property holding corporation" for U.S. federal income tax purposes.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax or other treaty provides otherwise and, therefore, may be subject to U.S. federal estate tax.

Information Reporting and Backup Withholding

Information returns will be filed with the U.S. Internal Revenue Service in connection with payments of dividends and the proceeds from a sale or other disposition of our common stock. Dividends paid to you may be subject to information reporting and U.S. backup withholding. You generally will be exempt from such backup withholding if you provide a properly executed Form W-8BEN or otherwise meet documentary evidence requirements for establishing that you are a non-U.S. holder or otherwise establish an exemption.

The gross proceeds from the disposition of our common stock may be subject to information reporting and backup withholding. If you sell your shares of our common stock outside of the United States through a non-U.S. office of a non-U.S. broker and the sales proceeds are paid to you outside of the United States, then the U.S. backup withholding and information reporting requirements generally (except as provided in the following sentence) will not apply to that payment. However, information reporting, but not backup withholding, will apply to a payment of sales proceeds, even if that payment is made outside of the United States, if you sell our common stock through a non-U.S. office of a broker that:

- is a U.S. person;
- derives 50% or more of its gross income in specific periods from the conduct of a trade or business in the United States;
- is a "controlled foreign corporation" for U.S. tax purposes; or
- is a foreign partnership, if at any time during its tax year, one or more of its partners are U.S. persons who in the aggregate hold more than 50% of the income or capital interests in the partnership, or the foreign partnership is engaged in a U.S. trade or business,

unless the broker has documentary evidence in its files that you are a non-U.S. person and various other conditions are met or you otherwise establish exemption.

If you receive payments of the proceeds of a sale of our common stock to or through a U.S. office of a broker, the payment is subject to both U.S. backup withholding and information reporting unless you provide a properly executed Form W-8BEN certifying that you are a non-U.S. person and various other conditions are met or you otherwise establish an exemption.

You generally may obtain a refund of any amount withheld under the backup withholding rules that exceeds your income tax liability by filing a refund claim with the U.S. Internal Revenue Service.

UNDERWRITERS

Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. Incorporated and Lehman Brothers Inc. are acting as representatives and joint book-running managers, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. Incorporated	
Lehman Brothers Inc.	
Credit Suisse Securities (USA) LLC	
Natexis Bleichroeder Inc.	
Total	6,000,000

The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the public offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $ a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of 900,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table. If the underwriters' option is exercised in full, the total price to the public would be $, the total underwriters' discounts and commissions would be $ and the total proceeds to us would be $.

172,289 shares of common stock acquired by certain affiliates of Lehman Brothers Inc. on December 14, 2006 have been deemed underwriting compensation by the NASD and will therefore be subject to the transfer restrictions in NASD Rule 2710(g).

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed five percent of the total number of shares of common stock offered by them.

Application has been made to have our common stock listed on the NASDAQ Global Market under the symbol "JAZZ".

We and our directors, executive officers and certain other stockholders have agreed that, without the prior written consent of Morgan Stanley & Co. Incorporated and Lehman Brothers Inc. on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of

directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;

- file any registration statement with the SEC relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise.

The restrictions described in the preceding paragraph do not apply to:

- in our case, (1) the sale of shares to the underwriters, (2) the issuance of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing and (3) the issuance of shares of common stock in connection with (a) any strategic transaction that includes a commercial or development relationship involving us and other entities or (b) any equipment loan or leasing arrangement, real property leasing arrangement or debt financing from a bank or similar financial institution; *provided* that, in the case of any issuance pursuant to clause (3), (i) each recipient shall sign and deliver in respect of such shares of common stock a lock-up agreement substantially in the form of the agreement entered into by our directors and officers and (ii) the aggregate number of shares so issued shall not exceed 5% of the number of shares of common stock issued and outstanding immediately following completion of this offering;
- in the case of our directors, officers and stockholders, (1) transactions relating to shares of common stock or other securities acquired in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Securities and Exchange Act of 1934, as amended, shall be required or shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in such open market transactions, (2) transfers of shares of common stock or any security convertible into common stock as a bona fide gift, or (3) distributions of shares of common stock or any security convertible into common stock to limited partners or stockholders of such persons; *provided* that in the case of any transfer or distribution pursuant to clause (1) or (2), (i) each donee, distributee or transferee shall sign and deliver in respect of shares of common stock and any security convertible into common stock so transferred or distributed, a lock-up agreement substantially in the form of the agreement entered into by our directors and officers and (ii) no filing under Section 16(a) of the Securities Exchange Act of 1934, as amended, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the 180-day restricted period referred to in the preceding paragraph; and
- in the case of any of our executive officers, dispositions by such executive officer or such executive officer's estate of such executive officer's vested shares of restricted common stock to us in connection with such executive officer's death or complete disability as described under "Management—Executive Employment Agreements—Vested Share Repurchase Right; Executive Put Right".

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue a release regarding earnings or regarding material news or events relating to us, or
- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the release or the occurrence of the material news or material

event; provided, however, that the restrictions described in the preceding paragraph will not extend beyond 214 days after the date of this prospectus.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. As an additional means of facilitating the offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing the common stock in the offering, if the syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities, and may end any of these activities at any time.

The underwriters may in the future provide investment banking services to us for which they would receive customary compensation. In addition, entities affiliated with Lehman Brothers Inc. have entered into certain transactions with us, including the acquisition of shares of our capital stock and warrants to purchase shares of our capital stock, as described under “Certain Relationships and Related Party Transactions.”

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Member State it has not made and will not make an offer of shares of common stock to the public in that Member State, except that it may, with effect from and including such date, make an offer of shares of common stock to the public in that Member State:

- at any time to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- at any time to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts; or
- at any time in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of the above, the expression an “offer of shares of common stock to the public” in relation to any shares of common stock in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe the shares of common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in that Member State.

Each underwriter has represented and agreed that it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000) in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of such Act does not apply to us and it has complied and will comply with all applicable provisions of such Act with respect to anything done by it in relation to any shares of common stock in, from or otherwise involving the United Kingdom.

Pricing of the Offering

Prior to this offering, there has been no public market for the shares of common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. Among the factors to be considered in determining the initial public offering price will be our future prospects and our industry in general, our sales, earnings and certain other financial operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. The estimated initial public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley Godward Kronish LLP, Palo Alto, California. The underwriters are being represented by Davis Polk & Wardwell, Menlo Park, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule at December 31, 2005 and 2006, and for each of the three years in the period ended December 31, 2006, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 2 to the consolidated financial statements). We have included our consolidated financial statements and schedule in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Ernst & Young LLP, independent auditors, has audited the financial statements of Orphan Medical, Inc. for the period from January 1, 2005 to June 24, 2005, as set forth in their report. We have included Orphan Medical, Inc.'s financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to Jazz Pharmaceuticals and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at *http://www.sec.gov*. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at *http://www.jazzpharmaceuticals.com*, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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JAZZ PHARMACEUTICALS, INC.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Jazz Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals, Inc. as of December 31, 2005 and 2006, and the related consolidated statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in Item 16(b) of this Registration Statement. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of the internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Jazz Pharmaceuticals, Inc. at December 31, 2005 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 2 to the consolidated financial statements, Jazz Pharmaceuticals Inc.'s recurring losses from operations and cash used in operating activities raise substantial doubt about its ability to continue as a going concern. Management's plans as to these matters also are described in Note 2. The 2006 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 2 to the consolidated financial statements, Jazz Pharmaceuticals, Inc. changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", on January 1, 2006.

/s/ Ernst & Young LLP

Palo Alto, California
March 6, 2007
except for the seventh paragraph of Note 2,
as to which the date is May 15, 2007

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2005	December 31, 2006	March 31, 2007 (Unaudited)	Pro Forma March 31, 2007 (Unaudited)
ASSETS				
Current assets:				
Cash and cash equivalents	$ 20,614	$ 78,948	$ 67,667	$ 67,667
Restricted cash	300	275	275	275
Accounts receivable, net of allowances of $122, $198 and $244 at December 31, 2005 and 2006 and March 31, 2007 (unaudited), respectively	3,597	5,380	6,167	6,167
Inventories	3,262	3,026	2,303	2,303
Prepaid expenses	3,240	3,447	2,174	2,174
Other current assets	371	487	680	680
Total current assets	31,384	91,563	79,266	79,266
Property and equipment, net	1,941	2,107	2,116	2,116
Intangible assets, net—purchased developed technology	71,023	63,130	57,657	57,657
Intangible assets, net—other	7,717	6,010	5,582	5,582
Goodwill	38,883	38,213	38,213	38,213
Long-term restricted cash and investments	12,000	12,000	12,085	12,085
Other long-term assets	1,833	1,548	2,991	2,991
Total assets	$ 164,781	$ 214,571	$ 197,910	$ 197,910
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:				
Line of credit	$ —	$ 2,191	$ 3,104	$ 3,104
Accounts payable	4,786	5,443	3,145	3,145
Accrued liabilities	11,121	12,943	13,097	13,097
Deferred revenue	—	1,422	1,659	1,659
Preferred stock warrant liability (including $5,107, $5,965 and $8,469 as of December 31 2005, December 31, 2006 and March 31, 2007 (unaudited), respectively, held by related parties)	7,429	8,521	11,588	—
Total current liabilities	23,336	30,520	32,593	21,005
Liability for early exercise of options and unvested restricted common stock	184	98	77	77
Deferred rent	649	436	387	387
Non-current portion of deferred revenue	—	13,495	13,243	13,243
Senior secured notes (including $50,620, $51,998 and $52,100 as of December 31, 2005 and 2006 and March 31, 2007 (unaudited), respectively, held by related parties)	73,629	74,283	74,429	74,429
Development financing obligation	15,445	—	—	—
Commitments and contingencies (Note 8)				
Convertible preferred stock, $.0001 par value; 27,851,839 authorized at December 31, 2005 and 2006 and March 31, 2007 (unaudited), none pro forma (unaudited); 11,295,076, 17,921,551 and 17,921,551 shares issued and outstanding at December 31, 2005 and 2006 and March 31, 2007 (unaudited), respectively, none pro forma (unaudited); aggregate liquidation preference of $165,000 at December 31, 2005 and $265,000 at December 31, 2006 and March 31, 2007	163,862	263,852	263,852	—
Common stock subject to repurchase	5,924	8,183	8,749	12,954
Stockholders' equity (deficit):				
Common stock, $.0001 par value; 22,835,080 shares authorized at December 31, 2005, December 31, 2006 and March 31, 2007 (unaudited), respectively; 617,974, 623,986 and 629,003 shares issued and outstanding at December 31, 2005, December 31, 2006 and March 31, 2007 (unaudited), respectively; 18,550,554 issued and outstanding pro forma (unaudited)	—	—	—	2
Additional paid-in capital	—	1,335	1,807	273,040
Accumulated other comprehensive income	4	12	—	—
Accumulated deficit	(118,252)	(177,643)	(197,227)	(197,227)
Total stockholders' equity (deficit)	(118,248)	(176,296)	(195,420)	75,815
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 164,781	$ 214,571	$ 197,910	$ 197,910

The accompanying notes are an integral part of these financial statements.

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
Revenues:					
Product sales, net	$ —	$ 18,796	$ 43,299	$ 9,771	$ 11,625
Royalties, net	—	146	594	66	211
Contract revenue	—	2,500	963	—	2,252
Total revenues	—	21,442	44,856	9,837	14,088
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technology)	—	4,292	6,968	1,569	2,003
Research and development	17,988	45,783	54,956	12,894	14,867
Selling, general and administrative	7,459	23,551	51,384	12,219	14,339
Amortization of intangible assets	—	4,960	9,600	2,400	2,362
Purchased in-process research and development	—	21,300	—	—	—
Total operating expenses	25,447	99,886	122,908	29,082	33,571
Loss from operations	(25,447)	(78,444)	(78,052)	(19,245)	(19,483)
Interest income	643	1,318	2,307	581	1,091
Interest expense (including $4,595 and $9,024 for the years ended December 31, 2005 and 2006, respectively, and $2,185 and $2,254 for the three months ended March 31, 2006 and 2007 (unaudited), respectively, pertaining to related parties)	—	(7,129)	(14,129)	(3,777)	(3,268)
Other income (expense)	—	(901)	(1,109)	62	(3,069)
Gain on extinguishment of development financing obligation	—	—	31,592	—	—
Gain on sale of product rights	—	—	—	—	5,145
Net loss	(24,804)	(85,156)	(59,391)	(22,379)	(19,584)
Beneficial conversion feature	—	—	(21,920)	(3,501)	—
Loss attributable to common stockholders	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$ (19,584)
Loss per share attributable to common stockholders, basic and diluted	$ (1,550.25)	$ (14,192.67)	$ (6,524.69)	$ (2,875.56)	$ (851.48)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	16	6	13	9	23
Pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted			$ (6.04)		$ (1.11)
Weighted-average common shares used in computing pro-forma loss per share attributable to common stockholders (unaudited), basic and diluted			13,466		17,666

The accompanying notes are an integral part of these financial statements.

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share and per share amounts)

	Convertible Preferred Stock						Common Stock Subject to Repurchase	Stockholders' Deficit					
	Series A		Series B		Series B Prime			Common Stock		Additional Paid-in Capital	Other Compre-hensive Income	Accum-ulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Shares	Amount				
Balance at January 1, 2004	646,060	$ 7,076	—	$ —	—	$ —	$ —	577,841	$ 16	$ —	$ —	$ (2,528)	$ (2,512)
Reincorporation in Delaware and reissuance of common stock with $.0001 par value	—	—	—	—	—	—	—	—	(16)	16	—	—	—
Issuance of common stock subject to repurchase rights for cash	—	—	—	—	—	—	—	40,133	—	230	—	—	230
Transfer of common stock subject to repurchase to temporary equity	—	—	—	—	—	—	1,773	—	—	(21)	—	(1,752)	(1,773)
Vesting of common stock subject to repurchase	—	—	—	—	—	—	1,892	—	—	(24)	—	(1,839)	(1,863)
Repurchase rights to shares issued under restricted stock purchase agreements	—	—	—	—	—	—	—	—	—	(201)	—	—	(201)
Issuance of Series A convertible preferred stock net of issuance costs of $0	709,317	7,850	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $441	—	—	1,590,334	23,560	—	—	—	—	—	—	—	—	—
Issuance of Series B Prime convertible preferred stock, net of issuance costs of $477	—	—	—	—	1,722,883	25,523	—	—	—	—	—	—	—
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(24,804)	(24,804)
Balance at December 31, 2004	1,355,377	14,926	1,590,334	23,560	1,722,883	25,523	3,665	617,974	—	—	—	(30,923)	(30,923)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements	—	—	—	—	—	—	—	—	—	53	—	—	53
Vesting of common stock subject to repurchase	—	—	—	—	—	—	2,259	—	—	(53)	—	(2,173)	(2,226)
Issuance of Series B convertible preferred stock, net of issuance costs of $11	—	—	3,180,714	47,989	—	—	—	—	—	—	—	—	—
Issuance of Series B Prime convertible preferred stock, net of issuance costs of $136	—	—	—	—	3,445,768	51,864	—	—	—	—	—	—	—
Comprehensive loss:													
Net loss	—	—	—	—	—	—	—	—	—	—	—	(85,156)	(85,156)
Gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	—	4	—	4
Comprehensive loss													(85,152)
Balance at December 31, 2005	1,355,377	14,926	4,771,048	71,549	5,168,651	77,387	5,924	617,974	—	—	4	(118,252)	(118,248)

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT—(Continued)
(In thousands, except share and per share amounts)

	Convertible Preferred Stock						Common Stock Subject to Repurchase	Stockholders' Deficit					
	Series A		Series B		Series B Prime			Common Stock		Additional Paid-in Capital	Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Amount	Shares	Amount				
Balance at December 31, 2005	1,355,377	$ 14,926	4,771,048	$ 71,549	5,168,651	$ 77,387	$ 5,924	617,974	$ —	$ —	$ 4	$(118,252)	$ (118,248)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements	—	—	—	—	—	—	—	—	—	53	—	—	53
Vesting of common stock subject to repurchase	—	—	—	—	—	—	2,259	—	—	(2,226)	—	—	(2,226)
Issuance of Series B convertible preferred stock, net of issuance costs of $5	—	—	3,180,707	47,995	—	—	—	—	—	—	—	—	—
Issuance of Series B Prime convertible preferred stock, net of issuance costs of $5	—	—	—	—	3,445,768	51,995	—	—	—	—	—	—	—
Issuance of common stock for cash upon exercise of stock options	—	—	—	—	—	—	—	6,012	—	10	—	—	10
Stock-based compensation	—	—	—	—	—	—	—	—	—	3,498	—	—	3,498
Beneficial conversion feature—deemed dividend on issuance of Series B preferred stock	—	—	—	—	—	—	—	—	—	21,920	—	—	21,920
Beneficial conversion feature	—	—	—	—	—	—	—	—	—	(21,920)	—	—	(21,920)
Comprehensive loss:													
Net loss	—	—	—	—	—	—	—	—	—	—	—	(59,391)	(59,391)
Gain on available-for-sale securities	—	—	—	—	—	—	—	—	—	—	8	—	8
Comprehensive loss													(59,383)
Balance at December 31, 2006	1,355,377	14,926	7,951,755	119,544	8,614,419	129,382	8,183	623,986	—	1,335	12	(177,643)	(176,296)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements (unaudited)	—	—	—	—	—	—	—	—	—	13	—	—	13
Vesting of common stock subject to repurchase (unaudited)	—	—	—	—	—	—	566	—	—	(557)	—		(557)
Issuance of common stock for cash upon exercise of stock options (unaudited)	—	—	—	—	—	—	—	5,017	—	76	—	—	76
Stock-based compensation expense (unaudited)	—	—	—	—	—	—	—	—	—	940	—	—	940
Comprehensive loss:													
Net loss (unaudited)	—	—	—	—	—	—	—	—	—	—	—	(19,584)	(19,584)
Loss on available-for-sale securities (unaudited)	—	—	—	—	—	—	—	—	—	—	(12)	—	(12)
Comprehensive loss (unaudited)													(19,596)
Balance at March 31, 2007 (unaudited)	1,355,377	$ 14,926	7,951,755	$119,544	8,614,419	$129,382	$ 8,749	629,003	$ —	$ 1,807	$ —	$(197,227)	$ (195,420)

The accompanying notes are an integral part of these financial statements.

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
Operating activities					
Net loss	$(24,804)	$ (85,156)	$ (59,391)	$ (22,379)	$ (19,584)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization	122	479	710	161	262
Amortization of intangible assets	—	4,960	9,600	2,400	2,362
Loss on disposal of property and equipment	—	—	481	—	—
Fair value adjustment to acquired finished goods	—	1,584	775	400	54
Purchased in-process research and development	—	21,300	—	—	—
Excess of cash paid over accrued for interest	—	476	949	178	219
Revaluation of preferred stock warrant liability	—	901	1,092	(62)	3,067
Stock-based compensation expense	—	—	3,480	820	940
Interest on development financing	—	445	1,147	599	—
Gain on extinguishment of development financing	—	—	(31,592)	—	—
Gain on sale of product rights	—	—	—	—	(5,145)
Changes in assets and liabilities:					
Accounts receivable	—	(249)	(1,783)	(1,099)	(778)
Inventories	—	(219)	(521)	(121)	344
Prepaid expenses and other current assets	(1,915)	1,158	(473)	(253)	1,080
Other assets	(151)	—	323	(2)	(1,528)
Accounts payable	1,564	2,408	657	(143)	(2,298)
Accrued liabilities	3,340	(210)	2,492	(2,361)	155
Deferred revenue	—	—	14,917	—	(15)
Deferred rent	688	(39)	(213)	(51)	(49)
Net cash used in operating activities	(21,156)	(52,162)	(57,350)	(21,913)	(20,914)
Investing activities					
Purchases of property and equipment	(992)	(1,413)	(1,682)	(121)	(271)
Proceeds from sale of property and equipment	—	—	150	—	—
Purchases of available-for-sale securities	(45,946)	—	(1,705)	—	—
Proceeds from sales of available-for-sale securities	40,000	3,450	—	—	—
Proceeds from maturities of available-for-sale securities	—	2,500	—	—	—
Cash paid for shares of Orphan Medical, Inc., net of cash acquired	—	(146,116)	—	—	—
Proceeds from maturities of long term restricted cash equivalents	—	—	1,705	—	—
Decrease (increase) in restricted cash and investments	150	(12,175)	25	—	(85)
Proceeds from sale of product rights	—	—	—	—	9,000
Net cash provided by (used in) investing activities	(6,788)	(153,754)	(1,507)	(121)	8,644
Financing activities					
Proceeds from issuances of Convertible Preferred Stock, net of issuance costs	56,933	99,853	99,990	34,994	—
Proceeds from issuances of Common Stock, net of issuance costs	58	—	10	—	76
Proceeds from issuances of Common Stock with repurchase rights and the early exercise of stock options	171	—	—	—	—
Proceeds from line of credit	—	—	3,283	—	6,077
Repayments under line of credit	—	—	(1,092)	—	(5,164)
Proceeds from sale of senior secured notes, net of issuance costs (including $53,624 from related parties)	—	77,999	—	—	—
Proceeds from development financing	—	15,000	15,000	15,000	—
Net cash provided by financing activities	57,162	192,852	117,191	49,994	989
Net increase (decrease) in cash and cash equivalents	29,218	(13,064)	58,334	27,960	(11,281)
Cash and cash equivalents, at beginning of period	4,460	33,678	20,614	20,614	78,948
Cash and cash equivalents, at end of period	$ 33,678	$ 20,614	$ 78,948	$ 48,574	$ 67,667
Supplemental disclosure of cash flow information:					
Cash paid for interest (including $4,263 and $4,556 for the years ended December 31, 2005 and 2006, respectively, and $2,063 and $2,100 for each of the three months ended March 31, 2006, and 2007 (unaudited), paid to related parties)	$ —	$ 6,200	$ 12,000	$ 3,000	$ 3,000
Supplemental disclosure of non-cash financing activities:					
Warrants to purchase Series BB Convertible Preferred Stock issued in conjunction with senior secured notes	$ —	$ 6,696	$ —	$ —	$ —
Beneficial conversion feature—deemed dividend attributable to preferred stockholders	$ —	$ —	$ 21,920	$ 3,501	$ —

The accompanying notes are an integral part of these financial statements.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

Jazz Pharmaceuticals, Inc. ("the Company") was incorporated in California in March 2003 and reincorporated in Delaware in January 2004. The Company is a specialty pharmaceutical company focused on identifying, developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. The Company's goal is to build a broad portfolio of products through a combination of internal development activities and acquisition and in-licensing opportunities, and to utilize its specialty sales force to promote its products in specific therapeutic markets.

Since its inception, the Company has built a commercial operation and assembled a portfolio that currently includes two marketed products, two product candidates for which new drug applications ("NDAs") have been submitted to the U.S. Food and Drug Administration ("FDA") and five product candidates in various stages of clinical development. The Company also has additional product candidates in early-stage development and feasibility activities. In March 2007, the Company sold its rights to a third marketed product.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Jazz Pharmaceuticals, Inc. and its wholly-owned subsidiary, Orphan Medical, Inc. ("Orphan Medical"), after elimination of intercompany transactions and balances.

Significant Risks and Uncertainties

The Company has incurred significant losses from operations since its inception and expects losses to continue for the next several years. To achieve profitable operations, the Company must successfully identify, develop and commercialize its products. Products developed by the Company will require approval of the FDA or a foreign regulatory authority prior to commercial sales. The regulatory approval process is expensive, time consuming and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company's products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products. The Company will need to raise additional funds to support its operations, and such funding may not be available to it on acceptable terms, or at all. The Company's board of directors has approved the filing of a registration statement on Form S-1 with respect to a proposed initial public offering of its common stock. The Company may seek additional sources of financing through development financings, collaborations or public or private debt or equity financings, and may also seek to reduce expenses related to its operations.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The 2006 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts and disclosures reported in the consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Unaudited Interim Financial Data

The accompanying consolidated balance sheet as of March 31, 2007, the consolidated statements of operations and of cash flows for the three months ended March 31, 2006 and 2007 and the consolidated statements of convertible preferred stock and stockholders' deficit for the three months ended March 31, 2007 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company's financial position as of March 31, 2007 and the results of its operations and cash flows for the three months ended March 31, 2006 and 2007. The financial data and other information disclosed in these notes to the financial statements related to the three month periods are unaudited. The results for the three months ending March 31, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007 or for any other interim period or for any future year.

Unaudited Pro Forma Balance Sheet

In February 2007, the board of directors authorized management of the Company to file a registration statement with the Securities and Exchange Commission permitting the Company to sell shares of its common stock to the public. The unaudited pro forma balance sheet as of March 31, 2007 and pro forma basic and diluted loss per share attributable to common stockholders reflect the automatic conversion of all of the Series A, Series B and Series B Prime convertible preferred stock outstanding at March 31, 2007 into 17,921,551 shares of common stock immediately prior to the closing of the Company's initial public offering. In addition, the unaudited pro forma balance sheet as of March 31, 2007 reflects the impact of the reclassification of the preferred stock warrant liability into additional paid-in capital as a result of the automatic conversion of warrants to purchase preferred stock into warrants to purchase common stock immediately prior to the closing of the Company's initial public offering and the reclassification of convertible preferred stock owned by certain executive officers, which is subject to a right of repurchase as discussed in Note 13, into common stock subject to repurchase.

Reverse Stock Split

On May 15, 2007, the Company filed a third amended and restated certificate of incorporation with the Delaware Secretary of State effecting a 1-for-11.06701 reverse split of the Company's preferred and common stock. All share and per share amounts have been retroactively restated in these financial statements and notes for all periods presented.

Concentration of Credit Risks and Fair Value of Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash equivalents, restricted cash, marketable securities and accounts receivable. The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of investments to the extent recorded on the balance sheet.

The Company monitors its exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit to pharmaceutical companies, pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company primarily in the U.S. in the normal course of business. Customer creditworthiness is monitored and collateral is not normally required. Historically, the Company has not experienced significant credit losses on its accounts receivable. The Company's five largest

customers accounted for an aggregate of approximately 88%, 90% and 93% of gross accounts receivable as of December 31, 2005, December 31, 2006 and March 31, 2007, respectively.

The fair value of financial instruments, including cash, cash equivalents, marketable investments, accounts receivable, accounts payable, accrued liabilities and senior secured notes approximate their carrying value.

Cash Equivalents, Restricted Cash and Available-for-Sale Securities

The Company considers all highly liquid investments, readily convertible to cash, that mature within three months or less from date of purchase to be cash equivalents. Restricted cash and available-for-sale securities consist of cash equivalents and available-for-sale securities, the use of which is restricted either by contract or agreement. At December 31, 2006 and March 31, 2007, the Company held a money market account in the amount of $275,000 as collateral securing a letter of credit. The Company has a $12.0 million investment account which is restricted under the agreement governing the Company's senior secured notes. Available-for-sale securities are investments in debt securities with maturities of less than one year from the balance sheet date, or securities with maturities of greater than one year that are specifically identified to fund current operations. Collectively, cash equivalents, restricted cash and available-for-sale securities are classified as available-for-sale and are recorded at fair value, based on quoted market prices. Unrealized gains and losses, net of tax, are recorded in other comprehensive income and included as a separate component of stockholders' deficit. The Company uses the specific-identification method for calculating realized gains and losses on securities sold. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest income in the statement of operations. Realized gains and losses on sales of available-for-sale securities have not been material.

Inventories

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the noncancelable term of the Company's operating lease or their economic useful lives. Maintenance and repairs are charged to operations as incurred.

Goodwill and Intangible and Long-Lived Assets

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. The Company has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates an impairment, then the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. Management tests goodwill for impairment annually in October and concluded that no impairment existed as of October 1, 2006. Management will also test for impairment whenever events or changes in circumstances indicate that the carrying value may not be

recoverable. There have been no changes since October 1, 2006 that would cause management to reevaluate its conclusion.

Intangible assets consist primarily of purchased developed technology, agreements not to compete and trademarks. Intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from three to ten years. The estimated useful lives associated with intangible assets are consistent with underlying agreements, or the estimated lives of the products. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. The Company evaluates purchased intangibles and other long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value, calculated using discounted cash flows. Since the Company's inception, there has been no such impairment loss recognized.

Preferred Stock Warrant Liability

Effective July 1, 2005, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Staff Position ("FSP") No. 150-5, *Issuer's Accounting under Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable* ("FSP 150-5"), an interpretation of FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. Pursuant to FSP 150-5, freestanding warrants for shares that are puttable, or warrants for shares that are redeemable are classified as liabilities on the consolidated balance sheet at fair value. At the end of each reporting period, changes in fair value during the period are recorded as other expense.

Upon adoption of FSP 150-5, the Company reclassified the fair value of its warrants to purchase shares of convertible preferred stock from equity to a liability. There was no cumulative effect on adoption. The Company recorded other expense of $901,000 and $1.1 million during the years ended December 31, 2005 and 2006, respectively, and $3.1 million during the three months ended March 31, 2007, to reflect the increase in the fair value of the warrants. The Company recorded a benefit of $62,000 during the three months ended March 31, 2006 to reflect a decrease in the fair value of the warrants. The Company will continue to adjust the preferred stock warrant liability for changes in the fair value of the warrants until the earlier of the exercise of the warrants, at which time the liability will be reclassified to temporary equity, or the conversion of the underlying convertible preferred stock issuable into common stock, at which time the liability will be reclassified to stockholders' equity (deficit).

Deferred Rent

The Company recognizes rent expense on a straight-line basis over the noncancelable term of its operating lease and, accordingly, records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. The Company also records landlord-funded lease incentives, such as reimbursable leasehold improvements, as a deferred rent liability which is amortized as a reduction of rent expense over the noncancelable terms of its operating lease.

Revenue Recognition

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. In evaluating arrangements

with multiple elements the Company considers whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on their respective fair values when there is reliable evidence of fair value for all elements of the arrangement. If there is no evidence of fair value for all the elements of the arrangement consideration is allocated based on the residual value method for the delivered elements. Under the residual method, the amount of revenues allocated to the delivered elements equals the total arrangement consideration less the aggregate fair value of any undelivered elements. The applicable revenue recognition criteria are applied to each of the separate units. Payments received in advance of work performed are recorded as deferred revenues and recognized when earned.

Product Sales, Net

Revenues from sales of Xyrem within the U.S. are recognized upon transfer of title, which occurs when the Company's specialty pharmaceutical distributor removes product from the Company's consigned inventory location at its facility for shipment to a patient. Antizol is, and prior to our sale of the Company's rights Cystadane was, shipped to the Company's wholesaler customers in the U.S. with free on board destination shipping terms, and the Company recognizes revenues when delivery occurs. The Company's international sales often have customer acceptance clauses and therefore the Company recognizes revenues when it is notified of acceptance or the time to inspect and reject the shipment has lapsed. When sales to international customers do not have acceptance clauses, the Company recognizes revenues when title transfers, which is generally when the product leaves the Company's logistics provider's facilities.

Revenues from sales of products within the U.S. are recorded net of estimated allowances for specialty distributor and wholesaler fees, prompt payment discounts, Medicaid rebates, government chargebacks and a customer rebate. Calculating these items involves estimates and judgments based on sales or invoice data and historical experience. Due to the nature of the Company's current products, product returns have been infrequent and immaterial.

Royalties, Net

The Company receives royalties from third parties based on sales of its products under out-licensing and distributor arrangements. For those arrangements where royalties are reasonably estimable, the Company recognizes revenues based on estimates of royalties earned during the applicable period, and adjusts for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenues upon receipt of royalty statements from the licensee or distributor.

Contract Revenues

Nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the performance period. The Company recognizes at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company or its licensees and distributors, as revenues when the milestone is accomplished

and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

Cost of Product Sales and Concentrations of Supply Risk

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability insurance, FDA user fees, freight, shipping, handling and storage costs, and salaries and related costs of employees involved with production. The Company's product exchange policy for Antizol allows and, prior to our sale of our rights to Cystadane, our product exchange policy for Cystadane allowed, customers to return expired product for exchange up to six months before or after the product's expiration date. These expiration date returns are exchanged for replacement product, and the estimated cost of such exchanges is included in cost of product sales. Amounts accrued for replacement product have not been material to date. In addition, as part of the acquisition of Orphan Medical, the Company recorded finished goods on-hand at the acquisition date at fair value, which is defined as inventory valued at estimated selling prices less the sum of (a) costs of disposal and (b) reasonable profit allowance for the selling effort of the acquiring entity. The fair value of inventory acquired is recorded as cost of product sales when the related product revenues are recorded. Excluded from cost of product sales as shown on the face of the consolidated statements of operations is amortization of developed technology of $4.1 million and $7.9 million for the years ended December 31, 2005 and 2006, respectively, and $2.0 million and $1.9 million for the three months ended March 31, 2006 and 2007, respectively.

The Company relies on certain sole suppliers for drug substance and certain sole manufacturing partners for each of its marketed products and certain of its product candidates. The Company attempts to mitigate this risk by establishing contractual relationships where appropriate.

Research and Development

The Company's research and development expenses consist of expenses incurred in identifying, developing and testing its product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing our clinical trials, clinical trial costs paid to sites and investigators' salaries, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates or drug delivery or formulation technologies that the Company has licensed, allocated expenses, such as facilities and information technology that support the Company's research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under the Company's license agreements. For products that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the trial and therefore is not included in inventory.

In-Process Research and Development

In connection with the acquisition of Orphan Medical, the Company recorded a charge of $21.3 million for acquired in-process research and development during the year ended December 31, 2005. This amount represented the estimated fair value related to three incomplete product candidate development projects for which, at the time of the acquisition, technological feasibility had not been established and there was no alternative future use.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses for the years ended December 31, 2004, 2005 and 2006 were zero, $551,000, and $2.3 million, respectively. Advertising expenses for the three months ended March 31, 2006 and 2007 were $442,000 and $820,000, respectively.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Comprehensive Loss

Comprehensive loss includes net loss and all changes in stockholders' deficit during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. For the years ended December 31, 2005 and 2006 and the three months ended March 31, 2006 and 2007, the difference between comprehensive loss and net loss represented unrealized gains on available-for-sale securities. For the year ended December 31, 2004, comprehensive loss was equal to the net loss.

Loss Per Common Share

Basic and diluted loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. Potentially dilutive securities consisting of convertible preferred stock, stock options, common stock subject to repurchase and warrants were not included in the diluted loss per share attributable to common stockholders for all periods presented because the inclusion of such shares would have had an antidilutive effect.

The calculation of pro forma basic and diluted net loss per common share assumes conversion of all outstanding shares of preferred stock into shares of common stock using the as-if-converted method as if such conversion had occurred at the beginning of the period or the original issuance date, if later.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
	(In thousands, except per share data)				
Historic					
Numerator:					
Loss attributable to common stockholders	$ (24,804)	$ (85,156)	$ (81,311)	$ (25,880)	$ (19,584)
Denominator:					
Weighted-average common shares outstanding	607	618	620	618	627
Less: weighted-average common shares outstanding subject to repurchase	(591)	(612)	(607)	(609)	(604)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	16	6	13	9	23
Loss per share attributable to common stockholders, basic and diluted	$ (1,550.25)	$ (14,192.67)	$ (6,254.69)	$ (2,875.56)	$ (851.48)
Pro Forma					
Weighted-average shares used in computation of basic and diluted loss per share applicable to common stockholders above			13		23
Pro forma adjustments to reflect assumed conversion of convertible preferred stock (unaudited)			13,453		17,643
Weighted-average shares used to compute pro forma basic and diluted loss per share attributable to common stockholders (unaudited)			13,466		17,666
			$ (6.04)		$ (1.11)

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following convertible preferred stock, stock options, common stock subject to repurchase and warrants were excluded from the computation of diluted loss per share attributable to common stockholders for the periods presented because including them would have an antidilutive effect (in thousands):

	Year Ended December 31,			Three Months Ended March 31,	
	2004	2005	2006	2006	2007
				(Unaudited)	
Series A convertible preferred stock (as if converted)	1,355	1,355	1,355	1,355	1,355
Series B convertible preferred stock (as if converted)	1,590	4,771	7,952	5,884	7,952
Series B Prime convertible preferred stock (as if converted)	1,723	5,169	8,614	6,375	8,614
Warrants to purchase Series BB convertible preferred stock (as if exercised and converted)	—	786	786	786	786
Options to purchase common stock	1,277	1,457	1,597	1,515	1,863
Early exercise of options and unvested restricted common stock	371	217	62	178	24
Common shares subject to repurchase	243	393	542	430	580

Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (“APB 25”) and related interpretations, and complied with the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, (“SFAS 123”) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123* (“SFAS 148”). Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of the Company’s common stock over the exercise price of the option on the date of grant. No stock-based compensation expense was recorded under APB 25 during the years ended December 31, 2004 and 2005.

Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment* (“SFAS 123R”), which requires compensation expense related to share-based transactions, including employee stock options, to be measured and recognized in the financial statements based on fair value. SFAS 123R revises SFAS 123, as amended, and supersedes APB 25. The Company adopted SFAS 123R using a modified version of prospective application. Under modified prospective application, SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date are recognized as the requisite service is rendered on or after the required effective date. The compensation expense for that portion of awards is based on the grant-date fair value of those awards. The compensation expense for awards with grant dates prior to January 1, 2006, are attributed to periods beginning on or after the effective date using the attribution method that was used under SFAS 123, except that the method of recognizing forfeitures only as they occur is not continued.

The Company is using the straight-line method to allocate compensation cost to reporting periods under SFAS 123 and SFAS 123R.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Beneficial Conversion Feature—Series B Preferred Stock and Series B Prime Preferred Stock

The Company accounts for potentially beneficial conversion features under EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* ("EITF 98-5") and EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. Issuances of convertible preferred stock during the year ended December 31, 2006 were deemed to result in a beneficial conversion feature calculated in accordance with EITF 98-5. For additional information regarding this beneficial conversion feature, see Note 12.

Reclassifications

Certain reclassifications have been made to the prior year amounts in order to conform to the current year presentation. Convertible preferred stock, which in prior year financial statements had been classified as part of stockholders' deficit, is now classified as temporary equity in accordance with EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. Previously the Company had recorded the original purchase price of unvested shares of common stock subject to a right of repurchase by the Company as a liability and reclassified amounts to stockholders' deficit at the original purchase price as these shares vested. In the financial statements as reclassified, all vested shares of common stock subject to repurchase held by the Company's executive officers have been classified as temporary equity at fair value as of the date the Company entered into certain executive employment agreements. Certain payments to a customer for services performed, which had previously been classified as part of selling, general and administrative expense, have been reclassified as a reduction of revenue. These reclassifications did not impact previously reported net loss.

Recent Accounting Pronouncements

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* ("FIN 48"). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted the provisions of FIN 48 effective January 1, 2007. No cumulative adjustment to the Company's accumulated deficit was required upon adoption.

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB 108"). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects on each of the Company's balance sheets and statement of operations and the related financial statement disclosures. SAB 108 was adopted by the Company in the first quarter of 2007. The Company has determined that the adoption of SAB 108 had no material effect on its results of operations and financial position.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company effective

January 1, 2008. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an amendment of FASB Statement No. 115* ("SFAS 159"). SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Most of the provisions in Statement 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. The Company is currently evaluating the effect that the adoption of SFAS 159 will have on its results of operations and financial position.

3. Cash, Cash Equivalents, Restricted Cash and Available-For-Sale Securities

Cash, cash equivalents, restricted cash and available-for-sale securities, all of which are classified as available-for-sale securities, consisted of the following as of December 31, 2005 and 2006 and March 31, 2007 (in thousands):

	December 31, 2005			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 5,189	$ —	$ —	$ 5,189
Obligations of U.S. government agencies	15,484	2	—	15,486
Corporate debt securities	7,578	2	—	7,580
Other debt securities, primarily money market funds	4,659	—	—	4,659
Total available-for-sale securities	$ 32,910	$ 4	$ —	$ 32,914
Amounts classified as cash and cash equivalents				$ 20,614
Amounts classified as restricted cash				300
Amounts classified as long-term restricted cash and available-for-sale securities				12,000
Total				$ 32,914

	December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 11,799	$ —	$ —	$ 11,799
Obligations of U.S. government agencies	35,106	10	—	35,116
Corporate debt securities	17,180	2	—	17,182
Other debt securities, primarily money market funds	27,126	—	—	27,126
Total available-for-sale securities	$ 91,211	$ 12	$ —	$ 91,223
Amounts classified as cash and cash equivalents				$ 78,948
Amounts classified as restricted cash				275
Amounts classified as long-term restricted cash and available-for-sale securities				12,000
Total				$ 91,223

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	March 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(Unaudited)		
Cash	$ 12,641	$ —	$ —	$ 12,641
Obligations of U.S. government agencies	39,503	—	—	39,503
Corporate debt securities	13,319	—	—	13,319
Other debt securities, primarily money market funds	14,564	—	—	14,564
Total available-for-sale securities	$ 80,027	$ —	$ —	$ 80,027
Amounts classified as cash and cash equivalents				67,667
Amounts classified as restricted cash				275
Amounts classified as long-term restricted cash and available-for-sale securities				12,085
				$ 80,027

All available-for-sale securities held as of December 31, 2005 and 2006 had contractual maturities of less than one year.

Since inception, there have been no material realized gains or losses on available-for-sale securities. No available-for-sale securities held as of December 31, 2005 or 2006 had been in a continuous unrealized loss position for more than 12 months. The aggregate fair value of available-for-sale securities held at December 31, 2005 and 2006 which had unrealized losses was $1.5 million and $1.6 million, respectively. The amount of the unrealized loss at December 31, 2005 and 2006 was immaterial and the Company does not believe that the impairment is other than temporary.

4. Certain Balance Sheet Items

Inventories consist of the following (in thousands):

	December 31,		March 31,
	2005	2006	2007
			(Unaudited)
Raw materials	$1,109	$ 541	$ 550
Finished goods	2,153	2,485	1,753
Total inventories	$3,262	$3,026	$ 2,303

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Property and equipment consist of the following (in thousands):

	December 31, 2005	December 31, 2006	March 31, 2007 (Unaudited)
Leasehold improvements	$ 616	$ 700	$ 704
Computer equipment	707	873	961
Computer software	558	1,271	1,413
Furniture and fixtures	160	182	208
Construction-in-progress	506	316	327
Total	2,547	3,342	3,613
Less accumulated depreciation and amortization	(606)	(1,235)	(1,497)
Property and equipment, net	$1,941	$ 2,107	$ 2,116

Accrued liabilities consists of the following (in thousands):

	December 31, 2005	December 31, 2006	March 31, 2007 (Unaudited)
Accrued research and development expense	$ 4,166	$ 5,119	$ 4,499
Accrued compensation	3,329	4,322	2,950
Accrued sales and marketing expense	2,231	783	2,071
Accrued general and administrative expense	365	1,440	1,397
Other	1,030	1,279	2,180
Total accrued liabilities	$11,121	$12,943	$ 13,097

5. Acquisition of Orphan Medical

On June 24, 2005, the Company acquired Orphan Medical, a developer and marketer of orphan drug products, primarily to establish a commercial presence through a specialty pharmaceutical sales organization focused on neurologists and psychiatrists. Orphan Medical marketed and sold three products and was conducting clinical trials in order to expand the potential use of one of those products to additional indications. The acquisition was accounted for as a business combination using the purchase method of accounting. Accordingly, the results of Orphan Medical are included in the Company's consolidated financial statements since the date of acquisition.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The purchase price was comprised of cash consideration (net of cash acquired) of $145.4 million plus direct acquisition costs of $750,000 and was allocated to the assets purchased and liabilities assumed based upon their respective fair values as follows (in thousands):

Accounts receivable	$ 3,348
Inventories	4,717
Other current assets	2,714
Noncurrent assets	112
Liabilities	(7,988)
Intangible assets	83,700
Goodwill	38,213
In-process research and development	21,300
Total fair value of assets acquired, net of liabilities assumed	$146,116

Liabilities of $8.0 million as shown above included $4.0 million of restructuring charges related primarily to employee severance payments and the closure of facilities, of which no amounts remained unpaid as of December 31, 2006.

Management performed a valuation of identifiable intangible assets acquired in the transaction. The estimated fair value of intangible assets identified and the useful lives assigned at the time of acquisition are as follows (in thousands):

	Gross Carrying Amount	Weighted-Average Estimated Useful Life (Years)
Developed technology—Xyrem	$39,700	9.5
Developed technology—Antizol	31,100	9.5
Developed technology—Cystadane	4,300	9.5
Agreements not to compete	5,600	4.4
Trademarks	2,600	9.5
Other	400	4.5
Amortizable intangible assets	$83,700	9.1

During the year ended December 31, 2005, the Company recorded a charge of $21.3 million for acquired in-process research and development. This amount represented the estimated fair value related to three incomplete product candidate development projects for which technological feasibility had not been established and that had no alternative future use at the time of acquisition. This charge is not deductible for federal tax purposes. The fair value of the in-process research and development was determined using the “income approach.” This method requires a forecast of all the expected future net cash flows associated with the in-process technology discounted to present value by applying an appropriate discount rate. The discount rate used reflects the weighted-average cost of capital for companies in the Company’s industry, as well as specific risks associated with the cash flows being discounted.

In January 2005, Orphan Medical submitted a supplemental New Drug Application, or sNDA, to the FDA seeking an expanded label indication for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy. At the time of the acquisition, the FDA had not yet approved the sNDA. The Company used a

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

discount rate of 26% to calculate the fair value of the expanded label indication for Xyrem and accounted for $15.2 million associated with the expanded label indication as in-process research and development expense. The sNDA was approved by the FDA in November 2005. At the time of acquisition, Orphan Medical was also conducting a Phase II clinical trial to evaluate the use of sodium oxybate, the active pharmaceutical ingredient in Xyrem, to treat fibromyalgia syndrome. The Company used a 50% discount rate to calculate the fair value associated with this development project and accounted for $5.9 million associated with the project as in-process research and development. In August 2006, the Company initiated a Phase III clinical trial of sodium oxybate for the treatment of fibromyalgia syndrome. In addition, at the time of acquisition, Orphan Medical was conducting initial research into new dosage forms of Xyrem. The Company used a 50% discount rate to calculate the fair value of these research efforts and accounted for $200,000 associated with this research as in-process research and development expense.

The excess of the purchase price over the fair value of the net tangible and identifiable intangible assets was recorded as goodwill. The primary factors contributing to the existence of goodwill relate to Orphan Medical's sales force and commercial infrastructure. During the year ended December 31, 2006 the Company finalized its estimates of the assets acquired and liabilities assumed and recorded a decrease in goodwill of $670,000. The total amount of goodwill recorded in connection with the acquisition was $38.2 million, none of which will be deductible for federal tax purposes.

In March 2007, the Company sold its rights to Cystadane, a product acquired in connection with the acquisition of Orphan Medical. See Note 19 for a further discussion of this transaction.

The following unaudited pro forma information presents the results of continuing operations and net income of Jazz Pharmaceuticals and Orphan Medical for the years ended December 31, 2004 and 2005 as if the acquisition of Orphan Medical had been consummated as of January 1, 2004 and 2005, respectively. The pro forma results exclude the nonrecurring charge for purchased in-process research and development that resulted directly from the June 24, 2005 acquisition of Orphan Medical by the Company. The unaudited pro forma condensed combined financial information does not reflect any incremental direct costs, including any restructuring charges to be recorded in connection with the acquisition, or any potential cost savings that may result from the consolidation of certain operations of the Company and Orphan Medical. Accordingly, the unaudited pro forma financial information is presented for illustrative purposes and not necessarily indicative of the results of operations of the combined company that would have occurred had the acquisition occurred at the beginning of each period presented, nor is it necessarily indicative of future operating results. The unaudited pro forma information is as follows (in thousands, except per share data):

	Year Ended December 31,	
	2004	2005
Revenues	$ 23,768	$ 37,275
Net loss	(60,318)	(77,643)
Loss per common share	$(3,769.88)	$(12,940.50)

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

6. Goodwill and Intangible Assets

The gross carrying amount and net book value of goodwill and intangible assets is as follows (in thousands):

	December 31, 2005			December 31, 2006			March 31, 2007		
	Gross Carrying Amount	Accum-ulated Amorti-zation	Net Book Value	Gross Carrying Amount	Accum-ulated Amorti-zation	Net Book Value	Gross Carrying Amount	Accum-ulated Amorti-zation (Unaudited)	Net Book Value
Developed technology—Xyrem	$ 39,700	$2,155	$37,545	$ 39,700	$ 6,327	$33,373	$ 39,700	$ 7,370	$32,330
Developed technology—Antizol	31,100	1,688	29,412	31,100	4,956	26,144	31,100	5,773	25,327
Developed technology—Cystadane	4,300	234	4,066	4,300	687	3,613	—	—	—
Agreements not to compete	5,600	696	4,904	5,600	2,042	3,558	5,600	2,379	3,221
Trademarks	2,600	141	2,459	2,600	414	2,186	2,600	483	2,117
Other	400	46	354	400	134	266	400	156	244
Amortizable intangible assets	83,700	4,960	78,740	83,700	14,560	69,140	79,400	16,161	63,239
Goodwill	38,883			38,213			38,213		
Total	$122,583			$121,913			$117,613		

Future amortization costs per year for the Company's existing intangible assets other than goodwill as of December 31, 2006 are estimated as follows (in thousands):

Year Ended December 31,	Estimated Amortization Expense
2007	$ 9,600
2008	9,307
2009	9,033
2010	8,542
2011	8,164

In March 2007, as discussed more fully in note 19, the Company sold its rights to the Cystadane product and as a result reduced the gross carrying amount and accumulated amortization of this intangible asset by $4.3 million and $761,000, respectively.

7. Debt and Financing Obligations

Line of Credit

In September 2006, the Company entered into a one year line of credit agreement with a financial institution under which the Company may borrow up to 80% of eligible receivables up to a maximum borrowing limit of $5.0 million. Borrowings under the line of credit bear interest at the lender's prime rate. The Company is subject to certain financial and operating covenants under the credit agreement. The lender has a security interest in all of the Company's assets, with the exception of intellectual property. As of December 31, 2006 and March 31, 2007, $2.2 million and $3.1 million, respectively, was outstanding under the line of credit with interest accruing at a rate of 8.25% per year.

Senior Secured Notes

In order to partially finance the acquisition of Orphan Medical, a wholly-owned subsidiary of the Company issued $80.0 million aggregate principal amount of senior secured notes (the "notes") and warrants to purchase

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

785,728 shares of the Company's Series BB preferred stock exercisable at $20.36 per share (the "warrants") to certain third parties, some of whom are affiliated with preferred stock investors in June 2005. The notes accrue interest at a rate of 15% per annum, payable quarterly in arrears. The principal on the notes is due in full on June 24, 2011 and can be repaid by the Company at any time, at certain premiums over the principal amount.

The Company estimated the fair value of the warrants to be $6.7 million using the Black-Scholes option pricing model with the following assumptions at the time of issuance: risk free interest rate of 3.96%, volatility of 60%, dividend yield of 0%, and an expected life of seven years. For additional information on the determination of fair value for the warrants as of December 31, 2005 and 2006 and March 31, 2007, see Note 11. The discount to the notes is being accreted to zero over the life of the notes using the effective interest rate method and is included as a component of interest expense. Total issuance costs of $2.0 million were allocated to the notes and the warrants based on their relative fair values. Of the total issuance costs, $1.8 million was allocated to the notes and included in other assets and is being amortized to interest expense using the effective interest method.

The Company and all existing and future domestic subsidiaries fully and unconditionally guarantee repayment of the notes. The notes and each guarantee are secured by a lien and security interest in substantially all of the Company's and each subsidiary's assets. The subsidiary of the Company that issued the notes is required to maintain a minimum cash balance equal to 15% of the outstanding principal amount on the notes. This amount was $12.0 million at December 31, 2005 and 2006 and March 31, 2007 and is reflected as long-term restricted cash and investments on the Company's consolidated balance sheet. The notes contain customary covenants including limitations on the Company's ability to pay dividends, make investments or other restricted payments, incur debt, grant liens, sell assets and enter into sale-leaseback transactions. Upon the occurrence of certain events of default under the notes, including a default by the Company in payment of principal or interest on the notes, a bankruptcy filing by the Company, or a change in control of the Company, the Company may be required to repay the notes at a premium. The repayment premium was 30.0% and 28.3% of the principal amount of the notes as of December 31, 2006 and March 31, 2007, respectively, and is reduced to zero ratably over the term of the notes.

Development Financing Obligation

In August 2005, the Company entered into an agreement pursuant to which a third party agreed to provide $30.0 million to partially fund a Phase III clinical trial of a product candidate in development in exchange for the Company's agreement to repay the third party $37.5 million subject to, and conditional upon, approval by the FDA to market the product in the U.S. In addition, the Company agreed to pay royalties at specified rates based on sales of the product within the U.S. The Company received $15.0 million in 2005 and $15.0 million in 2006 under the agreement. In June 2006, following analysis of the results of the Phase III clinical trial, the Company notified the third party of its intention to discontinue development of the product candidate. As a result, the Company recorded a gain of $31.6 million resulting from the extinguishment of liabilities related to this transaction, which represented principal and interest accrued as of the date notice that development would be discontinued was provided to the third party. Prior to this extinguishment of liabilities, the Company had recorded interest of $445,000, $1.1 million and $599,000 during the years ended December 31, 2005 and 2006 and the three months ended March 31, 2006, respectively, using the effective interest method.

8. Commitments and Contingencies

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated

with product liability or infringement of intellectual property rights. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company that may be, but have not yet been, made. To date, the Company has not paid any claims or been required to defend any action related to these indemnification obligations except as set forth in the description of legal proceedings below.

The Company has agreed to indemnify its officers and directors and the officers and directors of Orphan Medical for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments the Company could be required to make under this indemnification is unlimited; however, the Company maintains insurance policies that may limit its exposure and may enable it to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, the Company believes the fair value of these indemnification obligations is not material. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2005 and 2006 and March 31, 2007. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case the Company may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

In June 2004, the Company entered into a noncancelable operating lease for an office facility in Palo Alto, California which expires in August 2008. The lease is renewable through 2017 at the Company's option. In addition to these lease payments, the Company is obligated to pay for operating expenses for the leased property. The Company is also obligated to make payments under noncancelable operating leases for cars used by its sales force. Rent expense under all operating leases was $435,000, $930,000 and $1.3 million for the years ended December 31, 2004, 2005 and 2006, respectively. Rent expense under all operating leases was $268,000 and $361,000 for the three months ended March 31, 2006 and 2007, respectively. Future minimum lease payments under the Company's noncancelable operating leases at December 31, 2006, are as follows (in thousands):

Year ended December 31,	Lease Payments
2007	$ 1,227
2008	929
2009	238
2010	17
Total future minimum lease payments	$ 2,411

Future minimum lease payments under the Company's noncancelable operating leases at March 31, 2007, are as follows (unaudited) (in thousands):

Year ended December 31,	Lease Payments (Unaudited)
Remainder of 2007	$ 1,242
2008	1,338
2009	343
2010	57
Total future minimum lease payments	$ 2,980

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company uses third party contract manufacturers to manufacture products. As of December 31, 2006 and March 31, 2007, the Company had $1.5 million and $1.7 million, respectively, of noncancelable purchase commitments under agreements with contract manufacturers due in 2007.

Legal Proceedings

In April 2006, a physician who was a speaker for Orphan Medical (and for a short time for the Company), was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment alleges that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. Also in April 2006, the Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, issued to the Company and Orphan Medical subpoenas for documents relating to Xyrem. The Company is cooperating with this investigation and has provided documents to the U.S. Attorney's Office. As a result of the Company's acquisition of Orphan Medical, the Government may seek to hold the Company responsible for Orphan Medical's conduct. The Company has been in discussions with the U.S. Attorney's Office regarding the possible settlement of any potential government claims against Orphan Medical and/or the Company. It is currently unknown if any such settlement will be reached on reasonable terms, or at all. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome. Therefore, in accordance with Statement of Financial Accounting Standard No. 5, *Accounting for Contingencies* ("SFAS 5"), the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

On April 10, 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against Orphan Medical and former officers of Orphan Medical in the U.S. District Court for the District of Minnesota. The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by Orphan Medical in connection with the solicitation of proxies to be voted at the special meeting of Orphan Medical stockholders held on June 22, 2005 for the purpose of considering and voting upon a proposal to adopt the definitive merger agreement pursuant to which the Company acquired Orphan Medical. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys' fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the U.S. District Court for the District of Minnesota. On February 16, 2007, the U.S. District Court for the District of Minnesota granted the defendants' motion to dismiss the complaint, with leave to amend. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome. Therefore, in accordance with SFAS 5 the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

From time to time the Company is involved in legal proceedings arising in the ordinary course of business. The Company believes there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on the Company's results of operations or financial condition.

9. Collaboration and License Agreements

In October 2004, the Company entered into an agreement with GlaxoSmithKline to purchase worldwide rights to the active pharmaceutical ingredient in JZP-4. The Company paid and recorded research and development

expense of $2.0 million upon execution of the agreement and $3.0 million in July 2006 upon achievement of a development milestone. The Company also agreed to pay up to $113.5 million upon the achievement of future development and commercial milestones and royalties at specified rates based on net sales.

The Company paid and expensed as research and development $3.0 million and $10.4 million during the years ended December 31, 2004 and 2005, respectively, upon achievement of development milestones under the terms of three agreements which have since been terminated and under which no future obligations existed at December 31, 2006. In connection with its product development activities, the Company may enter into agreements with third party technology providers, patent holders and others. Patent licenses may require upfront payments, patent prosecution and maintenance fees and royalties on sales of products covered by the patents. Agreements with technology providers often provide for upfront payments and milestone payments based upon the achievement of specified development and commercial milestones and royalties based on sales of the products the Company develops with the technology provider. The Company currently has two such agreements pursuant to which it has agreed to pay up to $8.2 million upon achievement of development and commercial milestones.

10. Product License

In June 2006, the Company entered into an agreement with UCB Pharma Limited (“UCB”) that amended and restated a prior agreement between Orphan Medical and UCB. Under the terms of the amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia syndrome in 54 countries outside of the U.S. Under the prior agreement, UCB made a nonrefundable development milestone payment of $2.5 million in November 2005 and nonrefundable commercial milestone payments of $500,000 and $2.0 million in June 2006 and March 2007, respectively, which the Company recognized upon achievement of the milestones. UCB also made upfront payments of $5.0 million upon execution of the amended agreement in June 2006 and $10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia syndrome. The Company recognized revenues of $463,000 and $252,000 related to these upfront payments during the year ended December 31, 2006 and the three months ended March 31, 2007, respectively. The remaining $14.3 million was recorded as deferred revenues as of March 31, 2007 and is being recognized ratably through 2019, the expected performance period under the agreement. There has been no change in the expected performance period since its establishment in 2006 at the time of the initial upfront payment. The amended agreement requires UCB to make additional milestone payments of up to $146.0 million, of which up to $6.0 million relate specifically to Xyrem for the treatment of narcolepsy, up to $40.0 million relate to the development and approval of JZP-6 for the treatment of fibromyalgia syndrome and up to $100.0 million relate primarily to the commercialization of JZP-6 for the treatment of fibromyalgia syndrome as well as additional sales of Xyrem for the treatment of narcolepsy.

11. Convertible Preferred Stock Warrant Liability

In June 2005 in connection with the issuance of the notes referenced in Note 7, the Company issued warrants to purchase 785,728 shares of Series BB preferred stock at an exercise price of $20.36 per share. The warrants are exercisable, at the option of the holders, at any time until June 24, 2012, and are recorded as preferred stock warrant liability. The warrants may be exercised using the net exercise method. Under this method, the number of shares issued upon exercise is reduced by an amount equal to the product of the number of shares subject to the exercise and the exercise price per share, divided by the fair value of the Series BB preferred stock on the date of the exercise. The number of shares issuable upon exercise of the warrants, and the exercise price per share, are adjustable in the event of stock splits, dividends and similar fundamental changes. The preferred stock warrant liability is revalued at the end of each reporting period to fair value using the Black- Scholes option pricing model to determine the fair value of the warrants. The fair value of the warrants was

estimated to be $7.4 million, $8.5 million and $11.6 million as of December 31, 2005, December 31, 2006 and March 31, 2007, respectively, using the following assumptions:

	December 31, 2005	December 31, 2006	March 31, 2007 (Unaudited)
Series BB preferred stock fair value	$ 16.60	$ 19.37	$ 24.79
Volatility	60%	59%	57%
Contractual term	6.5	5.5	5.2
Risk-free rate	4.3%	4.7%	4.5%
Expected dividend yield	0%	0%	0%

The Company recorded other expense of $901,000 and $1.1 million during the years ended December 31, 2005 and 2006, respectively, and $3.1 million during the three months ended March 31, 2007, to reflect increases in the fair value of the preferred stock warrant liability. The Company recorded a benefit of $62,000 during the three months ended March 31, 2006 to reflect a decrease in the fair value of the preferred stock warrant liability. The Company will continue to adjust the preferred stock warrant liability for changes in the fair value of the warrants until the earlier of the exercise of the warrants to purchase Series BB preferred stock, at which time the liability will be reclassified to temporary equity, or the conversion of the underlying Series BB preferred stock into common stock, at which time the liability will be reclassified to stockholders' equity (deficit).

12. Convertible Preferred Stock

The Company's Second Amended and Restated Certificate of Incorporation authorizes the Company to issue shares of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock and Series BB preferred stock, which hereinafter are collectively referred to as preferred stock.

As of December 31, 2005, the preferred stock is comprised of the following (in thousands, except share amounts):

	Shares Authorized	Shares Issued and Outstanding	Carrying Amount	Aggregate Liquidation Preference
Series A	1,355,380	1,355,377	$ 14,926	$ 15,000
Series B	17,096,311	4,771,048	71,549	72,000
Series B Prime	8,614,420	5,168,651	77,387	78,000
Series BB	785,728	—	—	—
Total	27,851,839	11,295,076	$ 163,862	$ 165,000

As of December 31, 2006 and March 31, 2007, the preferred stock is comprised of the following (in thousands, except share amounts):

	Shares Authorized	Shares Issued and Outstanding	Carrying Amount	Aggregate Liquidation Preference
Series A	1,355,380	1,355,377	$ 14,926	$ 15,000
Series B	17,096,311	7,951,755	119,544	120,000
Series B Prime	8,614,420	8,614,419	129,382	130,000
Series BB	785,728	—	—	—
Total	27,851,839	17,921,551	$ 263,852	$ 265,000

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The Company initially recorded the preferred stock at their fair values on the dates of issuance, net of issuance costs. A redemption event will only occur upon a liquidation or winding up of the Company or a change of control as defined in the Company's Second Amended and Restated Certificate of Incorporation. All shares of preferred stock have been presented outside of permanent equity in accordance with EITF Topic D-98, *Classification and Measurement of Redeemable Securities*. The Company has elected not to adjust the carrying values of the preferred stock to their redemption value since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying values to the redemption values will be made when it becomes probable that such redemption will occur.

As of December 31, 2006 and March 31, 2007, the Company has reserved 8,614,420 shares of Series B preferred stock for conversion of the Series B Prime preferred stock.

In January and December 2006, the Company issued 2,319,264 and 4,307,211 shares, respectively, of Series B preferred stock and Series B Prime preferred stock at a purchase price of $15.09 per share. At the time of each of these issuances, the value of the common stock into which the Series B preferred stock and Series B Prime preferred stock is convertible had a fair value greater than the proceeds for such issuances. Accordingly, the Company recorded a deemed dividend on the Series B preferred stock and Series B Prime preferred stock of $3.5 million in January 2006 and $18.4 million in December 2006, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series B preferred stock and Series B Prime preferred stock exceeded the proceeds from such issuances.

The significant rights, privileges and preferences of the preferred stock are as follows:

Election of Directors

The Company has two classes of directors on the Company's board of directors, designated as standard directors and Series B Prime directors. The holders of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock, Series BB preferred stock and common stock, voting together as a single class on an as-if-converted to common stock basis, are entitled to elect the standard directors. The holders of Series B Prime preferred stock, voting as a single class on an as-if-converted-to-common-stock basis, are entitled to elect Series B Prime directors. The number of Series B Prime directors which the holders of Series B Prime preferred stock are entitled to elect and the number of votes which each Series B Prime director is entitled to cast with respect to any action of the Board of Directors is dependent upon (i) the total number of authorized directors; (ii) the ratio of outstanding Series B Prime preferred stock to the total outstanding shares of Series B preferred stock and Series B Prime preferred stock collectively, including common stock issued on conversion thereof; and (iii) the ratio of total capital committed by holders of Series B Prime preferred stock to the total capital commitments of all holders of Series B preferred stock and Series B Prime preferred stock.

Conversion

Each share of Series B Prime preferred stock is convertible into one share of Series B preferred stock at the option of the holder or automatically at any time that the holder, together with its affiliates, owns less than 8.7% of the aggregate total shares of Series B preferred stock and Series B Prime preferred stock, including common stock issued upon conversion thereof. Each share of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock, and Series BB preferred stock is convertible into one share of common stock, subject to adjustment for stock dividends, stock splits, subdivisions, combinations, reclassifications and similar matters affecting the common stock. Each share of preferred stock will automatically be converted into common stock at the conversion price then in effect upon the earlier of (i) the closing of a firm commitment underwritten public offering with aggregate proceeds to the Company in excess of $60 million and a per share price not less than

$4.09; or (ii) the consent of the holders of at least 55% of the total outstanding shares of preferred stock, voting together as a single class on an as-if-converted to common stock basis.

Voting Rights

The holder of each share of preferred stock is entitled to the number of votes equal to the number of shares of common stock into which the share of preferred stock could be converted. Other than as stated in the Second Amended and Restated Certificate of Incorporation or as required by law, holders of preferred stock vote together with holders of common stock and not as a separate class or series.

Dividends

Holders of the preferred stock are entitled to receive on a pari passu basis, prior and in preference to any declaration or payment of any dividend on the common stock, noncumulative dividends out of any assets legally available at an annual rate of 8% of the respective original purchase prices for the shares of preferred stock, when and if declared by the board of directors. No dividends on preferred stock have been declared through December 31, 2006 or March 31, 2007.

Liquidation

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, or any change of control of the Company, the holders of Series A preferred stock, Series B preferred stock, Series B Prime preferred stock and Series BB preferred stock are entitled to receive, in preference to distributions to holders of common stock, an amount per share equal to $11.07, $15.09, $15.09 and $20.36, respectively, plus any declared but unpaid dividends with respect to such shares of preferred stock. If the assets of the Company are insufficient to permit payment of the liquidation amount in full to all holders of preferred stock, the assets of the Company will be distributed ratably to holders of all series of preferred stock in proportion to the preferential amount each such holder would otherwise be entitled to receive. A change of control of the Company is defined in the Company's Second Amended and Restated Certificate of Incorporation as (i) a sale of all or substantially all the Company's assets other than to certain holders of Series B Prime preferred stock, their affiliates, a group including such holders or affiliates, or entities controlled by the existing stockholders of the Company; (ii) a transaction or series of transactions resulting in more than 50% of the Company's voting power being led by certain holders of Series B Prime preferred stock, their affiliates or a group including such holders or affiliates; or (iii) a merger or consolidation with an entity other than certain holders of Series B Prime preferred stockholders, their affiliates, or a group including such holder or affiliates if after such merger or consolidation the directors immediately prior to such merger or consolidation do not constitute a majority of the directors of the surviving entity or its parent.

13. Common Stock

The Company's Second Amended and Restated Certificate of Incorporation authorizes the Company to issue 22,835,080 shares of common stock. The Company has issued certain shares of its common stock under restricted stock purchase agreements with its executives and a non-employee director and upon the early exercise of stock options. Under the terms of these restricted stock purchase agreements and exercised stock options, the Company has the option to repurchase unvested shares of common stock at the initial purchase price upon the termination of a holder's services to the Company. The number of shares subject to repurchase is reduced ratably over 48 months from the date of purchase or, in the case of stock options early exercised, the date of grant of the stock option.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Unvested shares are subject to a right of repurchase at cost upon termination of employment. The original purchase price paid for these shares are recorded as a liability. Prior to 2004 these amounts were reclassified to permanent equity as these shares vested. In February 2004, each of the Company's executive officers entered into an employment agreement which permits the executive officer or the officer's estate to require the Company to repurchase vested shares at fair market value upon termination of the executive officer's employment due to death or disability. The fair value of vested shares held by the Company's executive officers as of the date of such agreements (the "Agreement Date Fair Value") was recorded as temporary equity and following the date of such agreements, the Agreement Date Fair Value of shares held by the Company's executive officers is recorded as temporary equity as such shares vest. The excess of the Agreement Date Fair Value over the original purchase price paid for such shares is charged against additional paid-in capital or, to the extent additional paid-in capital is insufficient, as an increase to stockholders' deficit. As of December 31, 2005 and 2006 and March 31, 2007 the Company had recorded a liability of $184,000, $98,000 and $77,000, respectively, associated with 216,622, 62,127 and 23,505 unvested shares, respectively. As of December 31, 2005 and 2006 and March 31, 2007, the Company had recorded $5.9 million, $8.2 million and $8.7 million as temporary equity, respectively, associated with 242,911, 392,622 and 542,336 vested shares held by executive officers, respectively.

The Company has reserved the following shares of authorized but unissued Common Stock:

	As of December 31, 2006	As of March 31, 2007 (Unaudited)
Reserved for conversion of Series A preferred stock	1,355,380	1,355,380
Reserved for conversion of Series B, Series B Prime and Series BB preferred stock	17,882,039	17,882,039
Reserved for the Company's equity incentive plan	2,083,339	2,078,322
Total reserved shares of common stock	21,320,758	21,315,741

14. Stock-Based Compensation

2003 Equity Incentive Plan

In March 2003, the board of directors adopted and the stockholders approved the 2003 Equity Incentive Plan (the "2003 Plan"). The 2003 Plan provides for the grant of incentive and nonstatutory stock options, stock issuances, cash awards and certain other equity-related awards to employees, directors and consultants of the Company. An aggregate of 2,125,042 shares of common stock is reserved under the 2003 plan. Incentive stock options may be granted by the board of directors or a committee of the board of directors to employees with an exercise price not less than 100% of the fair value of the common stock on the date of grant. Nonstatutory stock options may be granted to employees, directors and consultants with an exercise price not less than 85% of the fair market value of the common stock on the date of grant. Option grants to employees generally vest 25% upon the first anniversary of the date of hire and ratably each month thereafter for the next three years. The only activity under the 2003 Plan since adoption has related to the grant of stock options to employees and a non-employee director, all of which expire ten years from the date of grant if not exercised.

Change in Accounting Principle—Stock Based Compensation Under SFAS 123R

Effective January 1, 2006, the Company adopted SFAS 123R, which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Under both SFAS 123 and SFAS 123R the Company elected to use the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of stock options was estimated at the grant date with using the following assumptions:

	Year Ended December 31,			Three Months Ended March 31, (Unaudited)	
	2004	2005	2006	2006	2007
Weighted-average volatility	80%	60%	61%	61%	61%
Weighted-average expected term	5.0	5.0	6.0	6.0	6.5
Range of risk-free rates	3.0-4.0%	3.9-4.4%	4.6-5.1%	4.6%	4.5-4.8%
Expected dividend yield	0%	0%	0%	0%	0%

The weighted-average grant date fair value per share of employee stock options granted during the years ended December 31, 2004, 2005 and 2006 and the three months ended March 31, 2006 and 2007 was $8.96, $8.66, $10.68, $10.05 and $12.07, respectively.

Volatility

As the Company does not have any trading history for its common stock, the expected stock price volatility for the Company's common stock was estimated by taking the median historic stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. The Company did not rely on the implied volatilities of traded options in its industry peers' common stock, because either the term of those traded options was much shorter than the expected term of the Company's stock option grants, or the volume of activity was relatively low.

Expected Term

The Company has very little historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. As a result, for stock option grants made during the year ended December 31, 2006 and the three months ended March 31, 2007, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission SAB No. 107 *Share-Based Payment*. For stock options granted during the years ended December 31, 2004 and 2005 the Company estimated the expected term of stock options based on the expected terms of options granted by publicly traded industry peers.

Risk-Free Rate

The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock option grants.

Expected Dividend Yield

The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Common Stock Fair Value

The fair value of the Company's common stock during the years ended December 31, 2004 and 2005 was determined by its board of directors with assistance from management. In May 2006, the Company's board of directors directed management to perform an in-depth contemporaneous valuation of its common stock. In conducting this valuation, the Company used a two-step methodology that first estimated the fair value of the company as a whole, and then allocated a portion of the enterprise value to its common stock. This approach is consistent with the methods outlined in the AICPA Practice Aid *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The valuation methodology utilized the "income approach" to estimate enterprise value. This enterprise value was then validated utilizing the "market approach." The income approach involved projecting future cash flows, discounting them to present value using a discount rate of 15% based upon a risk adjusted weighted average cost of capital of comparable companies, and applying probabilities for success of its product candidates to the resulting discounted cash flows. The projection of future cash flows, the determination of an appropriate discount rate and the estimates of probability for success of its product candidates each involved a significant degree of judgment. For product candidates other than JZP-6 and an alternative dosage form of Xyrem, the probabilities for success ranged from five percent to 30%. For JZP-6, a project for which the Company was preparing to commence Phase III clinical trials, the probability of success ranged from 60% to 70% and for an alternative dosage form of Xyrem, probabilities of success ranged from 50% to 100%. The present value of projected future cash flows after application of the discount rate and, for product candidates, the Company's probabilities of success, ranged from $113.5 million to $124.1 million for its existing products, $112.8 to $156.1 million for JZP-6 and $66.7 million to $142.8 million for its other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $293.0 million to $423.0 million. The market approach used to validate the determination of enterprise value involved selecting a range of possible valuations by comparing a group of 14 publicly-traded specialty pharmaceutical and biotechnology companies with products and product candidates in similar stages of development. The range of enterprise values derived through application of the market approach method was $300.0 million to $350.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, the Company determined that the market approach provided an appropriate validation of its estimated enterprise value.

In order to allocate the enterprise value to the various securities that comprise the Company's capital structure, the option-pricing method was used. For purposes of applying the option-pricing method, the Company estimated its stock price volatility to be 60% and its time to liquidity to be one year. A 10% discount was then applied to account for a lack of marketability of its common stock based upon the assumed time to liquidity. The contemporaneous valuation of its common stock suggested a range of probable fair values from $12.17 per share to $17.26 per share. On June 28, 2006, the Company's board of directors made a determination that the fair market value of its common stock was $16.60 per share, after taking into consideration the contemporaneous valuation as well as other factors including its financial performance, the development status of its product candidates and research and development efforts and the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the Company, given prevailing market conditions.

In December 2006, the Company's board of directors directed management to perform a second in-depth contemporaneous valuation with an effective date of December 31, 2006. In conducting this valuation, the Company used the same methodology and assumptions as in the prior contemporaneous valuation for determining enterprise value, with the exception of adjustments in its estimated future cash flows for certain of its existing products and product candidates and the Company's estimated probabilities of success for certain of its product candidates for purposes of the income approach. The Company also made modifications to the comparison group of companies utilized for the market approach to reflect business developments at comparable

companies and to achieve an appropriate sample size. The present value of projected future cash flows after application of the discount rate and, for product candidates, the Company's probabilities of success ranged from $83.6 million to $93.2 million for its existing products, $138.5 to $186.0 million for JZP-6 and $94.9 million to $184.8 million for its other product candidates, including an alternative dosage form of Xyrem, resulting in a range of enterprise values from $317.0 million to $464.0 million. A number of companies included in the comparison group for purposes of the market approach in the June 28, 2006 contemporaneous valuation were not included in the comparison group as of December 31, 2006 as a result of material adverse events associated with significant development projects at those companies that the Company believed made their market values incomparable to its own. Appropriate specialty pharmaceutical and biotechnology companies were added to the comparison group for purposes of the December 31, 2006 contemporaneous valuation to provide an appropriate sample size of 13 comparable companies. The range of enterprise values derived through the application of the market approach method was $350.0 million to $425.0 million. As these values fell within the range of enterprise values suggested by application of the income approach, the Company determined that the market approach provided an appropriate validation of its estimated enterprise value.

For purposes of allocating enterprise value to the Company's common stock, time to liquidity assumed in the option pricing method was reduced to six months and the discount for marketability was consequently reduced to five percent. In addition to the option-pricing method, the Company also considered the probability weighted expected return method. The application of this method yielded a result within the range of probable fair values suggested by the option pricing method. For purposes of applying the probability-weighted expected return method the Company considered six potential liquidity scenarios. Two potential scenarios were each given a probability of five percent and involved the distressed sale or liquidation of the company at alternative valuations of $10.0 million and $100.0 million. Two other potential scenarios were each given a probability of 7.5% and involved the sale of the company following the failure to achieve positive clinical trial results for certain of the Company's product candidates at alternative valuations of $200.0 million and $270.0 million. The remaining potential scenarios involved the successful sale of the Company or an initial public offering of the Company's common stock at alternative valuations of $500.0 million and $800.0 million, which were given probabilities of 70% and five percent, respectively. The contemporaneous valuation of the Company's common stock suggested a range of probable fair values from $13.94 per share to $21.36 per share. On February 13, 2007, the Company's board of directors made a determination that the fair market value of its common stock was $19.37 per share after taking into consideration the contemporaneous valuation as well as other factors, including its financial performance, the development status of its product candidates and research and development efforts, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the Company, given prevailing market conditions and initial estimates of the potential initial public offering price of its common stock based on initial valuation discussions by and between management and the proposed underwriters for the Company's initial public offering. This determination was confirmed by the compensation committee of the Company's board of directors as of February 27, 2007, the last date in the three month period ended March 31, 2007 that the Company granted stock options.

In connection with the preparation of the Company's financial statements for the year ended December 31, 2006, it reassessed the fair value of its common stock at option grant dates from June 28, 2006 through December 31, 2006 by reviewing its corporate developments from June 28, 2006 through February 13, 2007. In undertaking this assessment, the Company determined that the increase in value from June 28, 2006 to December 31, 2006 was attributable to a decrease in expected timing to liquidity and general progress in the development status of the Company's product candidates and not the achievement of any particular business milestones which would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows. The Company also determined that no such milestones had been achieved during the period from December 31, 2006 to February 13, 2007. As a result, the Company concluded that a ratable

increase to the estimated fair value of its common stock from $16.60 to $19.37 over the period from June 28, 2006 to December 31, 2006 for purposes of calculating stock-based compensation expense associated with its stock option grants under SFAS 123R was appropriate. In connection with the grant of stock options on February 27, 2007, the compensation committee of the Company's board of directors confirmed that the fair market value of our common stock was $19.37 on the basis that we had not achieved any particular business milestone that would reasonably be expected to significantly change the relative timing or likelihood of expected future net cash flows in the period from February 13, 2007 to February 27, 2007. Therefore, the Company determined that no reassessment of the fair value of our common stock as of February 27, 2007 was appropriate.

On February 28, 2007, Solvay informed the Company that the FDA had issued an approvable letter to Solvay for Luvox and Luvox CR dated February 27, 2007. In April 2007, the audit committee of the Company's board of directors determined that as of March 31, 2007, the fair value of the Company's common stock was $24.79 per share after taking into account the contemporaneous valuation conducted in December 2006, the achievement of a significant business milestone associated with the issuance of the approvable letter for Luvox and Luvox CR to Solvay, the likelihood of achieving a liquidity event for the shares of common stock underlying stock options, such as an initial public offering or sale of the company, given prevailing market conditions, and further estimates of the potential initial public offering price of the Company's common stock based on valuation discussions by and between management and the proposed underwriters for the offering. The Company did not perform a contemporaneous valuation of its enterprise value or common stock using the income approach or market approach as of March 31, 2007. The fair market value determination made by the Company's board of directors as of March 31, 2007 was based on the midpoint of the valuation range then suggested by the Company's proposed underwriters in connection with the contemplated initial public offering.

Forfeitures

SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In determining the Company's historic forfeiture rate, the Company has excluded stock option grants totaling 1,133,862 shares issued to executives of the Company in February 2004. The Company believes these stock option grants will not be cancelled due to termination, and therefore has applied a forfeiture rate of 0% for those stock option grants. The annualized forfeiture rate used for the remaining stock option grants was 7%. The forfeiture rate selected did not have a material impact on stock-based compensation expense in the year ended December 31, 2006. Prior to adoption of SFAS 123R, the Company accounted for forfeitures of stock option grants as they occurred.

As a result of the Company's Black-Scholes option fair value calculations and the allocation of value to the vesting periods using the straight-line vesting attribution method, the Company recognized $3.5 million of stock-based compensation expense during the year ended December 31, 2006, of which $8,000, $661,000, and $2.8 million were charged to cost of product sales, research and development and selling, general and administrative expense, respectively. The adoption of SFAS 123R caused basic and diluted net loss per common share to increase by $267.71 in 2006. No income tax benefit was recognized in the statement of operations for the year ended December 31, 2006. Compensation cost capitalized as a component of inventory during 2006 was $18,000. During the three months ended March 31, 2007, the Company recognized $940,000 of stock-based compensation expense, of which $4,000, $201,000 and $735,000 were charged to cost of product sales, research and development and selling, general and administrative expense, respectively. During the three months ended March 31, 2006, the Company recognized $820,000 of stock-based compensation expense, of which $1,000, $144,000 and $675,000 were charged to cost of product sales, research and development and selling, general and administrative expense, respectively.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The total compensation cost related to unvested stock option grants not yet recognized as of December 31, 2006 was $5.5 million and the weighted-average period over which these grants are expected to vest is 1.9 years.

The total compensation cost related to unvested stock option grants not yet recognized as of March 31, 2007 was $7.2 million and the weighted-average period over which these grants are expected to vest is 2.7 years.

Certain information regarding employee stock option grants during the 12 months prior to March 31, 2007 is as follows:

Grant Date	Shares Underlying Option Grants	Exercise Price Per Share	Fair Value Per Share for Accounting Purposes	Black-Scholes Fair Value Per Share
April 2006	22,680	$ 16.60	$ 16.60	$10.12
June 2006	6,146	$ 16.60	$ 16.60	$10.15
August 2006	49,922	$ 16.60	$ 17.49	$10.80
October 2006	21,279	$ 16.60	$ 18.48	$11.61
December 2006	16,807	$ 16.60	$ 19.37	$12.38
February 2007 (unaudited)	100,259	$ 19.37	$ 19.37	$11.84
February 2007 (unaudited)	180,719	$ 19.37	$ 19.37	$12.19

The following table summarizes activity under the Company's stock option plans from January 1, 2004 through March 31, 2007:

	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at December 31, 2003	—	33,658	$ 1.11		
Shares authorized through Plan amendment	2,061,566	—			
Options granted	(1,249,254)	1,249,254	23.31		
Options exercised	—	(5,873)	1.11		
Outstanding at December 31, 2004	812,312	1,277,039	22.83		
Options granted	(209,509)	209,509	15.79		
Options forfeited	27,426	(27,426)	13.50		
Options expired	1,807	(1,807)	1.11		
Outstanding at December 31, 2005	632,036	1,457,315	22.02		
Options granted	(177,432)	177,432	16.60		
Options exercised	—	(6,012)	1.63		
Options forfeited	30,482	(30,482)	15.28		
Options expired	919	(919)	15.29		
Outstanding at December 31, 2006	486,005	1,597,334	21.62	7.5	$ 4,722
Options granted (unaudited)	(280,978)	280,978	19.37		
Options exercised (unaudited)	—	(5,017)	15.14		
Options forfeited (unaudited)	1,510	(1,510)	16.33		
Options expired (unaudited)	9,255	(9,255)	15.09		
Outstanding at March 31, 2007 (unaudited)	215,792	1,862,530	21.34	7.7	$12,297
Vested and expected to vest at March 31, 2007 (unaudited)		1,763,688	21.53	7.6	$11,625
Exercisable at March 31, 2007 (unaudited)		1,042,158	22.57	7.0	$ 6,856

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

At December 31, 2006 options to purchase 1,552,592 shares with a weighted-average exercise price of $21.78 per share, a weighted-average remaining contractual term of 7.5 years and aggregate intrinsic value of $4.6 million were vested or expected to vest. At December 31, 2006 options to purchase 956,073 shares with a weighted-average exercise price of $22.55 per share, a weighted-average remaining contractual term of 7.2 years and aggregate intrinsic value of $2.9 million were exercisable.

Aggregate intrinsic value shown is equal to the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in the money.

During 2004, stock options exercised had no intrinsic value. No options were exercised during 2005. The aggregate intrinsic value of options exercised during 2006 and the three months ended March 31, 2007 was $90,000 and $8,000, respectively.

The following table summarizes information about stock options outstanding as of December 31, 2006:

	Options Outstanding		Options Exercisable
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (Years)	Number of Shares
$ 1.11	15,586	6.6	15,586
15.09	871,585	7.2	585,463
16.60	256,617	9.1	33,742
30.18	226,773	7.1	160,641
45.27	226,773	7.1	160,641
	1,597,334	7.5	956,073

The following table summarizes information about stock options outstanding as of March 31, 2007:

	Options Outstanding		Options Exercisable
Exercise Price	Number of Shares	Weighted-Average Remaining Contractual Life (Years)	Number of Shares
		(Unaudited)	
$ 1.11	15,586	6.3	15,586
15.09	857,217	7.1	624,643
16.60	255,203	9.0	52,315
19.37	280,978	9.9	—
30.18	226,773	6.9	174,807
45.27	226,773	6.9	174,807
	1,862,530	7.7	1,042,158

The Company has issued new shares of common stock upon all exercises of stock options to date and does not currently expect to repurchase shares of common stock in future years to reserve for issuance upon exercise of stock options.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Accounting and Disclosures Under APB 25 and SFAS 123

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements using the intrinsic value method of APB 25 and related interpretations in accounting for its employee stock options and complied with the disclosure-only provisions of SFAS 123, as amended by SFAS 148. No stock-based compensation expense was recorded under APB 25 during the years ended December 31, 2004 and 2005.

The pro forma information required to be disclosed under SFAS 123 for the years ended December 31, 2004 and 2005 is as follows:

	Year Ended December 31,	
	2004	2005
	(In thousands except per share data)	
Loss attributable to common stockholders, as reported	$ (24,804)	$ (85,156)
Add: Employee stock-based compensation using the intrinsic value method	—	—
Deduct: Total employee stock compensation calculated using the fair-value method	(2,325)	(2,934)
Pro forma loss attributable to common stockholders	$ (27,129)	$ (88,090)
Loss per share attributable to common stockholders, basic and diluted		
As reported	$(1,550.25)	$(14,192.67)
Pro forma	$(1,695.56)	$(14,681.67)

The Company estimated fair value of stock options at the grant date using the assumptions set forth above. The Company granted options with exercise prices equal to fair value per share with weighted-average exercise price per share and fair value per share of $15.09 and $15.79 during the years ended December 31, 2004 and 2005, respectively. The Company granted options to purchase 453,546 shares with exercise prices greater than fair value per share with a weighted-average exercise price per share of $37.73 and weighted-average fair value per share of $15.09 during the year ended December 31, 2004.

15. Income Taxes

The Company has a history of losses and therefore has made no provision for income taxes. All of the Company’s losses result from domestic operations.

Deferred income taxes reflect the tax effects of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2005	December 31, 2006
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 48,552	$ 58,474
Federal and state tax credit carryforwards	8,420	9,876
Deferred contract revenues	—	5,453
Acquired capitalized research and development	4,256	3,889
Other	1,996	2,631
Total deferred tax assets	63,224	80,323
Deferred tax liabilities:		
Acquired intangible assets	(27,559)	(24,328)
Other	—	(457)
Total deferred tax liabilities	(27,559)	(24,785)
Valuation allowance	(35,665)	(55,538)
Net deferred tax assets	$ —	$ —

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence, management believes it more likely than not that the Company's deferred tax assets are not recognizable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $10.0 million, $24.6 million and $19.9 million for the years ended December 31, 2004, 2005 and 2006, respectively.

At December 31, 2006, the Company had net operating loss carryforwards for federal income tax purposes of approximately $161.0 million which expire in the period from 2008 to 2026, and federal tax credits of approximately $8.0 million which expire in the period from 2008 to 2026. The Company also has state net operating loss carryforwards of approximately $73.0 million which expire beginning in 2013 and state tax credits of approximately $2.0 million which have no expiration date. Utilization of the Company's net operating loss carryforwards and tax credit carryforwards are subject to annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of the net operating loss before utilization. Because our acquisition of Orphan Medical triggered an ownership change, approximately $37.0 million of the net operating loss carryforward is only available ratably through 2018 based upon the annual limitation under Section 382 of the Internal Revenue Code. Similarly, approximately $5.0 million of tax credits are only available from 2019 to 2024.

The Company adopted Financial Accounting Standards Board Interpretation No. 48 *Accounting for Uncertainties in Income Taxes—an interpretation of FASB Statement No. 109 ("FIN 48")* effective January 1, 2007. FIN 48 requires that the Company recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. No cumulative adjustment to the Company's accumulated deficit was required upon our adoption of FIN 48.

As of January 1, 2007, the Company had approximately $1.5 million of unrecognized tax benefits, substantially all of which would, if recognized, affect our tax expense. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. Because of net operating loss carryforwards, substantially all of the Company's tax years remain open to tax federal

examination. We file income tax returns in the United States and various states, which typically have three tax years open at any point in time.

16. Related Party Transactions

In June 2005, the Company issued senior secured notes in the aggregate principal amount of $80.0 million with interest payable on the notes at the rate of 15% per year, payable quarterly in arrears. The notes are due and payable on June 24, 2011. As of both December 31, 2006 and March 31, 2007, KKR TRS Holdings, Inc., an entity affiliated with Kohlberg Kravis Roberts & Co. L.P., and LB I Group, an entity affiliated with Lehman Brothers Holdings Inc., both of which are significant stockholders, held $25.0 million and $31.0 million, respectively, in principal amount of these senior secured notes. The interest expense recognized with respect to notes held by KKR TRS Holdings, Inc. during the years ended December 31, 2005 and 2006 was $2.1 million and $4.0 million, respectively, and $1.0 million during each of the three months ended March 31, 2006 and 2007. The interest expense recognized with respect to notes held by LB I Group during the fiscal years ended December 31, 2005 and 2006 was $2.5 million and $5.0 million, respectively, and $1.2 million during each of the three months ended March 31, 2006 and 2007. No payments of principal were made in either of these periods. As of December 31, 2006 and March 31, 2007, warrants to purchase 245,540 and 304,469 shares of our Series BB preferred stock were owned by KKR TRS Holdings, Inc. and LB I Group, respectively.

17. 401(k) Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. While the Company may elect to match employee contributions, no such matching contributions have been made through December 31, 2006.

18. Segment and Other Information

Management has determined that the Company operates in one business segment which is the development and commercialization of pharmaceutical products.

The following table presents a summary of product sales (in thousands):

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
			(Unaudited)	
Xyrem	$ 11,200	$ 29,049	$ 6,153	$ 8,624
Antizol	6,782	12,813	3,131	2,636
Cystadane	814	1,437	487	365
Total	$ 18,796	$ 43,299	$ 9,771	$ 11,625

The Company had no product sales or other revenues prior to the acquisition of Orphan Medical in June 2005. In March 2007, the Company sold its rights to Cystadane. See Note 19 for a further discussion of this transaction.

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table presents a summary of total revenues attributed to domestic and foreign sources (in thousands):

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
			(Unaudited)	
United States	$ 18,305	$ 42,326	$ 9,350	$11,513
Europe	3,020	1,757	231	2,524
All other	117	773	256	51
Total	$ 21,442	$ 44,856	$ 9,837	$14,088

The following table presents a summary of revenues from significant customers as a percentage of the Company's total revenues:

	Year Ended December 31,		Three Months Ended March 31,	
	2005	2006	2006	2007
			(Unaudited)	
Express Scripts	51%	65%	63%	61%
Cardinal Health	*	12%	15%	*
Amerisource Bergen	15%	*	*	*
UCB	12%	*	*	17%
McKesson Corporation	*	*	11%	*

* Less than 10% of the Company's total revenues.

19. Subsequent Events

Product License Agreement

In January 2007, the Company entered into a product license agreement with Solvay Pharmaceuticals, Inc. ("Solvay") for the rights to market Luvox CR and Luvox in the United States. The Company made a $2.0 million payment upon execution of the agreement, and agreed to make additional payments of up to $138.0 million upon achievement of development and commercial milestones. Up to $41.0 million of these milestone payments are payable at or prior to commercial launch of Luvox CR and $2.0 million of these milestone payments are payable if the Company commercially launches Luvox. As the initial $2.0 million payment has no alternative future use, the Company has expensed this amount as research and development expense in the three months ended March 31, 2007. In addition, the Company is required to pay Solvay royalties at specified rates on commercial sales.

Facilities Lease

In March 2007, the Company entered into a lease agreement for approximately 13,000 square feet of office space in Palo Alto, California. The annual lease payments for this space are approximately $460,000. The fixed term expires in August 2008, after which the Company may extend the term for up to six months subject to certain conditions.

Divestiture of Cystadane

In March 2007, the Company signed a Product Acquisition Agreement with an unrelated third party under which that third party purchased the Company's rights to Cystadane for cash consideration of $9.0 million, along

with its associated product registrations, commercial inventory and trademarks. The unrelated third party was also assigned certain contracts related to Cystadane, and assumed substantially all liabilities associated with Cystadane arising subsequent to March 1, 2007. The Company and the third party concurrently entered into a Transition Services Agreement under which the Company has agreed to perform substantially all of the ongoing services necessary for the sale and promotion of Cystadane on behalf of the third party for up to 90 days following the date of the transaction, subject to certain conditions. The Company recorded a gain of approximately $5.1 million on the sale of the rights to Cystadane in the first quarter of 2007.

Legal Proceedings

In April 2006, the Company and its subsidiary Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. In April 2006, a physician who was a speaker for Orphan Medical, and for a short time for the Company, was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for the Company, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce.

The Company and Orphan Medical have been in discussions regarding a possible settlement with the United States, acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services, relating to this matter. If the Company completes a settlement on the terms that the Company is currently discussing, Orphan Medical would plead guilty to one felony count of introducing a misbranded drug into interstate commerce and would pay a total of approximately $20.5 million in civil and criminal payments over the next several years in connection with this matter, with approximately $1.5 million payable in 2007, $2.0 million payable in 2008, $2.5 million payable in 2009, $3.0 million payable in 2010, $3.0 million payable in 2011 and $8.5 million payable in 2012. The Company would guarantee payment of these amounts by Orphan Medical.

If the Company completes a settlement on the terms that the Company is currently discussing, the U.S. Attorney has indicated that the Company would not be prosecuted. As part of the settlement, the Company would enter into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which would require the Company to maintain a comprehensive compliance program. The Company would have additional ongoing compliance-related operating costs related to this compliance program, which the Company does not expect to be material, as a result of the corporate integrity agreement.

The settlement terms described above are subject to the negotiation and execution of definitive agreements. Even if the Company reaches a settlement agreement with the U.S. Attorney's Office, the Company might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states' attorneys general with respect to activities covered by the settlement. If the Company does not reach a settlement, the Company could be required to spend significant amounts to defend itself and Orphan Medical, and the investigation could involve criminal charges, as well as criminal and/ or civil fines and penalties, against the Company, Orphan Medical, or both. If the Company is unable to complete the settlement described above, the Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome, and such an outcome could have a material adverse effect on the Company's financial position, liquidity and results of operations. Therefore, in accordance with SFAS 5, the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

Report of Independent Auditors

The Board of Directors and Stockholders
Jazz Pharmaceuticals, Inc.

We have audited the accompanying statements of operations and cash flows of Orphan Medical, Inc. for the period from January 1, 2005 to June 24, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of the internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Orphan Medical, Inc. for the period January 1, 2005 to June 24, 2005, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Palo Alto, California
March 6, 2007

ORPHAN MEDICAL, INC.

STATEMENT OF OPERATIONS
(In thousands, except per share amounts)

	Period from January 1, 2005 to June 24, 2005
Revenues:	
Product sales, net	$ 12,966
Royalties, net	71
Contract revenues	1,806
Total revenues	14,843
Operating expenses:	
Cost of product sales	1,975
Research and development	4,212
Selling, general and administrative	12,155
Total operating expenses	18,342
Loss from operations	(3,499)
Interest income	111
Interest expense	(13)
Net loss	(3,401)
Less: Preferred stock dividends	491
Loss attributable to common stockholders	$ (3,892)

The accompanying notes are an integral part of these financial statements.

ORPHAN MEDICAL, INC.

STATEMENT OF CASH FLOWS
(In thousands)

	Period from January 1, 2005 to June 24, 2005
Operating activities	
Net loss	$ (3,401)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation	196
Stock compensation expense for non-employee	25
Loss on disposal of property and equipment	37
Changes in assets and liabilities:	
Prepaid expenses and other current assets	(2,074)
Accounts receivable	(1,045)
Inventories	115
Accounts payable	(1,241)
Accrued liabilities	(510)
Deferred revenue	(806)
Net cash used in operating activities	(8,704)
Investing activities	
Purchases of property and equipment	(5)
Restricted cash	(1)
Net cash used in investing activities	(6)
Financing activities	
Proceeds from employee stock purchase plan	16
Proceeds from exercise of stock options	164
Payments on capital lease obligations	(9)
Payments on premium finance note	(683)
Preferred stock dividend payments	(388)
Net cash used in financing activities	(900)
Net decrease in cash and cash equivalents	(9,610)
Cash and cash equivalents, at beginning of period	12,709
Cash and cash equivalents, at end of period	$ 3,099
Schedule of non-cash financing activities:	
Issuance of preferred stock dividends	$ 491
Supplemental disclosure of cash flow information:	
Cash paid for interest	$ 4

The accompanying notes are an integral part of these financial statements.

ORPHAN MEDICAL, INC.

NOTES TO FINANCIAL STATEMENTS

1. Description of Business

Orphan Medical, Inc. (the "Company") acquires, develops, and markets products of high medical value intended to treat sleep disorders, pain and other central nervous system disorders that are addressed by physician specialists. On June 24, 2005, Jazz Pharmaceuticals, Inc. acquired the Company for cash consideration (net of cash acquired) of $145.4 million plus direct acquisition costs of $750,000. At the time of acquisition, the Company had three pharmaceutical products approved for marketing by the U.S. Food and Drug Administration ("FDA").

2. Summary of Significant Accounting Policies

Basis of Presentation

The Statement of Operations and Statement of Cash Flows have been prepared in accordance with U.S. generally accepted accounting principles. These statements were prepared for the purpose of complying with Regulation S-X, Rule 3.05 of the Securities and Exchange Commission and are being included in the Form S-1 of Jazz Pharmaceuticals, Inc.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Revenue Recognition

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. In evaluating arrangements with multiple elements the Company considers whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on their respective fair values when there is reliable evidence of fair value for all elements of the arrangement. If there is no evidence of fair value for all the elements of the arrangement consideration is allocated based on the residual value method for the delivered elements. Under the residual method, the amount of revenues allocated to the delivered elements equals the total arrangement consideration less the aggregate fair value of any undelivered elements. The applicable revenue recognition criteria are applied to each of the separate units. Payments received in advance of work performed are recorded as deferred revenues and recognized when earned.

Product Sales, Net

Revenues from sales of Xyrem within the United States are recognized upon transfer of title, which occurs when the Company's specialty pharmaceutical distributor removes product from the Company's consigned inventory location at its facility for shipment to a patient. Antizol is and, prior to our sale of the Company's

rights, and Cystadane was shipped to the Company's wholesaler customers in the United States with free on board destination shipping terms, and the Company recognizes revenues when delivery occurs. The Company's international sales often have customer acceptance clauses and therefore the Company recognizes revenues when it is notified of acceptance or the time to inspect and reject the shipment has lapsed. When sales to international customers do not have acceptance clauses, the Company recognizes revenues when title transfers, which is generally when the product leaves the Company's logistics provider's facilities.

Revenues from sales of products within the United States are recorded net of estimated allowances for prompt payment discounts, wholesaler and speciality distributor fees, government chargebacks and rebates. Significant judgment is inherent in the selection of assumptions and in the interpretation of historical experience, as well as the identification of external and internal factors affecting the estimates. Because Xyrem is sold to one distributor in the United States, allowances and adjustments to estimates for allowances have not historically been material.

Royalties, Net

The Company receives royalties from third parties based on sales of its products under out-licensing and distributor arrangements. For those arrangements where royalties are reasonably estimable, the Company recognizes revenues based on estimates of royalties earned during the applicable period, and adjusts for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenues upon receipt of royalty statements from the licensee or distributor.

Contract Revenues

Nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where the Company has continuing performance obligations, nonrefundable fees are deferred and recognized ratably over the performance period. The Company recognizes at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company or its licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when performance obligations are completed.

Cost of Product Sales

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability insurance, FDA user fees, freight, shipping, handling and storage costs. The Company's product exchange policy for Antizol and Cystadane allows customers to return expired product for exchange up to six months before or after the product's expiration date. These expiration date returns are exchanged for replacement product, and the estimated cost of such exchanges is included in cost of product sales. Amounts accrued for replacement product have not been material.

Research and Development

The Company's research and development expenses consist of expenses incurred in identifying, developing and testing its product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing our clinical trials, clinical trial costs paid to sites and investigators' salaries, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical

studies, fees paid to third parties for development candidates, allocated expenses, such as facilities and information technology that support the Company's research and development activities and related personnel expenses. For products that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. Research and development costs are expensed as incurred, including payments made under the Company's license agreements. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the trial and therefore not included in inventory.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The Company has a history of losses and therefore has made no provision for income taxes.

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, ("APB 25") and complies with the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, ("SFAS 123") as amended by Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123 ("SFAS 148")*. Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of the Company's common stock over the exercise price of the option on the date of grant. No stock-based compensation expense was recorded under APB 25 during the period January 1, 2005 to June 24, 2005. The following table illustrates the effect on net loss and loss per common share if the Company had applied the fair value recognition provisions of SFAS 123 as amended by SFAS 148 to stock-based employee compensation.

	Period from January 1, 2005 to June 24, 2005
Loss attributable to common stockholders, as reported	$ (3,892)
Add: Employee stock-based compensation using the intrinsic value method	—
Deduct: Total employee stock compensation calculated using the fair-value method	(1,240)
Pro forma loss attributable to common stockholders	$ (5,132)

ORPHAN MEDICAL, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The Company estimated the fair value of the stock options using the Black-Scholes method in accordance with SFAS No. 123 as amended by SFAS 148. The fair value of the stock options was estimated at the grant date with the following assumptions:

	Period from January 1, 2005 to June 24, 2005
Expected dividend yield	0%
Expected stock price volatility	65%
Risk-free interest rate	4%
Expected life of option (in years)	8

3. Product License

In October 2003, the Company entered into an agreement with Celltech Pharmaceuticals, Inc., which was subsequently acquired by UCB Pharma Limited ("UCB"), pursuant to which the Company has licensed to UCB all European sales and marketing rights for Xyrem for the treatment of narcolepsy. The Company received $2.5 million upon execution of the agreement which is being amortized on a straight-line basis as contract revenues through September 2005, the expected regulatory approval period. The Company recognized $806,000 of contract revenues in the period from January 1, 2005 to June 24, 2005 related to the upfront payment. UCB also made two $1.0 million milestone payments related to the filing of an application for marketing approval for Xyrem for the treatment of cataplexy in patients with narcolepsy with the European Agency for the Evaluation of Medicinal Products and to the Company's delivery to UCB of a supplemental new drug application package for Xyrem for the treatment the excessive daytime sleepiness in patients with narcolepsy. These payments were recognized as revenues upon the achievement of the milestones in March 2004 and January 2005, respectively.

4. Segment and Other Information

Management has determined that the Company operates in one business segment, which is the development and commercialization of pharmaceutical products.

The following table presents a summary of product sales (in thousands):

	Period from January 1, 2005 to June 24, 2005
Xyrem	$ 8,034
Antizol	4,267
Cystadane	665
Total	$ 12,966

ORPHAN MEDICAL, INC.

NOTES TO FINANCIAL STATEMENTS—(Continued)

The following table presents a summary of total revenues attributed to domestic and foreign sources (in thousands):

	Period from January 1, 2005 to June 24, 2005
United States	$ 12,464
Europe	2,107
All other	272
Total	$ 14,843

The following table presents a summary of revenues from significant customers as a percentage of the Company's total revenues:

	Period from January 1, 2005 to June 24, 2005
ExpressScripts	54%
UCB	12%
Cardinal Health	11%
Amerisource Bergen	10%

5. Subsequent Events

Legal Proceedings

In April 2006, a physician who was a speaker for the Company was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment alleges that the physician engaged in a scheme with the Company's sales representatives and other Company employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. Also in April 2006, the Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, issued to the Company and Jazz Pharmaceuticals subpoenas for documents relating to Xyrem. The Company is cooperating with this investigation and has provided documents to the U.S. Attorney's Office. There have been discussions with the U.S. Attorney's Office regarding the possible settlement of any potential government claims. It is currently unknown if any such settlement will be reached on reasonable terms, or at all. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any fines or penalties that might result from an adverse outcome. Therefore, in accordance with Statement of Financial Accounting Standard No. 5, *Accounting for Contingencies* ("SFAS 5"), the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

On April 10, 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against the Company and former officers of the Company in the U.S. District Court for the District of Minnesota. The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by the Company in connection with the solicitation of proxies to be voted at the special meeting of Company stockholders held on June 22, 2005 for the purpose of considering and voting upon a proposal to adopt the definitive merger agreement pursuant to which the Company was acquired by Jazz Pharmaceuticals. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys' fees and other disbursements, as well as

unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the U.S. District Court for the District of Minnesota. On February 16, 2007, the U.S. District Court for the District of Minnesota granted the defendants' motion to dismiss the complaint, but granted the plaintiff a one-month leave to amend the plaintiff's complaint. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome. Therefore, in accordance with SFAS 5 the Company has not recorded an associated liability. The Company will recognize a liability, if any, when it has an adequate basis to estimate any probable exposure, if any.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the NASD filing fee and the NASDAQ Global Market filing fee.

	Amount to be Paid
SEC registration fee	$ 5,508
NASD filing fee	18,400
NASDAQ Global Market initial listing fee	120,000
Blue sky qualification fees and expenses	15,000
Printing and engraving expenses	125,000
Legal fees and expenses	950,000
Accounting fees and expenses	950,000
Transfer agent and registrar fees and expenses	20,000
Miscellaneous expenses	96,092
Total	$ 2,300,000

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses that such officer or director has actually and reasonably incurred. Our fourth amended and restated certificate of incorporation and our amended and restated bylaws, each of which will become effective upon the closing of this offering, provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our fourth amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and officers that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding or alternative dispute resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of Jazz Pharmaceuticals or any of its affiliated enterprises, provided that such person's conduct did not constitute a breach of his or her duty of loyalty to us or our stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnity agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise. Messrs. Clammer, Michelson, Momtazee and Patel are further insured by liability insurance that has been purchased by Kohlberg Kravis Roberts & Co. L.P. on their behalf for any excess liabilities that are not covered by our liability insurance. Mr. Colella is insured by liability insurance purchased on his behalf by, and indemnified pursuant to the governing agreements of, Versant Ventures for his service on our board of directors.

We plan to enter into an underwriting agreement that provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities sold by us since our inception through March 31, 2007.

(1) Since our inception through March 31, 2007, we had granted options under our 2003 Equity Incentive Plan to purchase 1,980,649 shares of common stock to employees and directors, having exercise prices ranging from $1.11 to $45.27 per share. Of these, options to purchase 46,720 shares of common stock had been exercised for aggregate consideration of $125,333, at exercise prices ranging from $1.11 to $16.60 per share. As of March 31, 2007, we had cancelled options to purchase 71,399 shares of common stock.

(2) On March 20, 2003, we issued and sold an aggregate of 357,819 shares of common stock to two of our executive officers for aggregate consideration of $9,108.

(3) On March 31, 2003, we issued and sold 73,642 shares of common stock to one of our executive officers for aggregate consideration of $1,874.50.

(4) On April 18, 2003, we issued and sold 27,107 shares of common stock to one of our executive officers for aggregate consideration of $1,500.

(5) On April 23, 2003, we issued and sold 29,818 shares of common stock to one of our executive officers for aggregate consideration of $3,300.

(6) On April 30, 2003, we issued and sold an aggregate of 194,268 shares of Series A preferred stock to a total of six accredited investors for aggregate consideration of $2,150,000.

(7) On August 29, 2003, we issued and sold an aggregate of 451,792 shares of Series A preferred stock to a total of five accredited investors for aggregate consideration of $5,000,000.

(8) On October 30, 2003, we issued and sold 59,637 shares of common stock to one of our executive officers for aggregate consideration of $66,000.

(9) On January 9, 2004, we issued and sold an aggregate of 21,008 shares of common stock to one of our executive officers for aggregate consideration of $23,250.

(10) On January 14, 2004, we issued and sold an aggregate of 709,317 shares of Series A preferred stock to a total of five accredited investors for aggregate consideration of $7,850,000.

(11) On February 18, 2004, we issued and sold an aggregate of 1,563,829 shares of Series B preferred stock to a total of thirty-one accredited investors for aggregate consideration of $23,599,999.74.

(12) On February 18, 2004, we issued and sold an aggregate of 1,722,883 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of $25,999,999.83.

(13) On April 6, 2004, we issued and sold an aggregate of 26,505 shares of Series B preferred stock to a total of two accredited investors for aggregate consideration of $399,999.79.

(14) On September 24, 2004, we issued and sold an aggregate of 13,252 shares of common stock to one of our directors for aggregate consideration of $200,000.58.

(15) On June 20, 2005, we issued and sold an aggregate of 3,180,714 shares of Series B preferred stock to a total of thirty-four accredited investors for aggregate consideration of $47,999,997.69.

(16) On June 20, 2005, we issued and sold an aggregate of 3,445,768 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of $52,000,001.02.

(17) On June 24, 2005, in connection with the issuance of our senior secured notes in the aggregate principal amount of $80,000,000, we issued and sold warrants to purchase an aggregate of 785,728 shares of Series BB preferred stock to a total of eight accredited investors. Pursuant to the terms of

the agreement governing the issuance of the senior secured notes and warrants, the aggregate consideration allocated to the warrants was $5,360,000.00.

(18) On January 26, 2006, we issued and sold an aggregate of 1,113,245 shares of Series B preferred stock to a total of thirty-two accredited investors for aggregate consideration of $16,799,996.53.

(19) On January 26, 2006, we issued and sold an aggregate of 1,206,019 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of $18,200,000.56.

(20) On December 14, 2006, we issued and sold an aggregate of 2,067,462 shares of Series B preferred stock to a total of thirty-two institutional and accredited investors for aggregate consideration of $31,199,983.44.

(21) On December 14, 2006, we issued and sold an aggregate of 2,239,749 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of $33,799,997.74.

The offers, sales and issuances of the securities described in Item 15(1) were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were our employees or directors and received the securities under our 2003 Equity Incentive Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment or business relationships, to information about us.

The offers, sales, and issuances of the securities described in Items 15(2) through 15(21) were exempt from registration under the Securities Act under Section 4(2) of the Securities Act and Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description of Document
1.1*	Form of Underwriting Agreement.
2.1*	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.
3.1*	Third Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.2*	Form of Fourth Amended and Restated Certificate of Incorporation of the Registrant to be effective upon the closing of this offering.
3.3*	Amended and Restated Bylaws of the Registrant, currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant to be effective upon the closing of this offering.
4.1	Reference is made to exhibits 3.1 through 3.4.
4.2*	Specimen Common Stock Certificate.

Exhibit Number	Description of Document
4.3.1+*	Second Amended and Restated Investor Rights Agreement, dated as of June 24, 2005, by and between the Registrant and the other parties named therein.
4.3.2+*	Form of Third Amended and Restated Investor Rights Agreement, by and between the Registrant and the other parties named therein, to be effective upon the closing of this offering.
4.4*	Senior Secured Note and Warrant Purchase Agreement, dated as of June 24, 2005, by and among the Registrant, Twist Merger Sub, Inc. and the Purchasers.
4.5*	Form of Senior Secured Note of the Registrant.
4.6*	Form of Series BB Preferred Stock Warrant of the Registrant.
5.1*	Opinion of Cooley Godward Kronish LLP.
10.1+*	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.2+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce Cozadd.
10.3+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel Saks.
10.4+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert Myers.
10.5+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew Fust.
10.6+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol Gamble.
10.7+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne Wissel.
10.8+*	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.
10.9+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce Cozadd.
10.10+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce Cozadd.
10.11+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.12+*	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.13+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel Saks.
10.14+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel Saks.
10.15+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel Saks.
10.16+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert Myers.
10.17+*	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert Myers.

Exhibit Number	Description of Document
10.18+*	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert Myers.
10.19+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew Fust.
10.20+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol Gamble.
10.21+*	2003 Equity Incentive Plan, as amended.
10.22+*	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.
10.23+*	2007 Equity Incentive Plan.
10.24+*	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.
10.25+*	2007 Non-Employee Directors Stock Option Plan.
10.26+*	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.
10.27+*	2007 Employee Stock Purchase Plan.
10.28+*	Form of 2007 Employee Stock Purchase Plan Offering Document.
10.29+*	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.
10.30#	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.
10.31*	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32*	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.
10.33#*	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.34#*	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.35#*	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.36#*	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.37*	Xyrem Supply Agreement, dated as of June 30, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.38*	Letter Amendment No. 1, dated as of November 9, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.39*	Amendment No. 2 to the Xyrem Supply Agreement, dated as of August 19, 2002, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.40*	Amendment No. 3 to the Xyrem Supply Agreement, dated as of March 21, 2005, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.41#	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.

Exhibit Number	Description of Document
10.42#	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.43*	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.44*	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.45*	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.46#	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.47#*	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.48#*	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.
10.49#	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.
10.50#	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.51#*	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.52*	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.53*	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
10.54*	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.
10.55+*	Directors Deferred Compensation Plan.
10.56+*	Non-Employee Director Compensation Arrangements.
21.1*	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Auditors.
23.3*	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see page II-10 to the Registration Statement on Form S-1 (File No. 333-141164) filed with the SEC on March 9, 2007).
24.2*	Power of Attorney of Jaimin R. Patel.

* Previously filed.
\+ Indicates management contract or compensatory plan.
\# Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(b) Financial Statement Schedules. The following financial statement schedule is included herewith:

Schedule II

Valuation and Qualifying Accounts
(In thousands)

	Balance at beginning of period	Additions(3)	Additions charged to costs and expenses(4)	Deductions	Balance at end of period
For the year ended December 31, 2006					
Allowance for doubtful accounts(1)	$ 25	$ —	$ 28	$ (3)	$ 50
Allowance for sales discounts(1)	71	—	880	(857)	94
Allowance for chargebacks(1)	26	—	212	(233)	5
Allowance for customer rebates(1)	—	—	44	(26)	18
Allowance for wholesaler fees(1)	153	—	203	(325)	31
Allowance for government rebates(2)	88	—	229	(254)	63
For the year ended December 31, 2005					
Allowance for doubtful accounts(1)	$ —	$ 25	$ 14	$ (14)	$ 25
Allowance for sales discounts(1)	—	62	381	(372)	71
Allowance for chargebacks(1)	—	25	57	(56)	26
Allowance for customer rebates(1)	—	—	—	—	—
Allowance for wholesaler fees(2)	—	134	64	(45)	153
Allowance for government rebates(2)	—	115	135	(162)	88
For the year ended December 31, 2004					
Allowance for doubtful accounts	$ —	$ —	$ —	$ —	$ —
Allowance for sales discounts	—	—	—	—	—
Allowance for chargebacks	—	—	—	—	—
Allowance for customer rebates	—	—	—	—	—
Allowance for wholesaler fees	—	—	—	—	—
Allowance for government rebates	—	—	—	—	—

Notes
(1) shown as a reduction of accounts receivable
(2) included in accrued liabilities
(3) amounts represent the liabilities assumed as a result of the acquisition of Orphan Medical, Inc. on June 24, 2005
(4) all charges except doubtful accounts are reflected as a reduction of revenue

All other schedules are omitted because they are inapplicable or the requested information is shown in the consolidated financial statements of the registrant or related notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred

or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 5 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on the 31st day of May, 2007.

JAZZ PHARMACEUTICALS, INC.

By: /s/ Carol A. Gamble

Carol A. Gamble
Senior Vice President, General Counsel and Corporate Secretary

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Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 5 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
*	Chief Executive Officer and Member of the Board of Directors (*Principal Executive Officer*)	May 31, 2007
Samuel R. Saks, M.D.		
*	Senior Vice President and Chief Financial Officer (*Principal Accounting and Financial Officer*)	May 31, 2007
Matthew K. Fust		
*	Director	May 31, 2007
Adam H. Clammer		
*	Director	May 31, 2007
Samuel D. Colella		
*	Director	May 31, 2007
Bruce C. Cozadd		
*	Director	May 31, 2007
Bryan C. Cressey		
*	Director	May 31, 2007
Michael W. Michelson		
*	Director	May 31, 2007
James C. Momtazee		
*	Director	May 31, 2007
Kenneth W. O'Keefe		
*	Director	May 31, 2007
Jaimin R. Patel		
*	Director	May 31, 2007
Alan M. Sebulsky		
*	Director	May 31, 2007
James B. Tananbaum, M.D.		

*By: /s/ CAROL A. GAMBLE
Carol A. Gamble
Attorney-in-Fact

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EXHIBIT INDEX

Exhibit Number	Description of Document
1.1*	Form of Underwriting Agreement.
2.1*	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.
3.1*	Third Amended and Restated Certificate of Incorporation of the Registrant, currently in effect.
3.2*	Form of Fourth Amended and Restated Certificate of Incorporation of the Registrant to be effective upon the closing of this offering.
3.3*	Amended and Restated Bylaws of the Registrant, currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant to be effective upon the closing of this offering.
4.1	Reference is made to exhibits 3.1 through 3.4.
4.2*	Specimen Common Stock Certificate.
4.3.1+*	Second Amended and Restated Investor Rights Agreement, dated as of June 24, 2005, by and between the Registrant and the other parties named therein.
4.3.2+*	Form of Third Amended and Restated Investor Rights Agreement, by and between the Registrant and the other parties named therein, to be effective upon the closing of this offering.
4.4*	Senior Secured Note and Warrant Purchase Agreement, dated as of June 24, 2005, by and among the Registrant, Twist Merger Sub, Inc. and the Purchasers.
4.5*	Form of Senior Secured Note of the Registrant.
4.6*	Form of Series BB Preferred Stock Warrant of the Registrant.
5.1*	Opinion of Cooley Godward Kronish LLP.
10.1+*	Form of Indemnification Agreement between the Registrant and its officers and directors.
10.2+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce Cozadd.
10.3+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel Saks.
10.4+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert Myers.
10.5+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew Fust.
10.6+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol Gamble.
10.7+*	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne Wissel.
10.8+*	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.
10.9+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce Cozadd.
10.10+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce Cozadd.
10.11+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.
10.12+*	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce Cozadd.

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Exhibit Number	Description of Document
10.13+*	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel Saks.
10.14+*	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel Saks.
10.15+*	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel Saks.
10.16+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert Myers.
10.17+*	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert Myers.
10.18+*	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert Myers.
10.19+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew Fust.
10.20+*	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol Gamble.
10.21+*	2003 Equity Incentive Plan, as amended.
10.22+*	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.
10.23+*	2007 Equity Incentive Plan.
10.24+*	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.
10.25+*	2007 Non-Employee Directors Stock Option Plan.
10.26+*	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.
10.27+*	2007 Employee Stock Purchase Plan.
10.28+*	Form of 2007 Employee Stock Purchase Plan Offering Document.
10.29+*	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.
10.30#	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.
10.31*	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.
10.32*	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.
10.33#*	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.34#*	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.35#*	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.36#*	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.
10.37*	Xyrem Supply Agreement, dated as of June 30, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.
10.38*	Letter Amendment No. 1, dated as of November 9, 2000, by and between Orphan Medical, Inc. and Catalytica Pharmaceuticals, Inc.

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Exhibit Number	Description of Document
10.39*	Amendment No. 2 to the Xyrem Supply Agreement, dated as of August 19, 2002, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.40*	Amendment No. 3 to the Xyrem Supply Agreement, dated as of March 21, 2005, by and between Orphan Medical, Inc. and DSM Pharmaceuticals, Inc. (formerly Catalytica Pharmaceuticals, Inc.).
10.41#	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.
10.42#	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.43*	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.44*	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.
10.45*	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc and Elan Pharma International Limited.
10.46#	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.47#*	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc and Elan Corporation plc.
10.48#*	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.
10.49#	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.
10.50#	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.51#*	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.
10.52*	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.
10.53*	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.
10.54*	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.
10.55+*	Directors Deferred Compensation Plan.
10.56+*	Non-Employee Director Compensation Arrangements.
21.1*	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Auditors.
23.3*	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see page II-10 to the Registration Statement on Form S-1 (File No. 333-141164) filed with the SEC on March 9, 2007).
24.2*	Power of Attorney of Jaimin R. Patel.

* Previously filed.
\+ Indicates management contract or compensatory plan.
\# Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (the "Agreement") is made as of this 4th day of October, 2004 by and between Glaxo Group Limited, a company incorporated under the laws of England and Wales with offices at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN, UK ("GGL"), SmithKline Beecham Corporation, doing business as GlaxoSmithKline, a company incorporated under the laws of the Commonwealth of Pennsylvania with offices at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19101 U.S.A. ("SB") (GGL and SB are collectively referred to in this Agreement as "GSK"), and Jazz Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware with offices at 3180 Porter Drive, Palo Alto, California 94304, U.S. ("Jazz Pharmaceuticals"). GSK and Jazz Pharmaceuticals are referred to herein on occasion separately as a "Party" or together as the "Parties".

RECITALS

WHEREAS, GSK owns intellectual property rights covering a type IIa sodium channel antagonist compound, designated by GSK as GW273293, and other related compounds (hereinafter defined together as the "Compounds");

WHEREAS, Jazz Pharmaceuticals desires to purchase, and GSK desires to sell, the rights to the Compounds and certain assets relating to GW273293 including the intellectual property rights covering the Compounds; and

WHEREAS, Jazz Pharmaceuticals desires to **[*]** under the intellectual property rights covering the Compounds for **[*]**, as further provided herein.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1—DEFINITIONS; INTERPRETATION

1.1 Definitions. The following terms will have the following meanings in this Agreement:

1.1.1. "Additional Consideration Payment" has the meaning ascribed to it in Section 3.5.

1.1.2. "Additional Consideration Payment Statement" has the meaning ascribed to it in Section 4.2.

1.1.3. "Affiliate" of a Party means any corporation or other business entity which is directly or indirectly controlling, controlled by, or under common control with such Party for so long as such control exists. For purposes of this definition, "control" means the direct or indirect ownership of at least fifty percent (50%) of the

outstanding shares or voting interest in such corporation or other entity having the power to vote or direct the affairs of the entity. If the laws of the jurisdiction in which such entity operates prohibit ownership by a Party of at least fifty percent (50%), "control" will be deemed to exist at the maximum level of ownership allowed by such jurisdiction. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals, such as financial institutions, venture capital funds and private equity investors, will not be its "Affiliates" for purposes of this Agreement.

1.1.4. "Agreement" means this Asset Purchase Agreement, together with the Schedules hereto, and any instrument amending this Agreement as referred to in Section 12.7. The expressions "Article" and "Section" followed by a number mean and refer to the specified Article or Section of this Agreement.

1.1.5. "Asset Transfer Period" has the meaning ascribed to it in Section 2.4.

1.1.6. "Business Day" means any day other than Saturday or Sunday on which the New York Stock Exchange is open for business. If not designated as a "Business Day", a "day" shall include Saturdays, Sundays and holidays.

1.1.7. "Closing Date" means the date provided for in Section 5.1.

1.1.8. "Combination Product" means a product that is a pharmaceutical preparation for human use incorporating two or more therapeutically active ingredients, including a Compound, as active ingredients. Notwithstanding the foregoing, additives and excipients, including, but not limited to, drug delivery vehicles and formulations, adjuvants, carriers, bulking, stabilizing and flavoring agents, taste-masking agents, surfactants, antimicrobial agents and antioxidants will not be deemed to be "therapeutically active ingredients," and their presence will not be deemed to create a Combination Product under this Section 1.1.8.

1.1.9. "Compound(s)" means GSK's type IIa sodium channel antagonist compound designed by GSK as compound GW273293, any compound covered by the Patents, and all derivatives, and salts of such Compounds to the extent covered by the Patents.

1.1.10. "Confidential Information" has the meaning ascribed to it in Section 11.1.

1.1.11. "Diligent Efforts" means the carrying out of obligations in a sustained manner consistent with the efforts a Party devotes to a product of similar market potential, and profit potential resulting from its own research efforts, with the objective of launching a Product. Diligent Efforts requires that: (i) the Party promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (ii) the Party set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (iii) the Party consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

1.1.12. "Effective Date" means the date of this Agreement as set forth above, which shall be the same date as the Closing Date.

1.1.13. “EMEA” means the European Medicines Evaluation Agency (European Medicines Agency) and the Committee for Proprietary Medicinal Products (Committee for Medicinal Products for Human Use) or any successor agency thereof.

1.1.14. “Europe” or the “EU” means the countries comprising the European Union and includes any of the following twenty-five (25) countries that are members of the European Union as of the Effective Date, and any other countries that subsequently become part of the European Union as of the date such membership becomes effective, including, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia.

1.1.15. “FDA” means the U.S. Food and Drug Administration and any successor agency thereof.

1.1.16. “First Commercial Sale” of a Product means the first invoiced commercial sale by Jazz Pharmaceuticals, its Affiliates or sublicensees (excluding, however, sales made by one such entity to another such entity) to a Third Party for commercial purposes in a country after Marketing Approval to market such Product in such country has been granted by the governing health regulatory authority of such country.

1.1.17. “Grantback License” has the meaning ascribed to it in Section 6.1.

1.1.18. “Gross Sales” has the meaning ascribed to it in Section 1.1.28.

1.1.19. “Gross Selling Price” means the gross price at which a product is sold to a Third Party before discounts, deductions, credits, taxes, and allowances.

1.1.20. “GW273293” means GSK’s type IIa sodium channel antagonist compound with the chemical structure shown in Schedule 1.1.20.

1.1.21. “Know-How” means technical and other information that is not subject to published patent rights and that is not in the public domain, including, but not limited to, information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, assays, research, procedures, designs for experiments and tests and results of experimentation and testing, including results of research and development, manufacturing processes specifically related to GW273293, specifications and techniques, chemical, pharmacological, toxicological, clinical, analytical, and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries relating to the quantities of GW273293 being transferred hereunder, and information contained in submissions to and information from regulatory authorities. Know-How includes documents containing Know-How. Except as set forth above with respect to manufacturing process specifically related to GW273293, Know-How does not include GSK Know-How relating to manufacturing processes.

1.1.22. “Licensed GSK Patents” means those GSK patents set forth in Schedule 2.6, attached hereto and incorporated herein.

1.1.23. “Marketing Approval” means, in any country, all approvals, licenses, registrations or authorizations, (including, in Europe and Canada only, governmental pricing approvals and governmental formulary acceptance based on pricing approval (but excluding formulary acceptance of private parties)), of any federal regulatory agency, department, bureau or other governmental entity, necessary for the sale of the Product. Marketing Approval in a country shall be deemed to occur upon first receipt of notice from the FDA, EMEA or similar agency in such country that sale of a Product in such country has been approved, including governmental pricing approval and governmental formulary acceptance based on pricing approval in Europe and Canada. Marketing Approval in Europe shall include the approval of any Central Marketing Authorization that is filed through the centralized procedure for the EU and approved by the European Commission. If a Central Marketing Authorization is filed through the centralized procedure for the EU and approved by the European Commission, Marketing Approval for the EU shall be deemed to have occurred when pricing approval is received in at least one country in the EU. In the countries of Europe and in Canada, “Marketing Approval” shall not be deemed to occur until pricing or formulary approval is obtained. Marketing Approval shall be deemed to have occurred in such country where government approval of pricing has not been obtained if, at any time, Jazz Pharmaceuticals, its Affiliates or sublicensees makes the First Commercial Sale of Product in the country without obtaining pricing approval, with the date of MAA approval deemed to have occurred on the date of the First Commercial Sale of the Product in the country.

1.1.24. “Marketing Approval Application” or “MAA” shall mean a New Drug Application (“NDA”) (as defined in 21 C.F.R. § 314.50 *et. seq*.), or a comparable filing for Marketing Approval in a country, in each case with respect to a Product in the Territory.

1.1.25. “Major Market Country” means any one of the U.S., the United Kingdom, France, Germany, Italy, Spain or Japan.

1.1.26. “Milestones” mean the events identified in Section 3.3.

1.1.27. “Milestone Payments” mean the payments to be made by Jazz Pharmaceuticals to GSK pursuant to Section 3.3.

1.1.28. “Net Sales” means the aggregate gross sales amount (“Gross Sales”) invoiced for Product, as applicable, in the countries of the Territory on which Additional Consideration Payments are due hereunder, by Jazz Pharmaceuticals, its Affiliates and sublicensees, to Third Parties,

(a) less the following deductions:

(i) trade, quantity and cash discounts and rebates allowed and taken by Jazz Pharmaceuticals (and its Affiliates and sublicensees);

(ii) any adjustments on account of price adjustments, billing errors, rejected goods, damaged goods and returns;

(iii) credits, charge-backs and prime vendor rebates, fees, reimbursements, and similar payments granted or given to wholesalers and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or health care organizations or other customers; and

(iv) rebates or other price reductions provided, based on sales by Jazz Pharmaceuticals (and its Affiliates and sublicensees) of Product, as applicable, to any governmental or regulatory authority in respect of any state or federal Medicare, Medicaid or similar programs; and

(b) less an amount equal to all freight, insurance and handling costs, import costs, duties, tariffs, taxes, excises and other governmental charges incurred and paid by Jazz Pharmaceuticals (and its Affiliates and sublicensees).

The foregoing deductions from Gross Sales will only be deducted once and only to the extent not otherwise deducted from Gross Sales. Net Sales shall not include any sales among Jazz Pharmaceuticals, its Affiliates and sublicensees.

1.1.29. "Patents" means all the GSK granted patents and pending applications covering the Compounds and the processes for making a Compound, or any formulation or use thereof in the Territory, including any patent term extensions, supplementary protection certificates, registrations, extensions, reissues, reexaminations or divisionals thereof, and including any granted patents arising from the pending applications, which are listed in attached Schedule 1.1.29.

1.1.30. "Phase I Clinical Trial" means clinical trials for the first introduction into humans of a Product, including small scale clinical studies conducted in normal volunteers and/or patients to obtain information on the Product's safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 C.F.R. 312.21(a).

1.1.31. "Phase II Clinical Trial" means a human clinical trial that is intended to initially evaluate the effectiveness of a Product in the targeted patient population for a particular indication or indications in human subjects with the disease or indication under study, as more fully defined in 21 C.F.R. 312.21(b).

1.1.32. "Phase III Clinical Trial" means a pivotal efficacy trial whose primary objective is to obtain a definitive evaluation of the therapeutic efficacy and safety of a Product in patients for the particular indication in question that is needed to evaluate the overall risk-benefit profile of a Product and to provide adequate basis for obtaining requisite Marketing Approval(s) and product labeling, as more fully defined in 21 C.F.R. (S) 312.21(c).

1.1.33. “Product” means any pharmaceutical product that includes a Compound as an active pharmaceutical ingredient. “Product” shall include Combination Products.

1.1.34. “Purchase Price” has the meaning ascribed to it in Section 3.1.

1.1.35. “Purchased Assets” means the following Assets to be acquired by Jazz Pharmaceuticals pursuant to this Agreement on the Closing Date:

(a) the Patents and information and hard-copy (i.e., non-electronic) records used by GSK’s Corporate Intellectual Property group in filing, prosecuting, reviving, maintaining, renewing, enforcing and defending the Patents, and file wrappers and hard-copy (i.e., non-electronic) correspondence with the patent office in all jurisdictions in which the Patents are pending or granted;

(b) data (including without limitation, all pharmacological, pre-clinical, clinical, analytical and quality control data), manufacturing data (including batch records and technical reports) for the quantities of GW273293 being transferred hereunder, results and material correspondence, and other documents relating to the Purchased Assets, all of which are listed on Schedule 1.1.35, all in electronic form;

(c) quantities of GW273293 set forth on Schedule 1.1.35(c), and, to the extent they exist, retained stability samples of GW273293 and tissue samples used in the toxicology work relating to GW273293; and

(d) any Know-How specifically relating to GW273293 developed, acquired or licensed by GSK prior to the Closing Date, as set forth in Schedule 1.1.35.

The Purchased Assets do not include laboratory notebooks or other specific information pertaining to proof of invention or reduction to practice of GW273293 or the inventions claimed in the Patents. Should Jazz Pharmaceuticals require access to such information for purposes of responding to a challenge to the validity or enforceability of the Patents, or in order to initiate or participate in an interference proceeding in the United States (or a similar proceeding elsewhere), or to assert the Patents affirmatively against Third Parties, then in each case GSK shall promptly make such information available at no charge upon the reasonable request of Jazz Pharmaceuticals.

1.1.36. “ROW” means all countries and territories of the world except the U.S. and Europe.

1.1.37. “Territory” means all countries and territories of the world.

1.1.38. “Third Party” means any Party other than GSK or Jazz Pharmaceuticals or each of their respective Affiliates.

1.1.39. "Time of Closing" means 10:00 A.M. (Pacific Daylight Time) on the Closing Date or such other time and date as the Parties will mutually agree in writing at which time the Parties are to deliver the closing documents described in Section 5.2.

1.1.40. "U.S." means the United States of America, including the Commonwealth of Puerto Rico and the U.S. Virgin Islands.

1.1.41. "Valid Claim" means a claim of an issued, unexpired Patent which has not been revoked, held to be invalid or unenforceable by a final judgment of a court or other government agency of competent jurisdiction from which no appeal can be or is taken within the time allowed for appeal and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

1.2 Interpretation. In this Agreement, words importing the singular number only will include the plural and vice versa, words importing a specific gender will include the other genders and references to persons will include corporations and one or more persons, their heirs, executors, administrators or assigns as the case may be. In addition, the division of this Agreement into Sections and the insertion of headings are for convenience of reference only and will not affect the interpretation hereof.

ARTICLE 2—PATENT ASSIGNMENT; POST-CLOSING ASSISTANCE; LICENSE GRANT

2.1 Assignment of Patents. On the Closing Date, and subject to the terms and conditions of this Agreement, GSK will sell, assign, convey, transfer and deliver to Jazz Pharmaceuticals, and Jazz Pharmaceuticals will purchase and accept from GSK, the entire ownership, right title and interest of GSK in and to the Purchased Assets. Within fifteen (15) Business Days of the Closing Date, GSK will authorize and request the Commissioner or Director of Patents and Trademarks of the United States to issue all U.S. patents that may issue in the future as a result of the Purchased Assets to Jazz Pharmaceuticals, its successors and assigns, in accordance with this Agreement.

2.2 Registration of Purchased Assets. GSK will cooperate with and reasonably assist Jazz Pharmaceuticals in relation to Jazz Pharmaceuticals' registration as the new owner of the Purchased Assets in the registers of the respective patent offices in the Territory. GSK will execute and deliver, or cause to be executed and delivered, at no cost to Jazz Pharmaceuticals, any and all documents reasonably requested by Jazz Pharmaceuticals that may be necessary, in accordance with the rules and regulations of the various patent offices worldwide, to transfer to Jazz Pharmaceuticals, its successors or other legal representative, GSK's right, title and interest in and to the Purchased Assets and to register the transfer at the Patent and Trademark Office of the United States and patent offices in all other territories where patent rights have been granted or are pending. If Jazz Pharmaceuticals elects to record this Agreement or any other documents with the appropriate United States or foreign governmental authorities or registries, Jazz Pharmaceuticals will bear the costs and fees associated with recording, but GSK will provide timely cooperation to Jazz Pharmaceuticals as reasonably requested at no cost to Jazz Pharmaceuticals.

2.3 Post-Closing Assistance. Upon the reasonable request of Jazz Pharmaceuticals, GSK will provide reasonable support to Jazz Pharmaceuticals, at no cost to Jazz Pharmaceuticals, to

assist Jazz Pharmaceuticals with the transfer and registration of the Purchased Assets and to respond to official actions relating to the Purchased Assets. GSK's obligation to reasonably assist Jazz Pharmaceuticals as provided for under this Section 2.3 will terminate six (6) months after the Effective Date. Thereafter, if Jazz Pharmaceuticals requires the assistance of GSK, Jazz Pharmaceuticals shall reimburse GSK for the reasonable cost of any assistance provided, including direct costs for the time of internal GSK employees.

2.4 Transfer of Compound and Other Purchased Assets. Within ninety (90) days after the Closing Date (the "Asset Transfer Period") (which period may be extended by the mutual agreement of the Parties), GSK will transfer to Jazz Pharmaceuticals, at no additional cost to Jazz Pharmaceuticals, the quantities of GW273293 and other Compounds identified in Schedule 1.1.35(c). Jazz Pharmaceuticals acknowledges that GSK and its Affiliates **[*]** as permitted by this Agreement, certain **[*]** GW273293 **[*]** in its **[*]**, pursuant to **[*]** under Section 6.1.

2.5 Acknowledgement of Jazz Pharmaceuticals Regarding Purchased Assets. Jazz Pharmaceuticals acknowledges that GSK has not **[*]** GW273293 **[*]**, and that, as a result, the **[*]** contained in the **[*]** may be **[*]**. Jazz Pharmaceuticals acknowledges that it is purchasing the Purchased Assets with this knowledge and with the understanding that successful development of GW273293 or the other Compounds will require significant efforts and expense of Jazz Pharmaceuticals. In addition, Jazz Pharmaceuticals acknowledges that the quantities of GW273293 and other Compounds identified in Schedule 1.1.35(c) transferred to Jazz Pharmaceuticals may not be suitable in their current condition for use in human clinical trials, and that Jazz Pharmaceuticals may need to conduct additional testing, without the assistance of GSK, on such quantities prior to any use in human clinical trials.

2.6 Non-Exclusive License Grant. Subject to the terms and conditions of this Agreement, effective as of the Closing Date, GSK grants Jazz Pharmaceuticals a worldwide, perpetual, royalty-free, non-exclusive license under the Licensed GSK Patents solely for the purpose of exploiting the rights granted under the Patents and developing and commercializing a Product; provided, however, that, pursuant to Sections 3.3 and 3.5, Jazz Pharmaceuticals shall be obligated to pay milestones and Additional Consideration Payments on Net Sales of Products for the indications covered by the Licensed GSK Patents. Such license granted hereunder shall be sublicensable by Jazz Pharmaceuticals in connection with activities relating to the development and commercialization of Products and Compounds. Additionally, should Jazz Pharmaceuticals require a license under any GSK patent relating to the composition of matter or method of manufacturing sodium channel antagonist compounds or other GSK patents that would block Jazz Pharmaceuticals from making and selling the Compounds as described in the Patents, GSK shall grant Jazz Pharmaceuticals a non-exclusive, royalty-free license under such GSK patents, to the extent GSK has the right to grant such license at the time of Jazz Pharmaceutical's request.

ARTICLE 3—PURCHASE PRICE; MILESTONE PAYMENTS AND ADDITIONAL CONSIDERATION

3.1 Purchase Price. In consideration of GSK's assignment and transfer of the Purchased Assets to Jazz Pharmaceuticals pursuant to Section 2.1, Jazz Pharmaceuticals will pay a total of Two Million U.S. Dollars (U.S. $2,000,000) (the "Purchase Price") on the Closing Date as follows: One Million U.S. Dollars (U.S. $1,000,000) to GGL, and One Million U.S. Dollars (U.S. $1,000,000) to SB. Of the Purchase Price, $50,000 is paid in consideration of the transfer to

Jazz Pharmaceuticals of the quantities of GW273293 and other Compounds identified in Schedule 1.1.35(c), which Jazz Pharmaceuticals, may use for research and development, including clinical activities.

3.2 Manner of Payment of Purchase Price. On the Closing Date, Jazz Pharmaceuticals will pay the Purchase Price to GGL and SB as set forth in Section 3.1 by electronic wire transfer into accounts that have been designated by GGL and SB in writing at least two (2) Business Days prior to the Closing Date.

3.3 Milestone Payments. As further consideration for the assignment and transfer of the Purchased Assets pursuant to Section 2.1, Jazz Pharmaceuticals shall pay GGL and SB the following non-refundable, non-creditable, irrevocable amounts (each, a "Milestone Payment") within ten (10) days after the first achievement by or on behalf of Jazz Pharmaceuticals, its Affiliates or sublicensees of the corresponding events set forth below (each, a "Milestone") for the first Product to reach such Milestone, regardless whether the development, promotion, or marketing of such Product is discontinued at any time after the achievement of such Milestone:

PRE-COMMERCIAL MILESTONES	MILESTONE PAYMENT
1. First patient enrolled in the first Phase I Clinical Trial for a Product anywhere in the Territory, for the first Product to reach this Milestone	(a) U.S. $1,500,000 to GGL, and (b) U.S. $1,500,000 to SB
2. First patient enrolled in the first Phase II Clinical Trial for a Product anywhere in the Territory, for the first Product to reach this Milestone	(a) U.S. $2,500,000 to GGL, and (b) U.S. $2,500,000 to SB
3. First patient enrolled in the first Phase III Clinical Trial for a Product anywhere in the Territory, for the first Product to reach this Milestone	(a) U.S. $**[*]** and (b) U.S. $**[*]**
4. Filing of the first MAA for a Product in the U.S. for the first indication, for the first Product to reach this Milestone	(a) U.S. $**[*]** and (b) U.S. $**[*]**
5. Filing of the first MAA (or first supplement or amendment to an MAA) requesting approval to market a Product for each additional indication for a Product in the U.S. or filing of the first MAA for a second Product for indications other than those approved for a first Product	(a) U.S. $**[*]** and (b) U.S. $**[*]**
6. Filing of the first MAA for Marketing Approval for a Product in any country in the EU (or the first centralized EU filing requesting approval to market a Product)	(a) U.S. $**[*]** and (b) U.S. $**[*]**
7. Filing of the first MAA for a Product in any country outside the U.S. and the EU, for the first Product to reach such Milestone	(a) U.S. $**[*]** and (b) U.S. $**[*]**

COMMERCIAL MILESTONES	MILESTONE PAYMENT
1. Receipt of the first Marketing Approval for a Product in the U.S.	(a) U.S. $**[*]** and (b) U.S. $**[*]**
2. Receipt of the first U.S. Marketing Approval for each additional indication for any Product to receive approval for such indication (including receipt of the first approval for any additional Product for indications other than those approved for the first Product)	(a) U.S. $**[*]** and (b) U.S. $**[*]**

COMMERCIAL MILESTONES	MILESTONE PAYMENT
3. Receipt of the first Marketing Approval for a Product in any country in EU, for the first Product to achieve such Milestone	(a) U.S. $**[*]** and (b) U.S. $**[*]**
4. Receipt of the first Marketing Approval for a Product in any country outside U.S. or EU, for the first Product to achieve such Milestone	(a) U.S. $**[*]** and (b) U.S. $**[*]**
5. Worldwide Gross Sales of Product first exceed US $300,000,000 in any twelve month period	(a) U.S. $**[*]** and (b) U.S. $**[*]**
6. Worldwide Gross Sales of Product first exceed U.S. $500,000,000 in any twelve month period	(a) U.S. $**[*]** and (b) $**[*]**
7. Worldwide Gross Sales of Product first exceed U.S. $700,000,000 in any twelve month period	(a) U.S. $**[*]** and (b) U.S. $**[*]**

3.4 Notes on Milestone Payments.

(a) Each Milestone Payment shall be made only once regardless of how many times such Milestones are achieved for each Product, except for Pre-Commercial Milestone number 5 and Commercial Milestone number 2 above which may be paid more than once (but only once for each **[*]**). No payment shall be owed for a Milestone which is not reached (except that, upon achievement of a Milestone for a particular Product, any previous Milestone for that Product for which payment would have been due hereunder but was not yet made shall be deemed achieved and payment therefore shall be made), if such a payment was due under the terms hereof.

(b) In the event that more than one Milestone is achieved with respect to the same Product at one time, then all applicable payments under Section 3.3 shall be made.

(c) For purposes of Milestone payments, an “indication” means **[*]**.

(d) For purposes of **[*]** in the event federal governmental pricing approval is required to commercialize the Product in the U.S., then the Milestone Payment for **[*]** shall not become due until the earlier of (i) **[*]** or (ii) **[*]** of Marketing Approval.

3.5 Additional Consideration Payments. As further consideration for the assignment and transfer of the Purchased Assets pursuant to Section 2.1, Jazz Pharmaceuticals will pay GGL and SB the following percentage (each an “Additional Consideration Payment”) on Net Sales of Product in the Territory in each calendar year:

(a) with respect to Net Sales of Product (other than Combination Products) in countries of the Territory as to which payments are due, in each calendar year:

(i) **[*]** percent (**[*]**%) of annual Net Sales of Product up to and including **[*]** U.S. Dollars (U.S. $**[*]**) in such calendar year; and

(ii) **[*]** percent (**[*]**%) of annual Net Sales of Product in excess of **[*]** U.S. Dollars (U.S. $**[*]**) in such calendar year.

(b) After calculating the total Additional Consideration Payments due under Section 3.5(a) for all Net Sales in the Territory, Jazz Pharmaceuticals shall determine the

amount of Net Sales in the U.S. and shall pay SB **[*]** percent (**[*]**%) or **[*]** percent (**[*]**%) of such Net Sales in the U.S., as appropriate, at the Additional Consideration Payment level required by Section 3.5(a). After calculating the total Additional Consideration Payments due under Section 3.5(a) for all Net Sales in the Territory, Jazz Pharmaceuticals shall determine the amount of Net Sales in Europe and the ROW and shall pay GGL **[*]** percent (**[*]**%) or **[*]** percent (**[*]**%) of such Net Sales in Europe and the ROW, as appropriate, at the Additional Consideration Payment level required by Section 3.5(a). In no event will any calculations under this paragraph result in a larger payment by Jazz Pharmaceuticals than would have been made had the entire payment been made to one entity. Jazz Pharmaceuticals will use its Diligent Efforts to divide the Additional Consideration Payments as described above. If GSK believes that the division of the payment was not done correctly, GSK will, itself, reapportion the payments between the GSK entities and will not have any recourse to Jazz Pharmaceuticals or request any audits as to the allocation between the GSK entities, and Jazz Pharmaceuticals will have no liability to GSK with respect to any division of the payments as described above.

(c) With respect to Net Sales of Combination Products in the Territory in each reporting period in each country:

(i) if and to the extent all therapeutically active agents comprising the Combination Product are marketed and sold separately in such country in commercially relevant quantities in such Payment Period (as defined in Section 4.1) and the Gross Selling Price for each agent can be separately determined for such Payment Period, Net Sales of each Combination Product for determining the Additional Consideration Payment payable with respect to such Combination Product for such country shall be calculated by multiplying the Net Sales of the Combination Product by A divided by the sum of A plus B (A/(A+B)), in which A is the Gross Selling Price of the single therapeutically active agent Product contained in the Combination Product sold in such country during such Payment Period and B is the Gross Selling Price of the other single therapeutically active agent(s) contained in the Combination Product sold in such country during such Payment Period. All Gross Selling Prices of the therapeutically active ingredients in the Combination Product shall be calculated as the average Gross Selling Price of the therapeutically active ingredients in such Combination Products during the applicable Payment Period for which the Net Sales are being calculated.

(ii) In the event that (a) separate sales, in commercially relevant quantities, in a particular country of the other therapeutically active agent (not the Product) comprising a single compound as a therapeutically active ingredient are made during the Payment Period in which the sale was made or if the Gross Selling Price for such other therapeutically active agent (not the Product) can be determined for a Payment Period, but (b) there are no such separate sales of the Product as the sole therapeutically active agent or such separate sales of the Product cannot be determined for such Payment Period, then the Net Sales of the Combination Product in such country for determining the Additional Consideration Payment payable with respect to such Combination Product for such country for such period shall be calculated by multiplying Net Sales of such Combination Product in such country by the number one (1) minus the result of

dividing X over Y (1—(X/Y)), in which X is the Gross Selling Price of the therapeutically active ingredient that is not a Product sold separately in commercially reasonable quantities during the Payment Period in question and Y is the Gross Selling Price of the Combination Product sold in the Payment Period in question in such country.

(iii) If neither of the single therapeutically active agent components of the Combination Product is sold separately in commercially relevant quantities in a country during a particular Payment Period, then the Additional Consideration Payment payable on such Combination Product in such country for such period will be **[*]** percent (**[*]**%) of the Additional Consideration Payment that would be due on a Product that is not a Combination Product.

(d) Any Additional Consideration Payment due on Combination Products shall be paid to SB for Net Sales of Combination Products in the U.S. and to GGL for Net Sales of Combination Products in the ROW. After determining the total Additional Consideration Payments due on Combination Products in accordance with Section 3.5(c) above, Jazz Pharmaceuticals shall determine the Additional Consideration Payments due on Net Sales in the U.S. and in ROW, respectively, and shall pay such amounts to SB and GGL, respectively.

3.6 Starting Date of Additional Consideration Payment Obligations. The obligation of Jazz Pharmaceuticals to pay Additional Consideration Payments to GGL and SB at the rates specified in Section 3.5 will become effective on a country by country basis on the date of the First Commercial Sale of a Product in such country.

3.7 Termination of Additional Consideration Payment Obligations. Additional Consideration Payments will be payable on Net Sales of Products in the U.S. until the expiration of the last-to-expire Valid Claim in the Patents in force in the U.S. Additional Consideration Payments will be payable on Net Sales of Products in all countries of Europe until the expiration of the last-to-expire Valid Claim in the Patents in force in the last country in Europe in which such Valid Claim is in force. Additional Consideration Payments will be payable on Net Sales of Products in all countries in the ROW until the expiration of the last-to-expire Valid Claim in the Patents in force in the last country in the ROW in which such Valid Claim is in force. Additional Consideration on Net Sales of Products in Europe and the ROW is being paid in this manner as an administrative convenience to the Parties as a result of the difficulty in allocating value for each of the Patents in Europe and the ROW.

3.8 Transfer and Other Taxes. Jazz Pharmaceuticals will be responsible for and will pay all foreign, federal, state and local taxes payable in connection with the acquisition and transfer of the Purchased Assets to Jazz Pharmaceuticals by GSK. GSK will be responsible for and will pay all foreign, federal, state and local taxes payable on any income or gain resulting from the sale of the Purchased Assets to Jazz Pharmaceuticals. Notwithstanding the foregoing, Jazz Pharmaceuticals shall not be required to pay (i) any VAT in connection with the transfer of the Purchased Assets, or (ii) any tax as a result of the separate payment to SB pursuant to Sections 3.3 or 3.5 that it would not have been required to pay if making only one payment to GGL. In the event that Jazz Pharmaceuticals is required to withhold and remit any tax to the revenue authorities in any country in the Territory regarding the Purchase Price, any Milestone payment or any Additional Consideration Payments payable to GGL or SB due to the laws of such country, such amount shall be withheld by Jazz Pharmaceuticals, and Jazz Pharmaceuticals shall notify GSK and promptly furnish GSK with copies of any documentation evidencing such withholding.

ARTICLE 4—MANNER OF PAYMENTS; REPORTS; DILIGENCE

4.1 Manner of Additional Consideration Payments.

(a) Jazz Pharmaceuticals will deliver to GSK within sixty (60) days following the end of each "Payment Period", meaning a calendar quarter ending on March 31st, June 30th, September 30th or December 31st, the Additional Consideration Payment Statements (as defined in Section 4.2), along with Jazz Pharmaceuticals' payments to GGL and SB of any Additional Consideration Payment due and payable to GGL and SB for such Payment Period.

(b) Each Additional Consideration Payment will be computed and paid in U.S. Dollars. Monetary conversion calculations from the currency of a foreign country in which a Product is sold into U.S. Dollars will be made on a quarterly basis on the last day of each applicable calendar quarter using the exchange rate reported on the last Business Day of such calendar quarter in the Wall Street Journal, eastern edition.

(c) Whenever any Additional Consideration Payment is due on a day that is not a Business Day, such payment will be made on the immediately succeeding Business Day.

(d) In the event that any payment due hereunder is not made when due, the payment shall accrue interest from that date due at the rate of **[*]** percent (**[*]**%) per month, or the maximum rate allowed by law, whichever is less, and shall be calculated based on the number of days that the payment is delinquent. The payment of such interest shall not limit GSK from exercising any other rights it may have as a consequence of the lateness of any payment.

4.2 Additional Consideration Payment Statements. Each Additional Consideration Payment required hereunder will be accompanied by a report ("Additional Consideration Payment Statement") for the preceding Payment Period containing the following information:

(a) itemized accounting of the total Net Sales for Product during the applicable Payment Period in each country of sale in sufficient detail to permit confirmation of the accuracy of the Additional Consideration Payment;

(b) adjustments and calculation of Net Sales for the applicable Payment Period in each country of sale; and

(c) total Net Sales in U.S. dollars, together with the exchange rates used for conversion.

If no payment is due to GGL or SB for any Payment Period, the Additional Consideration Payment Statement will so state. All Additional Consideration Payment Statements will be considered Jazz Pharmaceuticals' Confidential Information under this Agreement, but GSK may disclose such Confidential Information in accordance with Section 11.2 or Section 11.3.

4.3 Additional Consideration Payment Post-Termination Report. Jazz Pharmaceuticals will make a written report to GSK within thirty (30) days after the date of any termination of

Additional Consideration Payment obligations under this Agreement, stating in such report the number, description and Net Sales of Products sold or otherwise disposed of and on which an Additional Consideration Payment is payable hereunder that was not previously reported to GSK.

4.4 Audit. Upon the written request of GSK (but not more frequently than **[*]**), GSK will have the right, upon thirty (30) days advance notice to Jazz Pharmaceuticals and at a mutually agreeable time, to have an independent certified public accountant or like individual reasonably acceptable to Jazz Pharmaceuticals (the "Auditor") inspect, during normal business hours, Jazz Pharmaceuticals' directly applicable records for the preceding two (2) years for the purpose of determining the accuracy of Additional Consideration Payment Statements and the associated Additional Consideration Payment made to GGL and SB pursuant to this Agreement. The results of any such examination shall be made available to Jazz Pharmaceuticals. In the event the Auditor concludes that there was an underpayment of the total Additional Consideration Payment to GGL and SB together, the underpayment will be paid by Jazz Pharmaceuticals to GGL or SB or both, as applicable (but subject to the provisions of Section 3.5(b) concerning allocations between GGL and SB), within sixty (60) Business Days after the date Jazz Pharmaceuticals receives such Auditor's written report; provided, however, if Jazz Pharmaceuticals desires to contest such audit results, Jazz Pharmaceuticals may do so by submitting the results of the audit to arbitration through JAMS New York or San Francisco offices within thirty (30) days after the receipt of such audit, and the arbitration shall be final and binding on GSK and Jazz Pharmaceuticals. Pending the results of such arbitration, Jazz Pharmaceuticals shall be entitled to withhold any disputed amounts claimed by GSK as a result of the audit. In the event the Auditor concludes that there was an overpayment of Additional Consideration Payment to GGL or SB or both, as applicable, the overpayment will be credited toward the next Additional Consideration Payment to be paid by Jazz Pharmaceuticals to GGL or SB or both, as applicable, under this Agreement until fully credited; provided, however, that in the event no further Additional Consideration Payment will become due under this Agreement, such overpayment will be paid by GGL or SB or both, as applicable, to Jazz Pharmaceuticals within sixty (60) Business Days after the date GSK receives such Auditor's written report. If the underpayment of Additional Consideration is greater than **[*]** percent (**[*]**%) of the Additional Consideration Payment determined by the Auditor to be payable to GSK, the reasonable fees and expenses charged by the Auditor will be paid by Jazz Pharmaceuticals; otherwise GSK will pay the reasonable fees and expenses charged by such Auditor. The Auditor will report to GSK only its conclusions as to whether Jazz Pharmaceuticals is in compliance with its Additional Consideration Payment obligations and the amount of any underpayment or overpayment, and such report and the conclusions contained therein will constitute Jazz Pharmaceuticals' Confidential Information in accordance with Section 11.1.

4.5 Diligence.

(a) Product Development Diligence. Jazz Pharmaceuticals shall exercise its Diligent Efforts to develop a Product for marketing and sale in the Territory. In connection therewith, Jazz Pharmaceuticals shall use its Diligent Efforts to achieve the development objectives set forth below by the corresponding times set forth below:

(i) enroll the first patient in a Phase I Clinical Trial for a Product not later than thirteen (13) months after the Closing Date;

(ii) **[*]**; and

(iii) file an MAA for a Product in the U.S. not later than twelve (12) months after completion of all Phase III Clinical Trials.

(b) Commercialization Diligence. Jazz Pharmaceuticals shall devote its Diligent Efforts to launch a Product in each of the Major Market Countries in which Marketing Approval of a Product is granted within twelve (12) months after the date on which such Marketing Approval is granted, subject to, with respect to each Major Market Country, the availability of commercially acceptable pricing, competitive conditions, product life cycle and other customary commercial conditions.

(c) Patent Diligence. Jazz Pharmaceuticals shall devote its Diligent Efforts to prosecute, maintain, defend and enforce, in the Major Market Countries, Patents in the Major Market Countries that have been transferred to Jazz Pharmaceuticals in accordance with Section 2.1.

(d) Failure to Achieve Objectives. Failure to achieve any of the development objectives described in Section 4.5(a) or the commercial objective set forth in Section 4.5(b) at the times set forth therein shall not be a breach of this Agreement and shall not result in the availability of the remedies set forth in Section 9.2; provided, however, that the failure of Jazz Pharmaceuticals to exercise Diligent Efforts to achieve the development and commercial objectives set forth above shall constitute material breach of this Agreement and, upon such breach, GSK, in its discretion, may terminate the Agreement in accordance with Section 9.2. Any time period described in Section 4.5(a) or (b) shall be extended for the same period of time as any delay caused by GSK in transferring the Purchased Assets to Jazz Pharmaceuticals or any delay which was outside the control of Jazz Pharmaceuticals.

4.6 Cessation or Suspension of Development Efforts. If Jazz Pharmaceuticals ceases or suspends development efforts for all of GW273293 and the other Products covered by the Patents (such that efforts have been suspended with respect to all of the Compounds) for a period of fourteen (14) successive months, such cessation or suspension of development efforts shall constitute a failure of Diligent Efforts by Jazz Pharmaceuticals and a material breach of this Agreement. Upon such material breach, GSK, in its discretion, may terminate this Agreement in accordance with Section 9.2.

4.7 Termination of Development or Commercialization by Jazz Pharmaceuticals.

(a) If Jazz Pharmaceuticals determines to cease Diligent Efforts (alone or with a Third Party) to develop and commercialize all Products prior to enrolling a patient in the first Phase II Clinical Trial for the first Product, Jazz Pharmaceuticals shall so notify GSK in writing. In such event, GSK shall have a period of sixty (60) days after the date of Jazz Pharmaceuticals' notice to reacquire the rights to all the Products in their then-current condition, for a price equal to all Milestone Payments paid by Jazz Pharmaceuticals to GSK hereunder with respect to the Products prior to the reacquisition by GSK. If GSK reacquires the Products under this Section 4.7(a), Jazz Pharmaceuticals shall have no obligation to provide GSK with any data generated by Jazz Pharmaceuticals regarding the Products.

(b) If Jazz Pharmaceuticals determines to cease Diligent Efforts (alone or with a Third Party) to develop and commercialize all Products at any time after enrolling a patient in the first Phase II Clinical Trial for the first Product, Jazz Pharmaceuticals shall so notify GSK in writing. In such event, GSK shall have a period of sixty (60) days after the date of Jazz Pharmaceuticals' notice to reacquire the rights to the Products in their then-current condition, for a price equal to the sum of (a) all amounts paid by Jazz Pharmaceuticals to GSK hereunder with respect to the Products, plus (b) all amounts expended by Jazz Pharmaceuticals to develop and commercialize the Products prior to the reacquisition by GSK. In its notice to GSK, Jazz Pharmaceuticals shall advise GSK of the total amount it has expended to develop and commercialize the Products. If GSK reacquires the Products under this Section 4.7(b), Jazz Pharmaceuticals shall provide GSK with all data generated by Jazz Pharmaceuticals regarding the Products.

Upon receipt of notice from Jazz Pharmaceuticals under Section 4.7(a) or 4.7(b), GSK shall have the option, exercisable by written notice to Jazz Pharmaceuticals given within sixty (60) days after Jazz Pharmaceuticals' notice, to reacquire the Product and all of Jazz Pharmaceuticals' rights to the Product. In the event that GSK exercises such option, the Parties shall work together

diligently to complete such reacquisition within the sixty (60) days following GSK's exercise of such option, and Jazz Pharmaceuticals shall provide assistance to GSK, on a level commensurate to the assistance provided by GSK to Jazz Pharmaceuticals pursuant to Section 2.2 and 2.3, to transfer and assign the Purchased Assets to GSK. If the option is not exercised within the sixty (60) day period described above, it will terminate, and GSK shall have no further right to reacquire any Products.

4.8 **[*]** Reports. On a **[*]** basis until **[*]**, Jazz Pharmaceuticals shall submit summary written reports to GSK describing Jazz Pharmaceuticals' **[*]**.

ARTICLE 5—CLOSING

5.1 Closing Date; Time and Place of Closing. The transfer of title to the Purchased Assets and the closing of the transactions contemplated by this Agreement will occur on October 4, 2004 (the "Closing Date") at or before the Time of Closing at 3180 Porter Drive, Palo Alto, California, U.S., or at such other place as may be agreed upon in writing by the Parties hereto.

5.2 Closing Arrangements.

(a) GSK's Delivery of Closing Documents. At the Time of Closing on the Closing Date, GSK will execute and deliver to Jazz Pharmaceuticals:

(i) a Bill of Sale in the form of Schedule A attached hereto and incorporated herein, duly executed by GSK;

(ii) an Assignment of Patent Rights in the form of Schedule B attached hereto and incorporated herein, duly executed by GSK; and

(iii) this Agreement, duly executed by GSK.

In addition, at the Time of Closing, GSK will pay and satisfy the [*] as provided in Section 6.1.

(b) Jazz Pharmaceuticals' Payment of Purchase Price and Delivery of Closing Documents: At the Time of Closing on the Closing Date, Jazz Pharmaceuticals will:

(i) pay and satisfy the Purchase Price as provided in Section 3.1, payable via wire transfer to accounts that have been designated by GGL and SB at least two (2) Business Days prior to the Closing Date; and

(ii) deliver this Agreement, duly executed by Jazz Pharmaceuticals.

5.3 Conditions of Obligations of Jazz Pharmaceuticals. The obligations of Jazz Pharmaceuticals to effect the transactions contemplated hereby are also subject to the satisfaction of the following conditions, unless waived in writing by Jazz Pharmaceuticals on or prior to the Closing Date:

(a) The representations and warranties of GSK set forth in this Agreement shall be true and correct as of the Time of Closing;

(b) GSK shall have performed all conditions, obligations and covenants required to be performed by it under this Agreement prior to the Time of Closing;

(c) Jazz Pharmaceuticals shall have received duly executed copies of all Third Party consents, approvals and assignments contemplated by this Agreement and necessary to transfer all of GSK's interest in the Purchased Assets, in form and substance reasonably satisfactory to Jazz Pharmaceuticals; and

(d) Subject to Section 2.5, there shall have been no material change in the Compounds or the Purchased Assets.

5.4 Conditions of Obligations of GSK. The obligations of GSK to effect the transactions contemplated hereby are also subject to the satisfaction of the following conditions, unless waived in writing by GSK on or prior to the Closing Date:

(a) The representations and warranties of Jazz Pharmaceuticals set forth in this Agreement shall be true and correct as of the Time of Closing;

(b) Jazz Pharmaceuticals shall have performed all conditions, obligations and covenants required to be performed by it under this Agreement prior to the Time of Closing; and

(c) There shall have been no material adverse change to the business or financial condition of Jazz Pharmaceuticals.

5.5 Transfer after Closing Date. While title to the Purchased Assets will pass to Jazz Pharmaceuticals on the Closing Date, the physical transfer of the Purchased Assets will take place during the Asset Transfer Period. In the event that Jazz Pharmaceuticals seeks additional data from GSK pertaining to the Purchased Assets, Jazz Pharmaceuticals may, during the Asset Transfer Period, make a specific request of GSK for copies of such additional data. GSK will endeavor to locate such data, where available, within a reasonable period of time. If, despite GSK's reasonable endeavors it cannot locate such additional data, GSK will promptly notify Jazz Pharmaceuticals in writing. GSK will be responsible for the physical transfer of the Purchased Assets (including compliance and costs associated with any export control laws or regulations and any required governmental authorizations) to Jazz Pharmaceuticals' chosen destination during the Asset Transfer Period. Risk of loss of the Purchased Assets will pass to Jazz Pharmaceuticals upon receipt of such by Jazz Pharmaceuticals.

5.6 Expenses for Transfer of the Purchased Assets. Except as provided in this Agreement, after the Time of Closing on the Closing Date, Jazz Pharmaceuticals will be responsible for all costs related to the recordation and perfection of the assignment of the Purchased Assets and Jazz Pharmaceuticals will bear all costs and fees imposed by governmental authorities related thereto and all postage costs. Except as otherwise expressly provided herein, all other costs, fees and expenses arising from the transfer of the Purchased Assets to Jazz Pharmaceuticals as contemplated by this Agreement will be paid by the Party incurring such costs and expenses.

ARTICLE 6 — LICENSE

6.1 Grantback License to GSK. Jazz Pharmaceuticals hereby grants to GSK for One U.S. Dollar (U.S. $1.00) ("License Fee") a fully paid-up and royalty-free, non-exclusive, worldwide, perpetual and irrevocable license under the Purchased Assets for GSK's internal research purposes only, excluding clinical research ("Grantback License"). In accordance with Section 6.3, until the expiration of the last to expire Valid Claim in the Patents in each of the U.S., Europe and ROW, respectively, GSK shall have no right under the Grantback License to develop, market, sell or promote any Compound in the U.S., Europe or the ROW, respectively. Prior to the expiration of the last Valid Claim in the Patents in the U.S., Europe and the ROW, respectively, should GSK wish to develop, market, sell or promote a Compound other than GW273293 in the U.S., Europe or the ROW where a Valid Claim exists, GSK shall notify Jazz Pharmaceuticals, and Jazz Pharmaceuticals and GSK shall negotiate, for a period of up to 90 days, the grant by Jazz Pharmaceuticals to GSK of a royalty-bearing license to permit GSK to develop, market, sell and promote such Compound, but Jazz Pharmaceuticals will have no obligation to grant such a license.

6.2 Sublicense. GSK will have the right to grant sublicenses under the Grantback License granted under Section 6.1 to its Affiliates and Third Parties that enter into bona fide research collaborations with GSK; provided that, in each instance (a) such sublicense shall be used solely for internal research, excluding clinical research, purposes only and (b) any such sublicensee shall be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in Article 11.

6.3 Development or Commercialization by GSK of Products. GSK will not develop, commercialize or sell any Product in the U.S. until the expiration of the last to expire Valid Claim in the Patents in force in the U.S. GSK will not commercialize or sell any Product in any country in Europe until the expiration of the last to expire Valid Claim in the Patents in the last country in Europe in which such Valid Claim was in force. GSK will not commercialize or sell any Product in any country in the ROW until the expiration of the last to expire Valid Claim in the Patents in the last country in the ROW in which such Valid Claim was in force. This provision shall not prevent GSK from researching any Compound covered by the Patents in accordance with the license granted to GSK in Section 6.1.

ARTICLE 7—REPRESENTATIONS AND WARRANTIES

7.1 Representations and Warranties of Jazz Pharmaceuticals. Jazz Pharmaceuticals hereby represents and warrants to GSK and acknowledges that GSK is relying on such representations and warranties in connection with the transactions contemplated by this Agreement that, as of the Closing Date:

(a) Incorporation, Organization and Qualification of Jazz Pharmaceuticals. Jazz Pharmaceuticals is a corporation duly incorporated, validly existing and in good standing under the laws of the jurisdiction of its incorporation, and has the corporate power to own or lease its property and to carry on its business as now being conducted by it and to execute, deliver and perform this Agreement. Jazz Pharmaceuticals is duly qualified to do business as a foreign corporation and is in good standing in every jurisdiction where the nature of the business conducted by it makes such qualification necessary, except in such jurisdictions where the failure to so qualify does not in the aggregate have a material adverse effect on its respective businesses taken as a whole.

(b) Corporate Action. This Agreement, and any other agreements and instruments executed in connection herewith and therewith are the valid and binding obligations of Jazz Pharmaceuticals, enforceable in accordance with their respective terms, subject to bankruptcy, insolvency or similar laws of general application affecting the enforcement of rights of creditors, and subject to equitable principles limiting rights to specific performance or other equitable remedies and subject to the effect of federal and state securities laws on the enforceability of indemnification provisions relating to liabilities arising under such laws. The execution, delivery and performance of this Agreement and any other agreement and instruments executed in connection herewith and therewith have been duly authorized by all necessary corporate action.

(c) Governmental Approvals. No authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable laws, rules or regulations presently in effect, is or will be necessary for, or in connection with, the offer, issuance, sale, execution or delivery by Jazz Pharmaceuticals of the Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement.

(d) Sufficient Funds. Jazz Pharmaceuticals represents that it has, or will have at the Time of Closing, sufficient funds to fulfill its obligation to pay the Purchase Price and Milestone Payments to GSK.

(e) Compliance With Law. Jazz Pharmaceuticals has complied and is in compliance with all applicable foreign, federal, state and local laws, statutes, licensing requirements, rules and regulations, and judicial or administrative decisions applicable to Jazz Pharmaceuticals in connection with the transaction contemplated hereby.

7.2 Representations and Warranties of GSK. GSK hereby represents and warrants to Jazz Pharmaceuticals and acknowledges that Jazz Pharmaceuticals is relying on such representations and warranties in connection with the transactions contemplated by this Agreement that, as of the Closing Date:

(a) Incorporation, Organization and Qualification of GSK. Each of GGL and SB is a corporation duly incorporated, validly existing and in good standing under the law of the jurisdiction of its incorporation, and has the corporate power to own or lease its property and to carry on its business as now being conducted by it. Each of GGL and SB is duly qualified to do business as a foreign corporation and is in good standing in every jurisdiction where the nature of the business conducted by it makes such qualification necessary, except in such jurisdictions where the failure to so qualify does not in the aggregate have a material adverse effect on its respective businesses taken as a whole.

(b) Corporate Action. This Agreement, and any other agreements and instruments executed in connection herewith and therewith are the valid and binding obligations of each of GSK, enforceable in accordance with their respective terms, subject to bankruptcy, insolvency or similar laws of general application affecting the enforcement of rights of creditors, and subject to equitable principles limiting rights to specific performance or other equitable remedies. The execution, delivery and performance of this Agreement and any other agreement and instruments executed in connection herewith and therewith have been duly authorized by all necessary corporate action.

(c) Governmental Approvals. No authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable laws, rules or regulations presently in effect, is or will be necessary for, or in connection with, the offer, issuance, sale, execution or delivery by GGL or SB of the Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of it obligations under this Agreement.

(d) Title to Purchased Assets.

(i) GSK is the sole and exclusive owner of the Purchased Assets, and the Purchased Assets are free and clear of any and all liens, pledges, mortgages, security interests, restrictions, and encumbrances. By virtue of the deliveries made at the Time of Closing, Jazz Pharmaceuticals will obtain good and marketable title to all of the Purchased Assets, free and clear of any and all liens,

pledges, mortgages, security interests, restrictions and encumbrances. To GSK's knowledge, no government funds, equipment, facilities, personnel or other resources were used in connection with the discovery or development of the Purchased Assets.

(ii) None of GSK, GGL or SB has granted and will not grant during the Term of this Agreement, any right to any Affiliate or Third Party which would conflict with the rights granted to Jazz Pharmaceuticals hereunder, and GSK will not take (or cause any other person or entity to take) any action that will conflict with, contravene or otherwise limit or restrict the rights of Jazz Pharmaceuticals hereunder or the right of Jazz Pharmaceuticals to enjoy the benefits of this Agreement.

(iii) The Purchased Assets constitute all of the material assets used by GSK and its Affiliates in the development of GW273293 and the manufacturing Know-how specifically relating to GW273293, other than manufacturing equipment. Except for the quantities of GW273293 duly retained by GSK pursuant to Section 2.4, neither GSK nor its Affiliates will have any supply of GW273293 at the expiration of the Asset Transfer Period, nor is GSK or its Affiliates in the process of, or planning to, manufacture any additional amounts of GW273293, except for the purposes permitted by the **[*]**.

(iv) Schedule 1.1.29 lists all Patents related to the Compounds, or any formulation or process of manufacture or formulation specifically related to GW273293, or use thereof in the Territory including any patent term extensions, supplementary protection certificates, registrations, extensions, reissues, reexaminations or divisionals thereof, and including any granted patents arising from the pending applications.

(e) Litigation. No action, claim, suit, proceeding or investigation is pending in respect of the Purchased Assets in the United States or Europe or, to GSK's knowledge, anywhere else in the Territory. To GSK's knowledge, no action, claim, suit, proceeding or investigation is threatened against GSK or its Affiliates in respect of the Purchased Assets anywhere in the Territory. There is no judgment, decree, injunction, rule or order of any court, governmental department, commission agency, instrumentality or arbitrator or other similar ruling outstanding against GSK or its Affiliates relating to the Purchased Assets. No action, claim, suit, proceeding or investigation is pending or threatened by GSK or its Affiliates, nor, to GSK's knowledge, is there any basis for such, against any Third Party relating to the Purchased Assets.

(f) No Existing Claims of Infringement. To the knowledge of GSK's Corporate Intellectual Property Group, there are no claims existing against GSK or its Affiliates asserting that the manufacture, use or sale of GW273293 infringes, constitutes contributory infringement, inducement to infringe or misappropriation of any patent rights, trade secret rights or other intellectual property or proprietary rights of any Third Party. GSK hereby represents and warrants that GSK's Corporate Intellectual Property group referenced in this Agreement is the only group within GSK that prosecutes and maintains patents.

(g) Taxes; Maintenance Fees. All taxes imposed by the United States, any state, municipality, other local government or other subdivision or instrumentality of the United

States or the countries of EU that are due or payable by GSK or any of its Affiliates with respect to the Purchased Assets, and all interest and penalties thereon, whether disputed or not, and that would result in the imposition of a lien, claim or encumbrance on any of the Purchased Assets, other than taxes that are not yet due and payable, have been paid in full, all tax returns required to be filed in connection therewith with respect to the Purchased Assets have been accurately prepared and duly and timely filed in the United States and countries of the EU. To GSK's knowledge, all taxes imposed by any other country or any state or other government thereof, or any other taxing authority, that are due or payable by GSK or any of its Affiliates with respect to the Purchased Assets, and all interest and penalties thereon, whether disputed or not, and that would result in the imposition of a lien, claim or encumbrance on any of the Purchased Assets, other than taxes that are not yet due and payable, have been paid in full, all tax returns required to be filed in connection therewith with respect to the Purchased Assets have been accurately prepared and duly and timely filed. GSK is not delinquent in the payment of any foreign or domestic tax, assessment or governmental charge or deposits in the U.S. or the EU or, to GSK's knowledge, in any other country that would result in the imposition of a lien, claim or encumbrance on any of the Purchased Assets or against Jazz Pharmaceuticals, and neither GSK nor any of its Affiliates has a tax deficiency or claim outstanding, proposed or assessed against it, and, to GSK's knowledge, there is no basis for any such deficiency or claim, that would result in the imposition of any lien, claim or encumbrances on any of the Purchased Assets or against Jazz Pharmaceuticals. All maintenance fees and any other fees for the Patents have been timely paid.

(h) Compliance With Law. To GSK's knowledge, GSK and its Affiliates have complied and are in compliance with all applicable foreign, federal, state and local laws, statutes, licensing requirements, rules and regulations, and judicial or administrative decisions applicable to their ownership and use of the Purchased Assets, including without limitation all laws, rules and regulations regarding the development, clinical testing, manufacture, licensing, marketing, promotion, importation, exportation or other use of pharmaceutical products, except where such failure to do so would not materially adversely affect, or reasonably be expected to so affect, any of the Purchased Assets or the ability of GSK to consummate the transactions contemplated herein. GSK and its Affiliates have been granted any and all licenses, permits (temporary and otherwise), authorization and approvals from federal, state, local and foreign government regulatory bodies necessary to own and use the Purchased Assets, except where the failure to possess such license, permit, authorization or approval would not have a materially adverse effect, or reasonably be expected to so affect, any of the Purchased Assets or the ability of GSK, GGL and SB have to consummate the transactions contemplated herein.

(i) Full Disclosure. This Agreement and the Schedules attached hereto, when taken as a whole, do not contain any untrue statement of a material fact nor, to GSK's knowledge, information and belief, omit to state a material fact necessary in order to make the statements contained herein or therein not misleading.

(j) Limitations.

(i) EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 7.2, THE COMPOUNDS AND PURCHASED ASSETS ARE PROVIDED "AS IS," AND

GSK MAKES NO REPRESENTATIONS OR WARRANTIES (WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE COMPOUNDS OR PURCHASED ASSETS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, INCLUDING USE IN CLINICAL TRIALS, OR FREEDOM FROM INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. JAZZ PHARMACEUTICALS ACKNOWLEDGES THAT ALL CHARACTERISTICS OF THE COMPOUNDS ARE NOT FULLY UNDERSTOOD AND ANY USE THEREOF MAY INVOLVE RISKS OR DANGERS THAT ARE NOT KNOWN OR FULLY APPRECIATED.

(ii) NOTWITHSTANDING ANYTHING ELSE IN THIS AGREEMENT, JAZZ PHARMACEUTICALS WILL BE RESPONSIBLE FOR (AND GSK WILL HAVE NO RESPONSIBILITY FOR) ALL LIABILITIES ARISING SOLELY FROM ACTS OR OMISSIONS TO ACT BY JAZZ PHARMACEUTICALS, ITS AFFILIATES OR SUBLICENSEES AFTER THE TIME OF CLOSING RELATED TO THE PURCHASED ASSETS OR THE USE BY JAZZ PHARMACEUTICALS, ITS AFFILIATES OR SUBLICENSEES OF THE PURCHASED ASSETS TO IDENTIFY, RESEARCH, DEVELOP, MANUFACTURE, MARKET, PROMOTE, DISTRIBUTE, SELL OR IMPORT ANY PRODUCTS, EXCEPT WHERE SUCH LIABILITY, LOSS, DAMAGE, COST AND EXPENSE HAS BEEN INCURRED OR SUFFERED AS A RESULT OF A MATERIAL BREACH OF GSK'S REPRESENTATIONS, WARRANTIES OR OBLIGATIONS UNDER THIS AGREEMENT OR BY GROSS NEGLIGENCE OR WILLFUL MISCONDUCT ON THE PART OF GSK.

(k) Any representation or warranty by GSK herein will also be deemed to have been made by each of GGL and SB, individually as to itself, and the breach of any representation or warranty by any one of them will be deemed to be a breach by the others.

ARTICLE 8—LIABILITY AND INDEMNIFICATION

8.1 Indemnification by GSK. GSK will indemnify, defend and hold harmless Jazz Pharmaceuticals, its Affiliates, and each of their respective members, directors, officers, employees, advisors and agents (collectively, "Jazz Pharmaceuticals Indemnitees") from and against any and all suits, actions, damages, liabilities, claims (including death and bodily injury), demands, obligations, losses, fees, costs and expenses or money judgments (including reasonable attorneys' fees) (collectively, "Claims") incurred by or rendered against any Jazz Pharmaceuticals Indemnitee which arise out of or in connection with:

(a) any Claims related to the Purchased Assets or against the Purchased Assets, in each case based upon events which occurred at or prior to the Time of Closing; or

(b) liabilities of GSK or its Affiliates to the extent related to the Purchased Assets and existing as of, or prior to, the Closing Date or based on actions taken or omissions to act that occurred prior to the Time of Closing (including any infringement or misappropriation of Third Party patents or intellectual property);

(c) any breach or inaccuracy of any representation, warranty or covenant of GSK set forth in this Agreement; or

(d) the negligence or willful misconduct of any GSK Indemnitees;

provided, however, that in each case GSK will not be obligated to indemnify any Jazz Pharmaceuticals Indemnitee with respect to, and to the extent of, any Claims for which Jazz Pharmaceuticals is obligated to indemnify GSK pursuant to Section 8.2.

8.2 Indemnification by Jazz Pharmaceuticals. Jazz Pharmaceuticals will indemnify and hold harmless GSK and its Affiliates and each of their directors, officers, employees, advisors and agents (collectively, the "GSK Indemnitees") from and against any and all Claims incurred by or rendered against any GSK Indemnitee which arise out of or in connection with:

(a) the development, manufacture, licensing, marketing, promotion, importation, exportation, sale or other use of the Purchased Assets from and after the Time of Closing by or on behalf of any Jazz Pharmaceuticals Indemnitees of any Product or service or any product or material embodying or made through the use of any part of the Purchased Assets; provided however, it is agreed by the Parties that such indemnification will not apply to the extent that any product or service arises from the exercise of the **[*]** by GSK, its Affiliates, agents **[*]**;

(b) any breach or inaccuracy of any representation, warranty or covenant made by Jazz Pharmaceuticals pursuant to this Agreement; or

(c) the negligence or willful misconduct of any Jazz Pharmaceuticals Indemnitees;

provided, however, that in each case Jazz Pharmaceuticals will not be obligated to indemnify any GSK Indemnitees with respect to, and to the extent of, any Claims for which GSK is obligated to indemnify Jazz Pharmaceuticals Indemnitees pursuant to Section 8.1.

8.3 Indemnification Process. No Party against whom a claim of indemnity is made under this Agreement (the "Indemnifying Party") will be liable unless the Party making such claim (the "Claimant Party") (a) promptly notifies the Indemnifying Party in writing of such claim upon becoming aware of the existence or threatened existence of any such claim giving rise to or which may give rise to a claim of indemnity (provided, however that the failure to provide written notice of such claim within a reasonable period of time will not relieve the Indemnifying Party of any obligations hereunder, except to the extent that the Indemnifying Party is prejudiced by such failure), (b) permit the Indemnifying Party to assume direction and control of the defense of the claim, and (c) cooperates in the defense of such claim. Notwithstanding the foregoing, the Indemnifying Party shall not enter into any settlement or compromise of any claims without the express written consent of the Claimant Party in each instance where such settlement would include any admission of liability on the part of the Claimant Party, where the settlement would impose any material restriction on the conduct of the Claimant Party of any of its activities, or where the settlement would not include an unconditional release of the Claimant Party from all liability for claims that are the subject matter of such claim.

8.4 Limitation on Indemnification. NEITHER JAZZ PHARMACEUTICALS AND ITS AFFILIATES NOR GSK AND ITS AFFILIATES WILL BE LIABLE HEREUNDER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE REMEDIES FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOST PROFITS.

ARTICLE 9—TERM AND TERMINATION

9.1 Term; Expiration.

(a) This Agreement shall become effective as of the Effective Date, and GSK's sale, transfer and assignment of its rights to the Purchased Assets to Jazz Pharmaceuticals, and the transfer of title to such Purchased Assets shall be accomplished on the Closing Date, subject to satisfaction of the conditions set forth in Sections 5.3 and 5.4. As provided in Section 5.5, the physical transfer of the Purchased Assets will occur during the Asset Transfer Period. After the Closing Date, unless earlier terminated pursuant to Section 9.2, this Agreement shall expire on expiration of the last-to-expire Valid Claim in the Patents anywhere in the Territory.

(b) The period from the Effective Date to the expiration of the entire Agreement pursuant to this Section 9.1 shall be the "Term." The end of the Term shall not terminate or affect the transfer of Patents pursuant to Section 2.1 or the license granted under Section 2.6; and no Purchased Assets transferred to Jazz Pharmaceuticals hereunder shall be returned at the end of the Term.

9.2 Termination for Cause.

(a) Material Breach. Either Party (the "Non-breaching Party") may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in its entirety in the event the other Party (the "Breaching Party") shall have committed a material breach, and such material breach shall have continued and/or remained uncured for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-breaching Party. Any such termination shall become effective at the end of such sixty (60) day period, unless the Breaching Party has cured any such material breach prior to the expiration of such sixty (60) day period. The sixty (60) day cure period provided for herein shall be extended for as long as a Breaching Party is making Diligent Efforts to cure such material breach. The right of either Party to terminate this Agreement as provided in this Section 9.2 shall not be affected in any way by such Party's waiver or failure to take action with respect to any previous default.

(b) Effect of Termination by Jazz Pharmaceuticals on GSK's Material Breach. In the event Jazz Pharmaceuticals terminates this Agreement pursuant to Section 9.2(a) as a result of an uncured material breach by GSK, (i) all rights granted to Jazz Pharmaceuticals hereunder will continue unaffected, including the license granted to Jazz Pharmaceuticals pursuant to Section 2.6, (ii) no further payments will be due to GSK hereunder, (iii) Jazz Pharmaceuticals' diligence obligations under Section 4.5 will terminate, and (iv) Section 6.3 will continue in accordance with its terms.

(c) Effect of Termination by GSK on Jazz Pharmaceutical's Material Breach. In the event GSK terminates this Agreement pursuant to Section 9.2(a) as a result of an uncured material breach by Jazz Pharmaceuticals, (i) Jazz Pharmaceuticals shall cease all development and marketing of the Compounds or Products and immediately shall assign and transfer back to GSK all rights to the Purchased Assets; and (ii) the license

granted to Jazz Pharmaceuticals pursuant to Section 2.6 shall terminate. In consideration of the transfer of the Purchased Assets to it, GSK shall pay Jazz a sum equal to the sum of all amounts previously paid by Jazz Pharmaceuticals to GSK hereunder, excluding the Purchase Price. In the event of such termination, the Parties will work together diligently to complete the reacquisition of the Purchased Assets by GSK within ninety (90) days following GSK's notice of termination and intent to reacquire the Purchased Assets. Jazz Pharmaceuticals shall provide assistance to GSK, on a level commensurate to the assistance provided by GSK to Jazz Pharmaceuticals pursuant to Section 2.2 and 2.3, to transfer and assign the Purchased Assets to GSK. In addition, Jazz Pharmaceuticals shall transfer to GSK all data generated by Jazz Pharmaceuticals regarding the Purchased Assets prior to termination by GSK pursuant to Section 9.2(a).

9.3 Survival. Termination of this Agreement will terminate all outstanding obligations and liabilities between the Parties arising from this Agreement except those described in Sections 2.1, 2.3, 2.5, 2.6 (except with respect to termination pursuant to Section 9.2(c)), 4.3, 4.4, 6.1, 6.2 and 9.2(b) and (c), 9.3, and Articles 1, 7, 8, 10, 11, and 12. Additionally, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement will also survive, but only to the extent required for the full observation and performance of this Agreement.

ARTICLE 10—DISPUTE RESOLUTION

10.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the following procedures if and when a dispute arises under this Agreement:

(a) Any such disputes will be first referred by either Party to senior representatives designated by each Party. If such senior representatives are unable to resolve such a dispute within thirty (30) days of being requested by a Party to resolve the dispute, the matter will be presented to the chief executive officers of Jazz Pharmaceuticals and GSK, for resolution through good faith discussions. In the event that the chief executive officers of Jazz Pharmaceuticals and GSK cannot resolve the dispute within thirty (30) days of being requested by a Party to resolve a dispute, either Party may, by written notice to the other, invoke the mediation provisions of Section 10.1(b).

(b) Upon invocation as provided by Section 10.1(a), the Parties agree to try in good faith to resolve such dispute by non-binding mediation administered by the Center for Public Resources ("CPR") in accordance with the then current CPR Model Procedure for Mediation of Business Disputes, provided that specific provisions of this Section 10.1(a) will override inconsistent provisions of such CPR Model Procedure. The mediator will be selected from the CPR Panel of Neutrals and the location of the mediation be selected by mutual agreement of the Parties, and absent such mutual agreement, will be New York, New York. If the Parties cannot agree upon the selection of the mediator or its location within ten (10) Business Days of the initiation of the mediation, then CPR will appoint the mediator and the mediator will select the location. The Parties will attempt to resolve such dispute through mediation until one of the following occurs: (i) the Parties reach a written settlement; (ii) the mediator notifies the Parties in writing that

they have reached an impasse; (iii) the Parties agree in writing that they have reached an impasse; or (iv) the Parties have not reached a settlement within sixty (60) days of the initiation of the mediation. All aspects of any such mediation, including any resolution or decision relating thereto, will be non-binding, and will be held as confidential and all participants, including the mediator, will be bound by judicially enforceable obligations of strict confidentiality except to the extent the Parties agree in writing to waive in whole or part such confidentiality.

(c) If the Parties fail to resolve such dispute through mediation, then either Party may take such other action as such Party deems appropriate in its sole discretion, including pursuing litigation against the other Party.

10.2 Injunctive Relief. Notwithstanding the foregoing dispute resolution procedures, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek restraining orders, specific performance or other injunctive relief without submitting to such dispute resolution procedure.

10.3 Tolling. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the procedures set forth in this Article 10 are pending, and the Parties will cooperate in taking any and all actions necessary to achieve such a result.

ARTICLE 11—CONFIDENTIALITY

11.1 "Confidential Information" means all information disclosed by a Party to the other Party that would reasonably be regarded as of a confidential or commercially sensitive nature by the disclosing Party, including any matter relating to or arising in connection with this Agreement or the business or affairs of the disclosing Party. Without limitation, Confidential Information will include any confidential or commercially sensitive information relating to Jazz Pharmaceuticals and GSK and any of its or their Affiliates. For purposes of clarification, up to and on the Time of Closing, the Purchased Assets will be deemed the Confidential Information of GSK and thereafter will be deemed the Confidential Information of Jazz Pharmaceuticals and no longer the Confidential Information of GSK.

11.2 Exclusions. Confidential Information excludes the following:

(a) information which at the time of disclosure hereunder is already in the public domain;

(b) information which becomes available to the public after the date of disclosure hereunder through no fault of the receiving Party;

(c) information which the receiving Party can demonstrate by written records that (i) it already possessed without any confidentiality obligation therefore at the time of receipt thereof from the disclosing Party or (ii) it or its employees independently developed without use of, or reliance on, the disclosing Party's Confidential Information; or

(d) information which the receiving Party receives from a Third Party which has no confidentiality obligation to the disclosing Party and duly possesses it.

11.3 Disclosure Required By Law. Notwithstanding the foregoing, Confidential Information may be disclosed to the extent required by law, regulation or order of a competent authority (including any regulatory or governmental body or securities exchange) to be disclosed by the receiving Party; provided that, where practicable, the disclosing Party is given reasonable advance notice of the intended disclosure and the right to attempt to protect the confidentiality of the Confidential Information before any governmental agency.

11.4 Confidential Information and the Grantback License. With respect to Confidential Information of Jazz Pharmaceuticals that may be necessary for GSK to exercise or sublicense the Grantback License, GSK, its Affiliates and sublicensees will maintain the confidentiality of such Confidential Information, and will only use such Confidential Information as may be required to exercise the Grantback License or sublicense thereof.

11.5 Publicity. Each of the Parties hereto agrees not to disclose to any Third Party the financial or other material terms of this Agreement without the prior written consent of the other Party hereto, except to advisors, investors and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law.

11.6 Publications. After the Closing Date **[*]** shall submit any proposed publication (or other public disclosure, such as a lecture, presentation or seminar) related to the Purchased Assets containing Confidential Information of **[*]** at least sixty (60) days prior to the proposed publication or public disclosure, to allow **[*]** to review such planned publication or public disclosure. **[*]** shall promptly review such proposed publication and respond in any event in writing to **[*]** within forty-five (45) days and make any objections that it may have to the publication or public disclosure of Confidential Information contained therein and if no response is received from **[*]** within such forty-five (45) day period, **[*]** may conclusively presume that the publication may proceed without delay. Should **[*]** make an objection to the publication or public disclosure of any such Confidential Information, then **[*]** will have no right to include the Confidential Information in such publication or public disclosure.

ARTICLE 12—MISCELLANEOUS

12.1 Assignment. This Agreement will not be assignable by either Party to any Third Party without the written consent of the other Party hereto. Notwithstanding the foregoing, either Party may assign this Agreement, without the written consent of the other Party, to an Affiliate or to an entity that acquires all or substantially all of the business or assets of such Party to which this Agreement pertains in connection with a merger, acquisition, sale or similar reorganization or the sale of all or substantially all of its assets or the sale of all or substantially all of its pharmaceutical and/or healthcare assets, and such Third Party agrees in writing to be bound by the terms and conditions of this Agreement. This Agreement will survive any such merger, acquisition or reorganization of either Party with or into, or such sale of assets to, another Third Party and no consent for such merger, acquisition, reorganization or sale will be required hereunder. This Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement will be void.

12.2 Consent/Approval. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval will not unreasonably be withheld, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval will not unreasonably be exercised.

12.3 Force Majeure. Neither Party will lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, earthquake, explosion, flood, strike, lockout, embargo, act of God, or any other similar or dissimilar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure.

12.4 Notices. All notices hereunder will be in writing and will be deemed given if delivered personally or by facsimile transmission (receipt verified), telexed, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as will be specified by like notice; provided, that notices of a change of address will be effective only upon receipt thereof). Further, any notice given by GGL and/or SB under this Agreement shall be deemed to have been given by GSK.

If to Jazz Pharmaceuticals:

Jazz Pharmaceuticals
3180 Porter Drive
Palo Alto, CA 94304
U.S.A.
Attn: General Counsel
Fax: 650.496.3781

If to GGL:

Glaxo Group Limited
Glaxo Wellcome House
Berkeley Avenue
Greenford, Middlesex, UB6 0NN,
UK
Attn: Corporate Secretary
Fax: 011.44.(0).20.8047.6904

If to SB:

SmithKline Beecham Corporation
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101
U.S.A.
Attn: Corporate Secretary
Fax: 215.751.5349

with a copy to:

GlaxoSmithKline
709 Swedeland Road
King of Prussia, PA 19406
UW 2214
U.S.A.
Attn: Head, Ventures Investment
Fax: 610.270.6299

and

GlaxoSmithKline
2301 Renaissance Blvd, RN0510
King of Prussia, PA 19406
U.S.A.
Attn: SVP and Associate General Counsel
R&D Legal Operations
Fax: 610.787.7084

12.5 No Waiver. The waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy will not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement or excuse a similar subsequent failure to perform any such term or condition. Neither Party may waive or release any of its rights or interests in this Agreement except in writing.

12.6 Invalidity of Provisions/Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance will, to any extent, be held to be invalid or unenforceable, then (i) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, will not be affected thereby and each term, covenant or condition of this Agreement will be valid and be enforced to the fullest extent permitted by law; and (ii) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

12.7 Entire Agreement. This Agreement, including the Schedules and hereto, constitutes the entire agreement between the Parties with respect to the transactions provided for herein and, except as stated in this Agreement and in the instruments and documents to be executed and delivered pursuant hereto, contains all of the agreements between the Parties and there are no verbal agreements or understandings between the Parties not reflected in this Agreement. This Agreement may not be amended or modified in any respect except by written instrument executed by each of the Parties.

12.8 Governing Law. This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the laws of the State of New York, U.S., without reference to conflicts of laws principles.

12.9 Performance Warranty. Each Party hereby warrants and guarantees the performance of any and all rights and obligations by its Affiliate(s).

12.10 Independent Contractors. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party will assume, either directly or indirectly, any liability of or for the other Party. Neither Party will have the authority to bind or obligate the other Party and neither Party will represent that it has such authority.

12.11 Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The Recitals and Annexes to this Agreement constitute an integral part of this Agreement. In the event of

any conflict or inconsistency between any of the terms and conditions of this Agreement, the conflict or inconsistency will be resolved according to the following order or priority: The Sections of the Agreement, the Annexes and the Recitals.

12.12 Payment of Transaction Expenses. All legal fees and other expenses incurred on behalf of GSK in connection with the negotiation of this Agreement and the consummation of the transactions contemplated herein will be borne by GSK, whether or not the Time of Closing shall have occurred. All legal fees and other expenses incurred on behalf of Jazz Pharmaceuticals in connection with the negotiation of this Agreement and the consummation of the transactions contemplated herein will be borne by Jazz Pharmaceuticals, whether or not the Time of Closing shall have occurred.

12.13 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing Party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such Party may be entitled.

12.14 Specific Performance. The Parties hereto agree that irreparable damage would occur in the event any provision of this Agreement was not performed in accordance with the terms hereof and that the Parties shall be entitled to specific performance of the terms hereof in addition to any other remedy at law or in equity.

12.15 Further Assurances. Each Party hereto shall execute and cause to be delivered to each other Party hereto such instruments and other documents, and shall take such other actions, as such other Party may reasonably request (prior to, at or after the Time of Closing) for the purpose of carrying out or evidencing any of the transactions contemplated by this Agreement.

12.16 Challenges by Each Party to the Agreement. Each of the Parties agrees that neither it nor any Affiliate will initiate or prosecute, or encourage or assist directly or indirectly any Third Party in initiating or prosecuting, any lawsuit attempting to challenge the validity of the transactions undertaken pursuant to this Agreement under any applicable law. In addition, GSK agrees that neither it nor any Affiliate shall seek to contest, or encourage or assist directly or indirectly any Third Party in contesting, the transfer of the Purchased Assets to Jazz Pharmaceuticals pursuant to this Agreement under any applicable law. Jazz Pharmaceuticals agrees that neither it nor any Affiliate shall seek to contest, or encourage or assist directly or indirectly any Third Party in contesting, the payment obligations of Jazz Pharmaceuticals to GSK hereunder under any applicable law.

12.17 Finder's Fee. Each Party represents that it neither is, nor will be, obligated for any finder's fee or commission in connection with this transaction. GSK agrees to indemnify and to hold harmless Jazz Pharmaceuticals from any liability for any commission or compensation in the nature of a finders' fee (and the costs and expenses of defending against such liability or asserted liability) for which GSK or any of its officers, partners, employees, or representatives is responsible. Jazz Pharmaceuticals agrees to indemnify and to hold harmless GSK from any liability for any commission or compensation in the nature of a finders' fee (and the costs and expenses of defending against such liability or asserted liability) for which Jazz Pharmaceuticals or any of its officers, employees or representatives is responsible.

12.18 Counterparts. This Agreement may be executed in two counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same instrument.

{Signatures continue on next page.}

IN WITNESS WHEREOF, the Parties have executed this Asset Purchase Agreement in duplicate originals by their duly authorized representatives as of the Effective Date.

GLAXO GROUP LIMITED

By: /s/ S. M. Bicknell
Name: S. M. Bicknell
Title: Company Secretary

JAZZ PHARMACEUTICALS, INC.

By: /s/ Carol Gamble
Name: Carol Gamble
Title: Senior Vice President and General Counsel

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE

By: /s/ Donald F. Parman
Name: Donald F. Parman
Title: Vice President and Secretary

SCHEDULE 1.1.20

Chemical Structure of GW273293

[*]

SCHEDULE 1.1.29

PATENTS TRANSFERRED TO JAZZ PHARMACEUTICALS

[*]

GW273293 [*]

[*]

Second Priority Application for [*]

Country	App./Date	App.Date	Patent No.	Status/ Grant Date
[*]	[*]	[*]	[*]	[*]

[*] GW273293 Process Case

Country	App./Date	App.Date	Patent No.	Status/ Grant Date
[*]	[*]	[*]	[*]	[*]

SCHEDULE 2.6

Licensed GSK Patents

[*]

Country	App No.	App.Date	Patent No.	Status/ Grant Date
[*]	[*]	[*]	[*]	[*]

[*]

Country	App No.	App.Date	Patent No.	Status/ Grant Date
[*]	[*]	[*]	[*]	[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

SCHEDULE 1.1.35

PURCHASED ASSETS

CLINICAL

#	Title	Author	Identifier	Date
[*]	[*]	[*]	[*]	[*]

PRECLINICAL TOXICITY, SAFETY AND EFFICACY

#	Title	Author	Identifier	Date
[*]	[*]	[*]	[*]	[*]

CHEMICAL AND PHARMACEUTICAL DEVELOPMENT

#	Title	Author	Identifier	Issue Date
[*]	[*]	[*]	[*]	[*]

SCHEDULE 1.1.35(c)

Quantities of GW273293 and other Compounds
Transferred to Jazz Pharmaceuticals

[*]

SCHEDULE A

BILL OF SALE

This is a BILL OF SALE from Glaxo Group Limited, a company incorporated under the laws of England and Wales with its registered offices at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN England ("GGL") and SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, a company incorporated under the laws of the Commonwealth of Pennsylvania with offices at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19101 U.S.A. ("SB") (GGL and SB are collectively referred to in this Bill of Sale as "GSK") to Jazz Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware with offices at 630 Hansen Way, Palo Alto, California 94304 U.S., ("Jazz Pharmaceuticals") pursuant to that certain Asset Purchase Agreement dated October 4, 2004 by and between GSK and Jazz Pharmaceuticals (the "Agreement").

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, GSK hereby sells, assigns, transfers, conveys, delivers and contributes to Jazz Pharmaceuticals, its successors and assigns, to have and to hold forever, all of its right, title and interest in and to the Purchased Assets (as defined in the Agreement), subject to all of the other provisions contained in the Agreement.

From and after the Closing Date (as defined in the Agreement) upon request of Jazz Pharmaceuticals, GSK will duly execute, acknowledge and deliver all such further acts, deeds, assignments, transfers, conveyances, powers of attorney and assurances as may be reasonably required to convey to and vest the Purchased Assets in Jazz Pharmaceuticals or its permitted assignees and as may be appropriate to protect Jazz Pharmaceuticals' rights, title and interest in and enjoyment of all the Purchased Assets and as may be appropriate otherwise to carry out the transactions contemplated by the Agreement and this Bill of Sale.

IN WITNESS WHEREOF, and intending to be legally bound, the undersigned has duly executed and delivered this Bill of Sale as of _____, 2004.

GLAXO GROUP LIMITED

By: _____
Name: _____
Title: _____

JAZZ PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE

By: _____
Name: _____
Title: _____

SCHEDULE B

ASSIGNMENT OF PATENT RIGHTS

Glaxo Group Limited, a company incorporated under the laws of England and Wales with offices at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 0NN England ("GGL") and SmithKline Beecham Corporation d/b/a GlaxoSmithKline, a company incorporated under the laws of the Commonwealth of Pennsylvania with offices at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19101 U.S.A. ("SB") (GGL and SB are collectively referred to in this Assignment as "Assignor"), hereby assign certain patent rights to Jazz Pharmaceuticals, Inc., a company incorporated under the laws of the State of Delaware with offices at 630 Hansen Way, Palo Alto, California 94304 ("Assignee").

Whereas, Assignor is the sole owner of the United States and foreign patents set forth on Exhibit 1 hereto (the "Patents"); and

Whereas, Assignor has agreed with Assignee for the transfer to it of Assignor's whole right, title and interest in and to such Patents and inventions described and/or claimed therein.

Now This Assignment Witnesseth that, for the consideration provided for in, and pursuant to that certain Asset Purchase Agreement between the Assignor and the Assignee dated October 4, 2004, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor, as beneficial owner, hereby assign and transfer to Assignee with full title guarantee the whole right, title and interest in and to the Patents covering the Purchased Assets, and any and all other patents in the United States of America or other countries which may be granted therefore and thereon, and in and to any and all reissues or extensions of the Patents or of such other patents, and the full exclusive benefits thereof, and all rights, privileges and advantages appertaining thereto, including the right to claim priority therefrom, including any and all rights to damages, profits or recoveries of any nature for past infringement of the Patents, and the payment of any and all maintenance fees, taxes, and the like, to hold the same unto and to the use of Assignee, its successors and assigns absolutely during the residue of the respective terms for which the Patents and such other patents were granted and during any such terms.

Assignor hereby covenants that Assignor has not executed and will not execute any agreements inconsistent with this Assignment.

Promptly upon Assignee's written request, Assignor hereby agrees to execute such additional form(s) of assignment for the foregoing Patents covering the Purchased Assets as may be required by the appropriate governmental authority of the United States of America or any foreign country for recordation of this Assignment. Without limitation, Assignor grants to Assignee the power to insert on this Assignment any further identification that may be necessary or desirable in order to record this Assignment.

Executed at _____, _____ this __ day of _____ 2004.

GLAXO GROUP LIMITED

By: _____
Name: _____
Title: _____

Executed at _____, _____ this __ day of _____ 2004.

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXOSMITHKLINE

By: _____
Name: _____
Title: _____

EXHIBIT 1 TO SCHEDULE B OF THE ASSET PURCHASE AGREEMENT

ASSIGNMENT OF PATENT RIGHTS

Assignor and Assignee hereby agree that this Exhibit 1 shall be identical to Schedule A to the Agreement. Assignee shall have the right to prepare multiple versions of this Exhibit 1 that list one or more of the Patents for a single country set forth on Schedule A for recordation with the appropriate governmental authority of such country.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKET BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

EXHIBIT 10.41

Execution Version

JAZZ PHARMACEUTICALS, INC.

AND

UCB PHARMA LIMITED

AMENDED AND RESTATED XYREM® LICENSE AND DISTRIBUTION AGREEMENT

AMENDED AND RESTATED XYREM LICENSE AND DISTRIBUTION AGREEMENT

This AMENDED AND RESTATED LICENSE AND DISTRIBUTION AGREEMENT (this **"Agreement"**) is made and entered into as of June 30, 2006 (**"Execution Date"**), by and between Jazz Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 3180 Porter Drive, Palo Alto, California 94304, USA (together with its Affiliates, **"Jazz Pharmaceuticals"**), and UCB Pharma Limited, a company organized under the laws of England having its principal place of business at 208 Bath Road, Slough, Berkshire, SL1 3WE (together with its Affiliates, **"UCB"**).

RECITALS

WHEREAS, Orphan Medical, Inc., a Delaware corporation ("**Orphan Medical**") and Celltech Pharmaceuticals, Ltd., a biopharmaceutical company organized under the laws of England ("**Celltech**") previously entered into that certain Xyrem License and Distribution Agreement (the "**Prior Agreement**") dated October 29, 2003 (**"Effective Date"**);

WHEREAS, under the Prior Agreement, Orphan Medical granted rights to commercialize the Product in certain territories within the field of narcolepsy and associated conditions;

WHEREAS, pursuant to Section 17.7 of the Prior Agreement, Orphan Medical assigned its rights and obligations under the Prior Agreement to Jazz Pharmaceuticals and all references to "Orphan Medical" in the Prior Agreement therefore have been replaced by "Jazz Pharmaceuticals";

WHEREAS, pursuant to Section 17.7 of the Prior Agreement, Celltech assigned its rights and obligations under the Prior Agreement to UCB and all references to "Celltech" in the Prior Agreement therefore have been replaced by "UCB"; and

WHEREAS, in accordance with Section 17.4 of the Prior Agreement, Jazz Pharmaceuticals and UCB wish to supersede and replace the Prior Agreement in its entirety with this Agreement to, amongst other things, (i) expand the Territory to include the Additional Countries (as defined below) on the terms and conditions of the Prior Agreement as amended herein and (ii) expand the Licensed Indications to include Fibromyalgia (as defined below) on the terms and conditions of the Prior Agreement as amended herein.

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Jazz Pharmaceuticals and UCB agree as follows:

ARTICLE I
DEFINITIONS AND INTERPRETATION

1.1 Definitions. In this Agreement:

"Affiliate" shall mean any corporation or non-corporate business entity controlled by, controlling or under common control with, a party to this Agreement. For the purpose of this definition, "control" shall mean the direct or indirect ownership or control of at least fifty percent (50%) of the voting stock of a corporation or a) in the absence of ownership of at least fifty percent (50%) of the voting stock of that corporation, or b) in the case of a non-corporate business entity, if it possesses, directly or indirectly, whether by virtue of an ownership interest of any kind, by contract or otherwise, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity or to elect or cause the election of a majority of the board of directors or other governing body of such corporation or non-corporate business entity. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals which are financial institutions, venture capital funds and private equity investors (other than a corporate venture fund which is an Affiliate of a publicly-traded pharmaceutical or biotechnology company) shall not be its "Affiliates" for purposes of this Agreement.

"Adverse Event" means the ICH guideline definition as further defined in the agreement entitled, "Agreement regarding the exchange of safety data between UCB S.A. and Jazz Pharmaceuticals, Inc. concerning Xyrem (sodium oxybate)" effective March 22, 2006 by and between the parties (a "**Pharmacovigilance Agreement**").

"API" means the active pharmaceutical ingredient sodium oxybate contained in the Product, having ATC code **[*]**.

"Claims" shall have the meaning provided in Section 9.1.

"Commercial Forecasts" shall have the meaning provided in Section 7.1.

"Commercially Reasonable Efforts" means those efforts that are commercially reasonable under the prevailing circumstances and which are no less than those that the applicable party would undertake for its own purposes in the Territory for one of its own pharmaceutical products with a similar profile and value to the Product (taking into account at all times the relevant patent, medical/scientific, technical, regulatory or commercial profile of the same).

"Competitive Product" shall have the meaning provided in Section 2.6.

"Components" means the dosing cups and lids, syringe, tamper resistant seal and PIBA included in the pack issued to customers along with each Product.

"Contract Year" means each twelve (12) month period during the Term of this Agreement starting on 01 January and ending on 31 December.

"Current Good Manufacturing Practices" or **"cGMP"** means the regulations set forth in 21 C.F.R. Parts 210 - 211, 820 and 21 C.F.R. Subchapter C (Drugs), Quality System Regulations and the requirements thereunder imposed by the FDA and EU Directive 2003/94/EC and 92/25/EEC or the equivalent regulations and requirements applicable in the Territory.

"DEA" means the United States Drug Enforcement Administration, or any successor thereto, having the administrative authority to regulate the scheduling and distribution of certain drugs in the United States.

"EMEA" means the European Medicines Evaluation Agency or any successor entity which coordinates the scientific review of human pharmaceutical products under the centralized licensing procedure in the European Union.

"FDA" means the United States Food and Drug Administration or any successor entity.

"Fibromyalgia" means the chronic pain syndrome (defined by widespread and longstanding pain sustained for at least three months determined by pain levels in response to the application of pressure in 11 of 18 tenderpoints) and its related symptoms (pain, stiffness, sleep disturbance, fatigue, mood disorders) diagnosed in patients as having fibromyalgia or fibromyalgia syndrome.

"Fibromyalgia Notice" means the written notice provided by UCB to Jazz Pharmaceuticals in accordance with Section 2.1 of this Agreement following receipt of the Final Advice Letter by UCB from Jazz Pharmaceuticals.

"Final Advice Letter" means a written letter provided by the Committee for Human Medicinal Products ("CHMP") to Jazz Pharmaceuticals (based on and referring to the submission of the Request for CHMP Scientific Advice dated April 25, 2006 for the conduct of registration trials with the Product in Fibromyalgia in Europe) which letter shall contain written recommendations and guidance regarding the use of the Product for Fibromyalgia.

"First Commercial Sale" means the first sale of the Product by or on behalf of UCB to a wholesaler, distributor or end-user in the Territory following Registration of the Product for a particular Licensed Indication(s) in the Territory.

"ICH" means International Conference on Harmonization of technical requirements for registration and manufacturing of pharmaceuticals for human use as may be amended from time to time.

"Indemnification Amounts" shall have the meaning provided in Section 9.1.

"Indication" means any medical condition or set of symptoms for the treatment of which a medicinal product is or may be prescribed.

"Improvements" means any and all modifications, amendments, improvements, inventions or discoveries (including, without limitation, manufacturing, manufacturing processes and procedures, analytical processes, procedures or methods and analytical results), any route(s) of synthesis, new formulations and/or delivery forms of or with respect to the API and/or Product (other than the current form of the Product as defined herein), including all information and data relating thereto, whether patentable or not, whether originating from Jazz Pharmaceuticals or from UCB, including copyrights, trademarks, patents, patent applications, trade secrets, NDAs and Know How.

"Know How" means data and information regarding toxicology, pharmacology, clinical trials, analytical methodologies, and use of the Product that is necessary or useful for UCB to fulfill its obligations hereunder, all of which is proprietary to Jazz Pharmaceuticals.

"LIBOR-3M" means the quarterly London Interbank Offered Rate.

"Licensed Indications" means (i) Narcolepsy, (ii) Fibromyalgia (only upon receipt of a Fibromyalgia Notice pursuant to Section 2.1 and receipt by Jazz Pharmaceuticals of the milestone payment set forth in Section 4.1(h) below), and (iii) any other Indication(s) for which UCB obtains the right to develop and commercialize the Product pursuant to Section 2.3 hereof. For clarity, if UCB does not deliver the Fibromyalgia Notice to Jazz Pharmaceuticals pursuant to Section 2.1 or fails to pay Jazz Pharmaceuticals the milestone payment set forth in Section 4.1(h) below, Fibromyalgia will not be considered a Licensed Indication for the purposes of this Agreement.

"Licensed Intellectual Property" shall have the meaning provided in Section 2.2.

"Major European Country(ies)" means France, Germany, Italy, Spain and the United Kingdom of Great Britain and Northern Ireland.

"Manufacturing Know How" means all data, information and materials relating to the manufacture of the Product that is not included in the Know How.

"Marketing Authorization" means a Regulatory Authority approval necessary to commercially promote and distribute the Product for a Licensed Indication including, where applicable, price and reimbursement approval which must be granted for the Product to be sold in any country. Marketing Authorization as applied to any country does not include the approval of a treatment IND (or any equivalent approval outside of the United States), pre-approval human use trials under a protocol or distribution of a product under an emergency use program, e.g., distribution on a Named Patient Basis.

"**Market Sales Price**" means the price for a Product approved by the Regulatory Authority in each country of the Territory, or in countries where pricing is not regulated, the price at which UCB sells that Product.

"Minimum Label Requirement" means the label achieved allows for, as a minimum, the treatment of pain associated with Fibromyalgia.

"Named Patient Basis" means any distribution of Product by Jazz Pharmaceuticals or UCB, as its designee, for sale prior to Registration of the Product for any Indication through approval by a Regulatory Authority in the Territory or as otherwise allowed by local law.

"Narcolepsy" means narcolepsy and its associated conditions, including without limitation, cataplexy and excessive daytime sleepiness.

"Narcolepsy Trademarks" means any trademarks for use with the Product in respect of the Narcolepsy Licensed Indication.

"NDA" means a New Drug Application filed by Jazz Pharmaceuticals with the FDA or any equivalent successor application for approval to commercially promote and distribute the Product in the United States.

"Net Sales" means for purposes of calculating the payments payable by UCB to Jazz Pharmaceuticals pursuant to Sections 4.1, 4.2, 4.3 and 4.4 of this Agreement, the gross sales prices received by UCB, its Subdistributors or Sublicensees from sales of the Product, not including Product samples, sold by or for UCB, its Subdistributors or Sublicensees to independent third parties in the Territory, after in each case, deduction of the following items allowed, given, granted, paid or borne by or for UCB, its Subdistributors or Sublicensees with respect to sales of the Product:

(a) bona fide discounts, credits, rebates, allowances, adjustments, rejections, recalls for which the customer has been credited the original sales price and returns;

(b) bona fide trade, quantity, or cash discounts or rebates customary to the industry and actually allowed, given or accrued (including, but not limited to, cash, governmental and managed care rebates, and hospital or other buying group chargebacks);

(c) sales, excise, turnover, inventory, value-added, and similar taxes assessed on the sale of such Product; and

(d) transportation, importation, insurance and other handling expenses.

For the avoidance of doubt, in order to avoid any double counting when determining Net Sales (i) Net Sales shall not include any royalties, proceeds or other amounts paid to UCB by any Sublicensee and (ii) if the gross sales price received by a Subdistributor from one or more sales has been counted, then Net Sales shall not include any royalties, proceeds or other amounts that are paid by such Subdistributor to UCB in connection with such sales.

"Orphan Drug Designation" means designation by the EMEA as an orphan drug, a drug for a specified rare disease or condition, or the equivalent designation by a Regulatory Authority of any country of the Territory.

"Other Licensed Trademarks" means any trademarks for use with the Product in relation to any Licensed Indication other than the Narcolepsy Licensed Indication.

"Patent Rights" means European patent **[*]** and any other patents listed on Appendix B hereto (including the inventions described and claimed therein), and any other future patents owned by or licensed to Jazz Pharmaceuticals necessary to make, use, sell or offer for sale the Product in the Territory, and any application for letters patent relating thereto, including, without limitation a continuation application, a continued prosecution application, a continuation in part application or a divisional application, and any supplementary protection certificates, extensions, substitutions, confirmations, divisions, continuations, continuations-in-part, patents issuing thereon and reissues or re-examinations thereof (each which shall be automatically incorporated in and added to this Agreement and shall periodically be added to Appendix B attached to this Agreement and made a part hereof).

"Person" means any individual, general or limited partnership, corporation, limited liability company, association, business trust, joint venture, regulatory authority, business entity or other entity of any kind or nature.

"PIBA" means a press-in-bottle adaptor.

"Product" means any Jazz Pharmaceuticals' proprietary pharmaceutical product containing the API as its active ingredient for use as a treatment for a Licensed Indication and all Components therefore (unless UCB shall elect to source such Components, at its own expense, from a Third Party as contemplated by Section 2.1(c)).

"Product Specifications" means specifications for the Product included in the relevant Regulatory Authority approval for a Licensed Indication, unless otherwise agreed in writing by Jazz Pharmaceuticals and UCB.

"Proprietary Information" shall mean the terms and provisions of this Agreement and all non-public information or data relating to the Product and the subject matter hereof first

communicated by or on behalf of one party to the other, whether in writing or orally, including without limitation, all scientific, clinical, commercial, financial and business information and data, know-how, compilations, formulae, processes, plans, technical information, new product information, compounds, formulations, methods of product-delivery, test procedures, product samples, specifications and other information or data.

"Quality Agreement" means the agreement effective July 6, 2004, as may be amended from time to time, by and between Orphan Medical Inc and Celltech Pharmaceuticals Ltd, or any further new quality agreement to be entered into by the parties.

"Registration" shall have occurred and shall continue in each country in the Territory when the Marketing Authorization required in respect of such country shall have been issued and shall continue to be effective.

"Regulatory Authority" means the EMEA and each other regulatory and drug scheduling or pricing authority equivalent to the FDA and DEA in the Territory or a country in the Territory, which has responsibility for scheduling or pricing drugs and/or approving Marketing Authorizations.

"Steering Committee" means the joint committee established pursuant to Section 3.8.

"Subdistributors" means any sub-distributor (exclusive of pre-wholesalers, wholesalers and Sublicensees) of the Product in the Territory appointed by UCB from and after the Effective Date pursuant to this Agreement.

"Sublicensee" means any Third Party who is licensed by UCB to promote, market, sell and distribute the Product in the Territory in consideration of the payment to UCB of a purchase price for the Product and royalties on sales of the Product to Third Parties.

"Term" shall have the meaning provided in Section 14.1 hereof.

"Territory" means all the countries set forth in Appendix A, as such Appendix may be amended from time by mutual written agreement of the parties.

"Third Party" means a Person who or which is neither a party to this Agreement nor an Affiliate thereof.

"Trademarks" means the Narcolepsy Trademarks and the Other Licensed Trademarks used for the Product including the trademarks set forth in Appendix B, as may be amended from time to time by Jazz Pharmaceuticals. As between Jazz Pharmaceuticals and UCB, all trademarks for the Product, including, but not limited to, the Narcolepsy Trademarks and the Other Licensed Trademarks, are owned by Jazz Pharmaceuticals.

"Transfer Price" means the price(s) Jazz Pharmaceuticals charges UCB for Product on a per bottle and per Component basis; provided, however, that the Transfer Price shall not exceed **[*]** of Jazz Pharmaceuticals' actual manufacturing cost for the Product, exclusive of Components plus, when Components are being purchased, **[*]** of Jazz Pharmaceutical's cost of Components. The constituents comprising Jazz Pharmaceuticals' standard manufacturing cost are listed on Appendix C, which also shows a Transfer Price of **[*]** for the Product including Components as of the date hereof.

"Weighted Average List Price" means UCB's total annual gross sales receipts for the Product received from UCB's customers in the Territory calculated based on the Market Sales Price, divided by the quantity of Product sold in the Territory.

1.2 Interpretation. In this Agreement:

(a) reference to:

(i) any statute or statutory provision includes a reference:

(A) to that statute or statutory provision as from time to time consolidated, modified, re-enacted (with or without modification) or replaced by any statute or statutory provision; and

(B) any subordinate legislation made under the relevant statutory provision;

(b) the singular includes the plural and vice versa and any gender includes other genders;

(c) the table of contents and the headings to clauses and schedules are to be ignored in construing this Agreement; and

(d) the schedules form part of this Agreement as if set out in full in this Agreement and a reference to "this Agreement" includes a reference to the schedules.

ARTICLE II
APPOINTMENT

2.1 Appointment. Subject to the terms and conditions of this Agreement, Jazz Pharmaceuticals hereby appoints UCB, and UCB accepts such appointment, as Jazz Pharmaceuticals' exclusive licensee and distributor of Product in the Territory; provided UCB

acknowledges that its appointment with respect to the Fibromyalgia Indication is contingent upon (i) UCB providing the Fibromyalgia Notice to Jazz Pharmaceuticals no later than the earlier of (A) the later of thirty (30) days after (x) the Execution Date and (y) receipt by UCB of a Final Advice Letter or (B) September 15, 2006 and (ii) making the milestone payment to Jazz Pharmaceuticals set forth in Section 4.1(h) below. Notwithstanding the foregoing, UCB shall only distribute, sell, market or otherwise commercialize Product in Mexico provided that the price of that Product shall be **[*]** of the **[*]** Product price in the USA. Furthermore, Jazz Pharmaceuticals hereby agrees to negotiate with UCB on an exclusive basis and in good faith **[*]** an amendment to this Agreement that would contain appropriate commercial terms upon which UCB shall be appointed the exclusive licensee and distributor of Product in Canada. Upon any such agreement being reached, Canada shall thereafter form part of the Territory; provided, however, that if the parties fail to reach such an agreement within the period set forth above, Jazz Pharmaceuticals shall be free to enter into an agreement with a Third Party with respect to the Product in Canada. During the Term of this Agreement, UCB shall purchase all of its requirements of the Product from Jazz Pharmaceuticals as the sole supplier subject to the following:

(a) UCB Manufacturing. Jazz Pharmaceuticals agrees to discuss with UCB the feasibility and commercial viability of transferring the manufacture of the Product to UCB's FDA approved facilities or qualifying and registering UCB as a back-up manufacturer for the Product for the Territory and/or for the rest of the world. Notwithstanding the foregoing, once aggregate Net Sales of the Product sold by or on behalf of UCB in the Territory have **[*]** then UCB shall have the option to notify Jazz Pharmaceuticals that it intends to transfer Product manufacturing to the facilities of UCB and/or its nominated Third Party no earlier than **[*]** from the date of UCB's initial notice to Jazz Pharmaceuticals. Following the exercise of UCB's option by notice in writing, Jazz Pharmaceuticals shall use its commercially reasonable efforts, at **[*]** expense for all **[*]**, to provide UCB with such assistance as is reasonable to take over manufacture or to obtain and qualify a Third Party manufacturer, including without limitation, giving effect to the licensing of its Manufacturing Know-How to UCB and/or such Third Party manufacturer (as the granting of such manufacturing license rights is thereby contemplated under Section 2.2) for the purposes of manufacturing API and/or Product. Jazz Pharmaceuticals will make available to UCB and/or its nominated Third Party, on a confidential basis and for use only to make the Product, such Manufacturing Know-How of Jazz Pharmaceuticals as may be reasonably necessary to make the Product. Such Manufacturing Know-How will not be used by UCB and/or its nominated Third Party for any other purpose or provided to any other Third Party without the prior written consent of Jazz Pharmaceuticals. Jazz Pharmaceuticals will work with UCB and/or its nominated Third Party to execute all documents and to take all action reasonably requested by Jazz Pharmaceuticals to preserve the confidentiality of such Manufacturing Know-How and Jazz Pharmaceuticals' intellectual property rights therein. UCB and/or its nominated Third Party will also use commercially reasonable efforts (including allowing Jazz Pharmaceuticals to negotiate an agreement not inconsistent with this Agreement regarding the

transfer of the Manufacturing Know-How directly with UCB's nominated Third Party concurrent with the time in which UCB is negotiating it supply agreement with such Third Party), to facilitate an agreement between Jazz Pharmaceuticals and such Third Party covering any improvements to the manufacturing process, so that Jazz Pharmaceuticals either owns such improvements, or has a worldwide, paid up, irrevocable, nonexclusive license, with the right to grant sublicenses, to such improvements to make, use, sell, offer to sell and import the Product. For the sake of clarity, UCB shall be free to enter into any agreement with a Third Party for the manufacture of the Product provided that such agreement provides, in Jazz Pharmaceuticals' reasonable opinion, appropriate safeguards for the protection of the Licensed Intellectual Property and Jazz Pharmaceuticals' Confidential Information and UCB has agreed to the terms and conditions required by Section 2.1(c) below. Notwithstanding the foregoing, any agreement between UCB and its nominated Third Party will restrict such Third Party's use of Jazz Pharmaceuticals' Manufacturing Know-How and Confidential Information solely to the manufacture of the Product only.

(b) UCB/ Third Party Manufacturing in the Event of Default. If at any time after December 31, 2007, (i) more than **[*]** percent (**[*]**%) of the aggregate Product supplied to UCB by Jazz Pharmaceuticals in any subsequent Contract Year is found, pursuant to Section 7.12, to have failed to conform to the Product Specifications and/or the relevant purchase order(s); or (ii) Jazz Pharmaceuticals is unable to manufacture or supply the quantity of Product ordered by UCB in accordance with this Agreement for any reason whatsoever, including, without limitation, by reason of an event described in Section 16.1 (Events of Force Majeure); then UCB shall have the right at its sole election to (A) take over the manufacture of the Product or appoint a Third Party manufacturer to fulfill Jazz Pharmaceuticals' manufacturing and supply obligations under this Agreement thereafter through the remaining Term of this Agreement and/or (B) purchase the API from Jazz Pharmaceuticals and itself convert, or appoint a Third Party manufacturer to convert, the API into Product through the Term of the Agreement; provided, however, that in the case of Section 2.1(b)(ii), such right shall be exercisable only if (1) Jazz Pharmaceuticals' inability to manufacture or supply the Product could reasonably be expected to result in a period of time of at least **[*]** during which less than **[*]** percent (**[*]**%) of Product ordered pursuant to UCB's last firm purchase order would be available to UCB for commercial sale, (2) UCB provides reasonable evidence of its ability to procure a Third Party manufacturer or take over the manufacture of the Product or the API more rapidly than Jazz Pharmaceuticals could restart production and supply of Product, and (3) Jazz Pharmaceuticals' inability to manufacture or supply Product did not result, wholly or in part, from a breach by UCB of its obligations hereunder. Jazz Pharmaceuticals shall, at **[*]** expense for all **[*]**, provide UCB with all reasonable assistance as is necessary to take over or obtain and qualify a Third Party manufacturer, including without limitation, giving effect to the licensing of its Manufacturing Know-How to UCB and/or such Third Party manufacturer (as the granting of such manufacturing license rights is thereby contemplated under Section 2.2) solely for the purpose of manufacturing API and/or Product pursuant to the terms of this Agreement.

(c) Price for Manufacturing Changes. In the event that UCB shall manufacture Product or API or cause Product or API to be manufactured pursuant to this Agreement, UCB agrees to pay Jazz Pharmaceuticals the following manufacturing royalties in accordance with Section 4.5 below:

(i) **[*]**% of Net Sales where UCB manufactures or has manufactured API; and

(ii) **[*]**% of Net Sales where UCB manufactures or has manufactured the Product (other than the API).

Any other related terms shall be negotiated in good faith by UCB and Jazz Pharmaceuticals. For the avoidance of doubt, the **[*]** royalty of **[*]**% of Net Sales under this Section 2.1(c) shall be payable by UCB to Jazz Pharmaceuticals only where UCB manufactures or has manufactured both the API and the Product.

(d) Component Sourcing. UCB shall be permitted at any time during the Term on sixty (60) days prior written notice to Jazz Pharmaceuticals to cease purchasing some or all Components from Jazz Pharmaceuticals and purchase some or all of the Components directly from Jazz Pharmaceuticals' suppliers or qualify another Third Party(ies) to supply Components; provided that, subject to Sections 7.6 and 7.12, UCB must purchase all Components delivered by Jazz Pharmaceuticals pursuant to a firm order regardless of whether such delivery is made after UCB delivers notice to Jazz Pharmaceuticals of its intent to purchase the Components from Jazz Pharmaceuticals' suppliers or another Third Party(ies). UCB shall bear any and all costs associated with qualifying any Third Party(ies) to supply Components pursuant to this Section 2.1(c); provided that if Jazz Pharmaceuticals desires to purchase the same Components from such Third Party(ies) as UCB is purchasing, then Jazz Pharmaceuticals and UCB shall **[*]** of any such costs.

(e) Manufacturing License. In the event that UCB assumed responsibility for the manufacture of the Product pursuant to this Section 2.1, UCB shall have a non-exclusive license under any necessary Licensed Intellectual Property during the Term, and subject to the terms of this Agreement, to make or have made the Product outside the Territory solely for sale and distribution in the Territory.

2.2 License Grant. Subject to the terms and conditions of this Agreement, Jazz Pharmaceuticals hereby grants UCB an exclusive nontransferable, royalty-bearing right and license (with the right of sublicense, as specifically set forth herein), to use the NDA, Know

How, Trademarks, Patent Rights and all Improvements and Proprietary Information of Jazz Pharmaceuticals related thereto or to the Product together with the goodwill associated therewith (the **"Licensed Intellectual Property"**) during the Term, solely in the Territory, to develop, make, have made, package, label, promote, market, sell, have sold, supply, distribute or otherwise commercialize Products in the Licensed Indications, or subject to Section 6.8 any other Indications on a Named Patient Basis, including without limitation (i) preparing applications for Marketing Authorizations and obtaining and maintaining Registrations for the Product in the Territory; and (ii) exercising its other rights under this Agreement including those provided in Articles X and XI hereof and making or having made API and/or Product but only as provided in Section 2.1. Subject to Section 2.3 and except as set forth in Section 6.8, no license is granted to UCB hereunder for any rights to market the Product for Indications other than the Licensed Indications. Except as provided in Section 14.6, the license set forth above shall terminate automatically upon termination of this Agreement. Subject only to the foregoing express license grant and its other rights as herein provided, UCB shall not have and shall not assert any claim, right, title or interest in or to the Licensed Intellectual Property.

2.3 Right of First Negotiation for Other Indications.

(a) Negotiation Notice. If, during the Term of this Agreement, Jazz Pharmaceuticals desires to pursue further development of the Product in the Territory for one or more Indications other than the Licensed Indications, Jazz Pharmaceuticals shall provide written notice to UCB (the "**Negotiation Notice**") of its intent to negotiate an agreement therefore. The Negotiation Notice shall identify the relevant Indication(s). Delivery of a Negotiation Notice shall create a mutual obligation to negotiate in good faith on an exclusive basis for the grant to UCB of exclusive rights to the Product for such Indication(s). If no response (a "**Negotiation Response**") is received by Jazz Pharmaceuticals **[*]** after delivery of the Negotiation Notice to UCB, the offer shall be deemed declined, and Jazz Pharmaceuticals may then negotiate with any Third Party for the grant of any license for the Product for such Indication(s) subject, however, to the last sentence of Section 2.3(b). Notwithstanding the foregoing, if UCB does not deliver the Fibromyalgia Notice to Jazz Pharmaceuticals in accordance with this Agreement, the development and commercialization of a product containing the API for the Fibromyalgia Indication by Jazz Pharmaceuticals or a Third Party will not be subject to UCB's right of first negotiation set forth in this Section 2.3.

(b) Procedure of Negotiations. UCB shall have **[*]** from the date of its delivery to Jazz Pharmaceuticals of a Negotiation Response to send a non-binding letter of intent or term sheet to Jazz Pharmaceuticals. The parties shall then have **[*]** from the date that UCB delivers such letter of intent or term sheet to Jazz Pharmaceuticals to negotiate in good faith (and on a confidential basis), and enter into a final agreement with regard to UCB's distribution of the Product in the Territory for the new Indication(s). In the event that (A) UCB shall have failed to

have responded to the Negotiation Notice **[*]** provided in Section 2.3(a) above or (B) failed to send a non-binding letter of intent or term sheet **[*]** set out in this Section 2.3(b) or (C) Jazz Pharmaceuticals and UCB have not entered into a final agreement **[*]** provided in this Section 2.3, Jazz Pharmaceuticals shall have no further obligation to undertake or continue negotiations with UCB for such license, and Jazz Pharmaceuticals shall be free to commence negotiations for a license to the Product for such Indication(s) with any Third Party subject to the following: (i) if a letter of intent, term sheet or final agreement with a Third Party shall not have been signed by Jazz Pharmaceuticals and such Third Party **[*]** of the termination of UCB's right of first negotiation, then UCB's right of first negotiation shall again become effective on the terms herein provided and (ii) without UCB's prior written consent, the terms and conditions agreed by Jazz Pharmaceuticals with such Third Party **[*]**.

(c) No Trademark License. If pursuant to this Section 2.3 Jazz Pharmaceuticals licenses to a Third Party the Product in the Territory for one or more Indications other than the Licensed Indications, then such Third Party shall be obligated to market the Product under a trademark different from the Trademarks. Jazz Pharmaceuticals shall not grant, license or otherwise transfer to such Third Party any rights to the Trademarks or otherwise permit any use of the Trademarks by such Third Party for such countries.

2.4 Subdistributors/Sublicensees. UCB may appoint Subdistributors and Sublicensees with the prior written approval of Jazz Pharmaceuticals, which approval shall not be unreasonably withheld. No such appointment or delegation shall relieve UCB from any obligations hereunder, and each agreement with a Subdistributor or Sublicensee shall include terms ensuring the protection of Jazz Pharmaceuticals' rights under this Agreement. UCB shall guarantee and be responsible for the making of all payments due, and the making of reports required under this Agreement by its Subdistributors and Sublicensees, and their compliance with all applicable terms of this Agreement. All agreements between UCB and its Subdistributors and Sublicensees shall include a provision prohibiting the further appointment of Subdistributors or Sublicensees, as the case may be, and a provision terminating the Subdistributor or Sublicensee agreement to the extent such agreement relates to the Product in the Territory upon termination of this Agreement for any reason.

2.5 UCB Sales Outside the Territory; Jazz Sales Inside the Territory. Except as otherwise set forth in this Agreement, UCB shall not distribute, sell or otherwise provide the Product outside of the Territory and shall not solicit customers for the Product outside the Territory or establish any office through which orders are solicited or any depot at which inventories of the Product are stored outside the Territory. UCB shall not sell the Product to customers outside the Territory, provided that nothing herein shall preclude UCB from selling the Product to any customer, wherever located, who purchases Product with a view to its use within any country of the Territory. Except as otherwise set forth in this Agreement, Jazz

Pharmaceuticals shall not sell the Product inside the Territory and shall not directly solicit customers for the Product inside the Territory; provided, however, that nothing herein shall preclude Jazz Pharmaceuticals from selling the Product to any customer, wherever located, who purchases Product with a view to its use within any country outside of the Territory.

2.6 Competitive Product. Jazz Pharmaceuticals acknowledges that (i) UCB has developed and is marketing methylphenidate in certain countries within the Territory for Indications other than the Licensed Indications, but that methylphenidate is occasionally used on an off-label basis to treat the Licensed Indications; (ii) UCB is marketing dexedrine in the United Kingdom for the Licensed Indications; and (iii) UCB will be marketing Equasym IR in France for the Licensed Indications. With the exception of the off-label use of methylphenidate in the Territory, dexedrine in the United Kingdom, and Equasym IR in France, UCB shall not, for **[*]** years from the Execution Date of this Agreement, either directly or indirectly through subdistributors, sublicensees or otherwise, promote, market or distribute Competitive Products in the Territory; provided, however, nothing herein shall prohibit UCB from acquiring, by stock purchase, asset purchase or merger any company, or division of a company, that is developing, marketing, manufacturing, promoting or distributing a Competitive Product where the annual sales (or in the case of a product in development, the projected sales) of such Competitive Product in the Territory are less than **[*]** of such company's or division's total annual sales. For purposes of this Section 2.6, a "**Competitive Product**" shall be one that is (i) approved for prescription for a Licensed Indication in the Territory and (ii) is directly competitive with the Product as evidenced by more than **[*]** of such product's annual sales in the Territory being for such Licensed Indication.

ARTICLE III
REGULATORY APPROVALS;
COMPLIANCE WITH LAWS AND REGULATIONS

3.1 Regulatory Approvals. For each Licensed Indication, UCB shall use Commercially Reasonable Efforts, at its expense, to seek Registration of the Product for each Licensed Indication in the Territory and UCB shall, in accordance with the terms of the Quality Agreement, maintain, at its own expense, the Registrations and other authorizations necessary to import, label, promote, market, sell and distribute the Product for each such Licensed Indication in the Territory. All applications for Marketing Authorizations for the Product shall be submitted in the name of UCB and all Marketing Authorizations for the Product shall be assigned to Jazz Pharmaceuticals upon termination of this Agreement for any reason. UCB shall ensure that all pages of documents submitted to Regulatory Authorities for the purpose of obtaining Registrations and Marketing Authorizations shall be coded as confidential. Notwithstanding the above, UCB shall have no obligation to use Commercially Reasonable Efforts to seek Registration of the Product for any Licensed Indication in any of the Major European Countries where a Regulatory Authority shall require of UCB any additional data or documentation or an additional action ("**Additional Step(s)**") and where any such Additional Step in a Major European Country would **[*]** or any series of Additional Steps in any one or more of the Major European Countries would, in aggregate, **[*]**.

3.2 Regulatory Timelines; Regulatory Assistance. Jazz Pharmaceuticals shall promptly provide to UCB, at Jazz Pharmaceuticals' cost and expense, copies of all documentation, Know How and Proprietary Information in its possession, and not previously provided, relating to the Product is necessary for UCB to prepare any relevant regulatory application for the Product in a relevant Licensed Indication in a timely manner as such documentation becomes available. Jazz Pharmaceuticals shall also promptly provide, at its own cost and expense, commercially reasonable assistance to UCB in obtaining and maintaining regulatory approval for the Product in the Territory for each Licensed Indication, including without limitation, the provision of services set forth in Appendix D hereto. Each party shall keep the other party informed of any significant or material issue including contact with Regulatory Authorities, related to their respective regulatory filings, submissions and approvals which might reasonably be expected to affect or impact the other party's regulatory activities in relation to the Product. Where a Regulatory Authority requires additional data or documentation or additional action that is not within Jazz Pharmaceuticals' obligations as set out in this Section 3.2 and that neither party has or could readily produce or which cannot readily be taken by either party, the parties shall negotiate in good faith the terms upon which such data or documentation should be generated or actions taken by either party, if at all.

3.3 Other Approvals. Subject to the provisions of this Agreement and the Quality Agreement, UCB undertakes and covenants that as soon as reasonably practicable following the Execution Date it shall take all other actions to obtain and maintain during the Term all other approvals, licenses and permits necessary to import, promote, market, package, sell and distribute Products in the Licensed Indications within the Territory.

3.4 Product Changes. Jazz Pharmaceuticals shall give UCB prompt written notice of any formulation or material packaging change to the Product submitted by Jazz Pharmaceuticals to the FDA or requested or required by the FDA, or any other U.S. regulatory authority, whenever such change may affect a Registration in any country within the Territory. Jazz Pharmaceuticals may change the Product, or analytical test methods as it deems appropriate, provided Jazz Pharmaceuticals continues to supply Product conforming to the Product Specifications and in accordance with cGMP then in effect (including continuing the use of the existing analytical test methods) until such times as the Marketing Authorizations are amended to reflect such changes. In the event of such changes, UCB shall be solely responsible for additional submissions and/or regulatory updates which may be required by the Regulatory Authorities in the Territory, provided that all necessary data and information in Jazz Pharmaceuticals' possession or control shall be furnished by Jazz Pharmaceuticals at Jazz Pharmaceuticals' expense for such purposes, and provided; further that in no event shall UCB's

failure to obtain any required amendments to the Marketing Authorizations to reflect such additional submissions and/or regulatory updates, relieve Jazz Pharmaceuticals of its obligation to supply Product conforming to the Product Specifications. In the event a Regulatory Authority in any country in the Territory requires a change to the Product Specifications, Jazz Pharmaceuticals and UCB shall cooperate to develop a mutually agreeable plan to address the regulatory requirement in accordance with the change management provisions of the Quality Agreement, as applicable, and, if necessary, to include the production of separate lots, at UCB's expense, for the Territory. In the event Jazz Pharmaceuticals and UCB mutually agree it is not commercially reasonable to meet such requirements, UCB shall cease promoting, marketing, selling and/or distributing the Product in that Licensed Indication in that country in the Territory and shall promptly terminate the Registrations in such country. If the parties are in disagreement as to whether it is commercially reasonable to meet such requirements, then they shall submit the matter to arbitration in accordance with the provisions of Section 15.2 of this Agreement.

3.5 Clinical Trials. The parties shall keep one another fully and currently informed through the Steering Committee as to all tests and trials of the Product that they intend to carry out for purposes of compliance with regulatory requirements or that might affect Marketing Authorization applications or Registrations in the Territory, provided always that if (i) Jazz Pharmaceuticals itself intends to conduct, or intends to have a Third Party conduct on its behalf, a test or trial of the Product in the Territory other than the clinical trials related to obtaining Marketing Authorization for the Product in Fibromyalgia and (ii) UCB reasonably determines that such proposed activity **[*]**, UCB shall be entitled to refer such proposed activity for due consideration by the Steering Committee. The parties shall cooperate in the design of such tests and trials in order to ensure to the maximum possible extent that duplication of effort shall be avoided, and that the results shall be suitable for filing with the Regulatory Authorities in the Territory and shall otherwise be useful for purposes of meeting all applicable regulatory requirements. Without limiting the generality of the foregoing, each party shall use its Commercially Reasonable Efforts to ensure that all clinical trials sponsored by that party which is undertaken for the Product after the Execution Date, if any, shall be designed and conducted in accordance with good clinical practices and good laboratory practices as established for both the United States and the European Union.

3.6 Compliance With Applicable Laws. UCB shall comply with all applicable laws and regulations of each country in the Territory (including, without limitation, any laws or regulations in the Territory governing the distribution of a scheduled drug, as designated under regulations promulgated by the DEA). UCB shall also comply with the U.S. Export Administration Regulations, the US Foreign Corrupt Practices Act and all regulations promulgated by the DEA, in each case, as applicable to the Registration, promotion, marketing, sale and distribution of the Product in the Territory. UCB shall comply with all Marketing Authorizations issued in the Territory and Jazz Pharmaceuticals shall comply with all regulatory

approvals issued in respect of the Product outside the Territory and/or for Indications other than Licensed Indications where, in the case of Jazz Pharmaceuticals, non-compliance could have a material adverse impact on the Product in the Territory.

3.7 Approved Product Packaging and Labeling; Relevant Testing. After Product in a particular Licensed Indication receives a Marketing Authorization in any country of the Territory, UCB shall, at its own expense, package and label such Product and shall include all required labeling for such Product sold in such country(ies). For all orders submitted by UCB after Registration is received in a particular country, Jazz Pharmaceuticals shall supply to UCB in bulk (manufactured in accordance with the cGMP requirements as set out in the Quality Agreement), and final labeling and packaging of Product for such country(ies) shall be completed by UCB. After Product receives Marketing Authorization in a country in the Territory for a particular Licensed Indication, UCB shall be solely responsible for all final release testing in such country(ies) and for ensuring in such country(ies) that the Product labeling and packaging complies with the relevant Marketing Authorizations and all other applicable laws of each such country in the Territory. UCB shall provide Jazz Pharmaceuticals with approved copies of all foreign language labels. To the extent permitted by applicable laws and regulations in each country in the Territory, where that Product has been manufactured by Jazz Pharmaceuticals all labels shall identify Jazz Pharmaceuticals as the manufacturer of the Product for UCB.

3.8 Steering Committee. Under the Prior Agreement, the parties have formed a Steering Committee made up of commercial and technical employees from both companies that has certain decision-making authority, and provide oversight for the administration of this Agreement. Each party shall maintain two (2) members on the Steering Committee with other members added as needed. The parties shall each select one of its representatives to serve as a co-chairperson of the Steering Committee. The Steering Committee shall have the authority to conduct the following activities and such other activities as may be agreed to in writing by the parties: (a) review ongoing regulatory issues, (b) review the medical aspects of standards of care in the Territory, (c) review clinical developments across territories to the extent permitted by Jazz Pharmaceuticals' agreements with Third Parties, (d) review marketing campaigns and new marketing plans, (e) review sales activities and results, (f) review aspects of Product manufacturing campaigns and Product forecasts, inventory stocks and ordering, and (g) establish a manufacturing sub-committee which shall review matters relating to the manufacture of Product. In the event and to the extent that the Steering Committee is unable to come to a consensus on any matter relating to the development (except to the extent that such development involves clinical trials that would occur solely in the Territory) or manufacture of the Product, Registration (including pre-Registration activities), packaging, labeling, promoting, marketing, sale or distribution of the Product outside the Territory, the views of the Jazz Pharmaceuticals Steering Committee members shall prevail. In the event and to the extent that the Steering

Committee is unable to come to a consensus on any matter relating to clinical trial activity that would occur solely in the Territory, Registration (including pre-Registration activities), packaging, labeling, promoting, marketing, sale or distribution of the Product within the Territory, and, if UCB has exercised its manufacturing option under Section 2.2, on any matter relating to the manufacture of the Product for sale within the Territory, the views of the UCB Steering Committee members shall prevail. Notwithstanding the foregoing, in the event a particular matter for which there is no consensus of the Steering Committee could, in the good faith judgment of the party who does not have the ultimate decision making authority as to such matter (as provided in the previous two sentences), materially affect the rights or obligations under this Agreement of such party, Jazz Pharmaceuticals and UCB shall attempt to resolve the matter in a manner which will minimize the impact on such rights or obligations of such party, but in default of agreement may be referred by either party to arbitration under Section 15.2. During each Contract Year, the parties shall hold at least four (4) regular meetings of the Steering Committee. Members of the Steering Committee may participate in meetings of the Steering Committee in person or by conference telephone call. At least one (1) of the four (4) Steering Committee meetings shall be conducted in-person. Employees of each party who are not members of the Steering Committee may attend meetings of the Steering Committee as required. In-person Steering Committee meetings shall alternate between Jazz Pharmaceuticals' designated facility and a facility designated by UCB. The co-chairpersons of the Steering Committee shall alternate responsibility for the preparation of minutes setting forth discussions made at each committee meeting, with the Jazz Pharmaceuticals Chairperson preparing minutes for the first Steering Committee meeting; provided, however, that such minutes shall not become official until agreed upon by both co-chairpersons.

ARTICLE IV
ROYALTIES AND MILESTONE PAYMENTS

4.1 Milestone Payments. In consideration of the rights and licenses granted hereunder, UCB has either already paid or shall pay to Jazz Pharmaceuticals non-refundable milestone payments according to the following schedule:

(a) $**[*]** Dollars on the Effective Date (receipt of which is acknowledged by Jazz Pharmaceuticals).

(b) $5,000,000 Dollars within five (5) days of the Execution Date.

(c) $**[*]** Dollars upon filing of Cataplexy Marketing Authorization application with the EMEA (receipt of which is acknowledged by Jazz Pharmaceuticals).

(d) $2,500,000 Dollars upon approval by the EMEA to commercially promote and distribute the Product for the cataplexy Licensed Indication (receipt of which is acknowledged by Jazz Pharmaceuticals).

(e) $500,000 Dollars upon pricing approval for the cataplexy Licensed Indication in France provided the price approved (ex works) is at least 115 Euros per 180 ml bottle.

(f) $**[*]** Dollars upon delivery to UCB by Jazz Pharmaceuticals of supplemental NDA package for the excessive daytime sleepiness Licensed Indication (receipt of which is acknowledged by Jazz Pharmaceuticals).

(g) $**[*]** Dollars upon approval by the EMEA to commercially promote and distribute the Product for the excessive daytime sleepiness Licensed Indication.

(h) $10,000,000 Dollars upon delivery of the Fibromyalgia Notice to Jazz Pharmaceuticals by UCB.

(i) $**[*]** Dollars upon Jazz Pharmaceuticals' written notice to UCB of the enrollment of the 200th patient in the first Phase III study in Fibromyalgia conducted by or on behalf of Jazz Pharmaceuticals.

(j) $**[*]** Dollars upon Jazz Pharmaceuticals' written notice to UCB of the completion of the last patient in the second Phase III study in Fibromyalgia conducted by or on behalf of Jazz Pharmaceuticals.

(k) A one-time only payment of either (i) $**[*]** Dollars upon approval by the EMEA (which would include a Major European Country) of the Product for the Fibromyalgia Licensed Indication where such approval has achieved the Minimum Label Requirement or (ii) $**[*]** Dollars upon the First Commercial Sale of Product for the Fibromyalgia Licensed Indication in a Major European Country where such approval has not achieved the Minimum Label Requirement, whichsoever such milestone is achieved first.

(l) A one-time only payment of $**[*]** Dollars in the first complete Contract Year in which UCB's and its Subdistributors annual Net Sales of Products covered by a Narcolepsy Trademark in the Territory exceed €14,565,000 Euros.

(m) A one-time only payment of $**[*]** Dollars in the first complete Contract Year in which UCB's and its Subdistributors annual Net Sales Products covered by a Narcolepsy Trademark in the Territory exceed €21,847,500 Euros.

(n) A one-time only payment of $**[*]** Dollars in the first complete Contract Year in which UCB's and its Subdistributors annual Net Sales of Products covered by a Narcolepsy Trademark in the Territory exceed €29,130,000 Euros.

(o) A one-time only payment of $**[*]** Dollars when UCB and its Subdistributors' Net Sales of Products covered by an Other Licensed Trademark in the Territory exceed $100,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

(p) A one-time only payment of $**[*]** Dollars when UCB and its Subdistributors' Net Sales Products covered by an Other Licensed Trademark in the Territory exceed $300,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

(q) A one-time only payment of $**[*]** Dollars when UCB and its Subdistributors' Net Sales Products covered by an Other Licensed Trademark in the Territory exceed $400,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

(r) A one-time only payment of $**[*]** Dollars when UCB and its Subdistributors' Net Sales Products covered by an Other Licensed Trademark in the Territory exceed $600,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

4.2 Notwithstanding the milestone payments set out in Section 4.1 above, in the event that (i) the Product is sold for the Fibromyalgia Licensed Indication by UCB using the same Trademark for the Product as for the Narcolepsy Licensed Indication in the Territory or (ii) there is sales leakage in the Territory between the Products covered by a Narcolepsy Trademark and the Products covered by an Other Trademark such that a Product is sold for a Licensed Indication not approved by the applicable Regulatory Authorities, the milestone payments set forth below in Sections 4.2 (a)—(g) shall be payable in place of the milestone payments set out in Sections 4.1 (l)—(r) to the extent that and only insofar as the milestone payments set out in Sections 4.1 (l)—(r) have not previously been paid by UCB to Jazz Pharmaceuticals;

(a) A one-time only payment of $**[*]** Dollars in the first complete Contract Year in which UCB's and its Subdistributors' annual Net Sales of the Product(s) in the Territory exceed €14,565,000 Euros irrespective of whether such sales reach that level in any subsequent period.

(b) A one-time only payment of $**[*]** Dollars in the first complete Contract Year in which UCB's and its Subdistributors' annual Net Sales of the Product(s) in the Territory exceed $30,000,000 Dollars irrespective of whether such sales reach that level in any subsequent period.

(c) A one-time only payment of $**[*]** Dollars in the first complete Contract Year in which UCB's and its Subdistributors' annual Net Sales of the Product(s) in the Territory exceed $35,000,000 Dollars irrespective of whether such sales reach that level in any subsequent period.

(d) A one-time only payment of $**[*]** Dollars when UCB's and its Subdistributors' annual Net Sales of the Product(s) in the Territory exceed $138,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

(e) A one-time only payment of $**[*]** Dollars when UCB's and its Subdistributors' annual Net Sales of the Product(s) in the Territory exceed $363,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

(f) A one-time only payment of $**[*]** Dollars when UCB's and its Subdistributors' annual Net Sales of the Product(s) in the Territory exceed $463,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

(g) A one-time only payment of $**[*]** Dollars when UCB's and its Subdistributors' annual Net Sales of the Product(s) in the Territory exceed $663,000,000 Dollars in any 12 month period irrespective of whether such sales reach that level in any subsequent period.

4.3 Royalty.

(a) In consideration of the licenses granted by Jazz Pharmaceuticals hereunder, UCB shall pay Jazz Pharmaceuticals quarterly royalties as follows:

(i) on each Product **[*]** in the Territory, **[*]**% of Net Sales of that Product by UCB and its Subdistributors in the Territory; and

(ii) on each Product **[*]** in the Territory:

(A) **[*]**% of Net Sales of such Products less than $**[*]** Dollars by UCB and its Subdistributors in the Territory in each Contract Year;

(B) **[*]**% of Net Sales of such Products between $**[*]** Dollars and $**[*]** Dollars by UCB and its Subdistributors in the Territory in each Contract Year; and

(C) **[*]**% of Net Sales of such Products equal to or greater than $**[*]** Dollars by UCB and its Subdistributors in the Territory in each Contract Year.

(b) Notwithstanding the milestone payments set out in Section 4.3(a) above, in the event that (i) the Product is sold for the Fibromyalgia Licensed Indication by UCB using the same Trademark for the Product as for the Narcolepsy Licensed Indication in the Territory or (ii) there is sales leakage in the Territory between the Products covered by a Narcolepsy Trademark and the Products covered by an Other Licensed Trademark such that a Product is sold for a Licensed Indication not approved by the applicable Regulatory Authorities, UCB shall pay Jazz Pharmaceuticals the following quarterly royalties, in place of the quarterly royalties set out in Section 4.3(a), beginning with the quarter in which such First Commercial Sale of Product for the Fibromyalgia Indication occurs:

(i) **[*]**% of Net Sales of the Product(s) less than $**[*]** Dollars by UCB and its Subdistributors in the Territory in each Contract Year;

(ii) **[*]**% of Net Sales of the Product(s) between $**[*]** Dollars and $**[*]** by UCB and its Subdistributors in the Territory in each Contract Year; and

(iii) **[*]**% of Net Sales of the Product(s) equal to or greater than $**[*]** Dollars by UCB and its Subdistributors in the Territory in each Contract Year.

(c) The royalty rates set forth above shall be reduced **[*]**% as of the date when UCB ceases to have the exclusive right in **[*]**, enforceable against Third Parties, to promote, market and sell the Product in at least one Licensed Indication because of the expiration or termination in the Territory of Patent Rights and/or regulatory exclusivity based on that Product's Orphan Drug Designation in the Territory. The royalty rate shall be further reduced **[*]**% for a Product covered by a Trademark on a country-by-country basis, following the first calendar quarter in which the commercial sale in such country of **[*]**, approved for a Licensed Indication by the applicable Regulatory Authorities, occurs in such country in the Territory.

(d) If (i) Jazz Pharmaceuticals licenses a product containing the API in the Territory to a Third Party for one or more Indications other than the Licensed Indications pursuant to Section 2.3(b), and (ii) such product containing the API licensed in the Territory to such Third Party by Jazz Pharmaceuticals is being used **[*]** and **[*]** percent (**[*]**%) of UCB's sales of the Product in a country in the Territory, and (iii) UCB can demonstrate that **[*]** result in a **[*]** in such countries in the Territory and/or a **[*]** in any countries in the Territory, then **[*]**, the royalty rate in such affected countries in the Territory for the Product covered by such Licensed Indication shall be **[*]** percent (**[*]**%), in such affected countries, to appropriately compensate UCB for such **[*]**. As part of its demonstration of such **[*]**, UCB shall obtain at its expense, and furnish to Jazz Pharmaceuticals, a report compiled by a recognized market research company having substantial expertise in the pharmaceutical industry, which sets forth both the **[*]** or sets forth other relevant information demonstrating that **[*]**.

4.4 Minimum Royalty Requirement. Commencing with the Contract Year beginning **[*]** if the royalties payable pursuant to Section 4.3 shall be less than the amounts set forth in this Section 4.4, then UCB shall pay such additional royalty amounts to Jazz Pharmaceuticals so that Jazz Pharmaceuticals shall have received aggregate royalty payments with respect to Net Sales of the Products in the Territory equal to the following minimum amounts (reducing the minimum for the Contract Year beginning **[*]** proportionally for the days therein prior to the date of the First Commercial Sale); provided, however that the following minimum royalty amounts shall be adjusted by written agreement of the parties after the Effective Date as appropriate to take into account any royalty rate reductions determined in accordance with Section 4.3(c) and (d):

	Minimum Royalty Payment (US$)		
Year	**[*]% or more**	**[*]%**	**[*]%**
[*]	**[*]**	**[** *]	**[** *]

4.5 Royalty and Milestone Payments. Unless otherwise agreed by Jazz Pharmaceuticals in writing, all milestone payments set forth in Sections 4.1 and 4.2 shall be payable within thirty (30) days after achievement of the relevant milestone, except for the milestone payments due on the Effective Date and the Execution Date under Sections 4.1(a) and 4.1(b), which shall be due and payable by UCB no later than ten (10) days after the Effective Date or Execution Date, as applicable. Royalty payments shall be paid within forty-five (45) days from the end of each calendar quarter and any additional royalty amounts payable as stated in Section 4.4 shall be paid within forty-five (45) days of the end of each Contract Year. All payments shall be made in United States Dollars by wire transfer to a USA bank designated by Jazz Pharmaceuticals. Any overdue payment from UCB to Jazz Pharmaceuticals under this Agreement shall accrue interest at **[*]**.

4.6 Exchange Rates. For purposes of determining the amount of Net Sales and the amount of royalties payable pursuant to Section 4.3 during any calendar quarter, the total of all sales in each currency during such quarter shall be converted into Euros or US Dollars, as applicable, at the average daily exchange rate for such calendar quarter as reported by Bloomberg. For purposes of determining the minimum royalty amount for each Contract Year as provided in Section 4.4, the amounts set forth therein shall be converted into US dollar currency at the average daily exchange rate for such Contract Year as reported Bloomberg.

4.7 Taxes. UCB shall be entitled to deduct from royalties paid hereunder the amount of any withholding taxes or other taxes, levies or charges required to be withheld by UCB, to the extent UCB pays to the appropriate governmental authority on behalf, and for the account of, Jazz Pharmaceuticals such taxes, levies or charges. UCB shall use reasonable efforts (including making, or assisting Jazz Pharmaceuticals in making, any relevant application to any tax authority) to minimize any such taxes, levies or charges which are required to be withheld by UCB from royalties paid hereunder and paid on behalf of Jazz Pharmaceuticals by UCB. UCB shall promptly deliver to Jazz Pharmaceuticals proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

4.8 Reports. Each royalty payment made by UCB hereunder shall be accompanied by a report showing all revenue generated by sales of the Product to Third Parties (including all sales by Subdistributors and Sublicensees) during the immediately preceding quarter, the computation of Net Sales, and the calculation of royalty payments due for such quarter, including

all exchange rate conversions related thereto and all on a country-by-country basis. If actual Net Sales of any Subdistributor or Sublicensee for that quarter is unavailable at the time such quarterly report is due, UCB shall include in its report for that quarter a good faith estimate of such Net Sales, and an appropriate adjustment for the difference between the actual and estimated Net Sales shall be made in the report for the following quarter, with a corresponding adjustment in the amount of royalties payable in respect of that quarter.

4.9 Books and Records; Audit. UCB shall keep for at least three (3) years or such longer period as may be required by law following the end of the calendar year to which they pertain, accurate and complete records showing all sales of the Product by UCB and its Subdistributors and Sublicensees. Such records shall include all information reasonably necessary to verify the total amount and computation of earned royalties and milestones hereunder, and shall be open to inspection and audit, during reasonable business hours, to the extent necessary to verify the amount of such royalties. Such inspection and audit shall be conducted at the request and expense of Jazz Pharmaceuticals by an independent Certified Public Accountant appointed by Jazz Pharmaceuticals. Such inspection and audit shall be made not more often than **[*]**. Such Certified Public Accountant shall undertake a confidentiality obligation to UCB permitting it to disclose only to Jazz Pharmaceuticals the amount of the payments due hereunder, and no other information. Jazz Pharmaceuticals shall bear the costs of any such inspection and audit; provided that if any inspection and audit reveals an underpayment of more than **[*]** percent (**[*]**%), UCB shall reimburse Jazz Pharmaceuticals for its reasonable, documented out-of-pocket costs for such inspection and audit.

ARTICLE V
REGULATORY COMPLIANCE; PRODUCT MANUFACTURE

5.1 Regulatory Reporting. UCB shall timely file all reports relating to the Product required by the Regulatory Authorities in each country in the Territory and shall deliver a copy of each such report in hardcopy and on diskette, or electronically, to Jazz Pharmaceuticals within thirty (30) calendar days of making such report in accordance with laws in the Territory regarding transfer of data and confidentiality of patient information.

5.2 Product Recalls. (a) Each party shall promptly notify the other party in the event of any recall, market withdrawal or correction of Product ordered by any regulatory authority, whether in the Territory, the United States, or anywhere in the world. The parties shall cooperate in good faith in relation to the handling and disposal of a recall, market withdrawal or correction in the Territory. The costs of any such recall, market withdrawal or correction shall be borne by the parties in accordance with Sections 5.2 (b) and (c) below.

(b) Subject to Section 5.2(c) below, in the event of a recall, market withdrawal or correction (i) by reason of the failure of all or part of the Product supplied by Jazz

Pharmaceuticals to meet the Product Specifications, any requirement of the FDA or any Marketing Authorization or other requirement of applicable law that is not the result of any action or omission of UCB or its Subdistributors or Sublicensees as described in paragraph (c) below or (ii) because Product that meets the Product Specifications, supplied by Jazz Pharmaceuticals, is inherently defective, unsafe, dangerous or may harm users of the Product, Jazz Pharmaceuticals shall bear the costs of such recall, market withdrawal or correction (including without limitation UCB's reasonable attorneys' fees).

(c) In the event of a recall, market withdrawal or correction by reason of the failure of UCB to have obtained or properly maintained or complied with a Marketing Authorization or as a result of UCB's (or its Subdistributors', Sublicensees' or Third Party manufacturers') breach of any of their obligations under this Agreement (including without limitation Section 3.7), or the willful misconduct or negligent acts or omissions of UCB (or its Subdistributors, Sublicensees' or Third Party manufacturers'), UCB shall bear all costs of such recall, market withdrawal, or correction (including without limitation Jazz Pharmaceuticals' reasonable attorneys' fees).

5.3 Adverse Event Notifications and Reporting. The exchange of Adverse Event reports relating to the Product between the parties shall be made according to the procedures set forth in the Pharmacovigilance Agreement.

5.4 Correspondence/Complaints. (a) Each party shall promptly provide to the other party copies of any material regulatory correspondence with respect to the Product and all related documentation, information and other materials received or prepared by each party, including, in the case of UCB, copies of the proposed applications for Marketing Authorization prepared by or on behalf of UCB for Registration of Products in the Territory and any subsequent amendments, supplements, or annual updates thereto.

(b) Each party agrees to inform the other in writing of all significant complaints regarding the Product received by that party which relate to Product Specifications within fifteen (15) business days after that party's receipt thereof in all countries of the Territory. Each party shall also provide written quarterly reports of all material complaints received by it regarding the Product, regardless of significance, in English, as well as the actions taken by it to address all such complaints. Such reports shall be delivered to the other party within thirty (30) days after the end of each calendar quarter during the Term.

5.5 Translations. UCB shall provide Jazz Pharmaceuticals English translations of any material regulatory correspondence received in a language other than the English language relating to a Serious Adverse Event (as defined in the Pharmacovigilance Agreement). Furthermore, each party shall provide to the other party copies of translations of any other regulatory correspondence and reports delivered pursuant to Sections 5.1, 5.3, 5.4 or the Quality Agreement to the extent the providing party has otherwise translated such correspondence and reports for its own purposes.

5.6 Manufacture; Quality. Subject to Article VII, Jazz Pharmaceuticals agrees to manufacture UCB's requirements for Product as necessary to satisfy UCB's forecasts and purchase orders submitted by UCB pursuant to this Agreement. Products delivered to UCB pursuant to this Agreement shall be manufactured in accordance with this Agreement and the Quality Agreement.

5.7 Product Specifications. Product supplied to UCB by Jazz Pharmaceuticals shall meet the Product Specifications and shall be produced in compliance with the terms of the Quality Agreement, as applicable, provided, however, in the event that a Regulatory Authority in the Territory requires a change to the Product Specifications in effect on the Execution Date, the cost of such changes shall be borne by UCB.

5.8 Manufacturing Audits by UCB. Upon forty-five (45) days prior written notice, unless earlier if agreed to by the parties, for cause, or with one hundred twenty (120) days written notice, unless earlier if agreed to by the parties, for an annual audit, UCB or a representative thereof shall have the right, if it is within Jazz Pharmaceuticals' power to grant such right, to participate in the conduct of compliance or other inspections, audits and/or investigations of the operations and facilities where the Product and the raw materials and components used to manufacture, package, inspect, test, store and supply the Product, including, without limitation, the API and the Components, are manufactured, packaged, inspected, tested and stored. Notwithstanding the above, Jazz Pharmaceuticals shall use commercially reasonable efforts to obtain the right for UCB to participate in the conduct of such inspections, audits and/or investigations. Such inspections, audits and/or investigations shall be carried out in accordance with the procedures set out in the Quality Agreement and shall take place during normal business hours at the relevant manufacturing site(s) in the presence of UCB and Jazz Pharmaceuticals' representatives. UCB shall abide by any reasonable confidentiality requirements or security procedures of Jazz Pharmaceuticals' suppliers. Jazz Pharmaceuticals shall facilitate and lead the audit (and shall use its commercially reasonable efforts to ensure that its sub-contractors and suppliers facilitate such an audit), and it shall be Jazz Pharmaceuticals' responsibility to discuss any audit findings with its sub-contractors and suppliers. UCB and Jazz Pharmaceuticals along with any other licensing partner will agree upon a final single audit report that will be sent to the vendor by Jazz Pharmaceuticals. In the event of any disagreement among the parties relating to the audit report, Jazz Pharmaceuticals shall be the deciding entity and will finalize the audit report. Jazz Pharmaceuticals shall use its commercially reasonable efforts to require its sub-contractors and suppliers to take all reasonably necessary corrective actions identified by UCB as necessary to comply with cGMP requirements and Registrations in the Territory. **[*]** Jazz Pharmaceuticals is generally allowed [*] each year of each vendor. If additional costs are imposed due to accompaniment of UCB with Jazz Pharmaceuticals during an annual audit, UCB shall bear the burden of any reasonable additional costs.

ARTICLE VI
MARKETING EFFORTS

6.1 Marketing Efforts. UCB shall have, directly or through its Subdistributors or Sublicensees, the following obligations with respect to the marketing and distribution of the Product in the Territory:

(a) To use its Commercially Reasonable Efforts to promote, market, sell and distribute Products for the Licensed Indications in the countries in the Territory where Registrations are in good standing; provided, however, that UCB shall not be required to market a Product in any country in the Territory where **[*]** and the **[*]**;

(b) To promptly respond to all inquiries or complaints from purchasers of the Product;

(c) To maintain adequate and qualified staff to enable it to fully perform its obligations hereunder;

(d) To provide adequate and appropriate training to its staff concerning the Product; and

(e) To conduct its business in a professional manner.

6.2 Approved Product Claims. UCB shall not make and shall cause its Subdistributors and Sublicensees to not make claims to any Third Party concerning the Product except as contained in or permitted by the relevant Marketing Authorization or as approved in the Territory by the appropriate Regulatory Authority.

6.3 Development of Marketing Strategy. UCB agrees to cooperate in the development of a consistent message strategy to promote the Product in an effort to protect and strengthen branding. The global positioning of the Product for the U.S. and the Territory should be discussed before UCB launches the Product in a country in the Territory and at least once per year (or more frequently if reasonably requested by Jazz Pharmaceuticals) to ensure a message which is consistent with the local Marketing Authorizations and local treatment guidelines in such country, and, where possible, consistent with the international message. UCB and Jazz Pharmaceuticals agree to work in good faith to develop such a strategy.

6.4 Marketing Materials. UCB agrees to provide Jazz Pharmaceuticals with copies of all significant marketing and promotional materials within thirty (30) days of first use. UCB shall be solely responsible for the text, graphics, and compliance of such materials with the laws and regulations of the Territory, but may rely (without further investigation) on all Product information provided by Jazz Pharmaceuticals, except that UCB may not rely on such information to the extent UCB knows or reasonably should know that such information is inaccurate.

6.5 Sales and Technical Literature Developed by Jazz Pharmaceuticals. From time to time during the Term, Jazz Pharmaceuticals shall provide to UCB samples of such training, sales and technical literature and materials relating to the Product as Jazz Pharmaceuticals may have prepared, including, without limitation, the materials set forth on Appendix D hereto, and shall make available copies of promotional artwork it may have. The cost of printing quantities or customizing materials shall be borne by UCB. Jazz Pharmaceuticals shall provide the same to UCB in electronic format. Jazz Pharmaceuticals shall also provide UCB with copies of all post-marketing studies and updates to its regulatory filings that it provides to the FDA. UCB shall use such materials solely as provided under this Agreement. Jazz Pharmaceuticals retains all right, title and interest in and to such materials subject, however, to the terms of this Agreement.

6.6 Marketing Reports. By 31 March of each Contract Year, UCB shall provide Jazz Pharmaceuticals with a written report summarizing its sales and marketing activities across the Territory for the immediately preceding Contract Year, and sales and marketing plans for the Territory, including sales estimates, for the current Contract Year.

6.7 Cooperation. Jazz Pharmaceuticals and UCB agree to maintain open communications relating to the ongoing performance of this Agreement to ensure joint understanding of current or new issues, data, and information. Jazz Pharmaceuticals shall answer reasonable technical or marketing questions UCB may submit to Jazz Pharmaceuticals. UCB acknowledges that Jazz Pharmaceuticals does not have international marketing and regulatory staff for preparation of regulatory submissions and marketing plans. Jazz Pharmaceuticals and UCB agree to provide each other copies of market research study protocols and subsequent results therefrom, which studies are designed to generate qualitative and/or quantitative data pertaining to the Product, subject to any Third Party rights therein.

6.8 Named Patient Basis Sales. UCB will be responsible for Named Patient Basis distribution of the Product in the Territory; provided, however, that if Jazz Pharmaceuticals licenses the Product to a Third Party in the Territory for any indication other than the Licensed Indications (each, an "**Additional Indication**"), UCB will, upon Jazz Pharmaceuticals' written request, cease all Named Patient Basis distribution activities in the Territory with respect to the Product for such Additional Indication(s). The sale of the Product on a Named Patient Basis by UCB will be subject to all of the terms and conditions of this Agreement and all such sales shall

be included in calculating the Net Sales of the Product and the payments payable to Jazz Pharmaceuticals by UCB pursuant to this Agreement. The parties acknowledge that nothing set forth in this Section 6.8 is intended to give UCB rights to the Product for any countries or Indications in addition to, or broader than, those granted pursuant to this Agreement.

ARTICLE VII
PURCHASE AND DELIVERY OF PRODUCT

7.1 Forecasts. UCB will provide Jazz Pharmaceuticals with rolling **[*]** calendar quarter forecasts (**"Commercial Forecasts"**) of its anticipated requirements of Product to assist Jazz Pharmaceuticals to adequately plan for and meet UCB's requirements for each country in the Territory. Each Commercial Forecast after the first (i) shall cover the **[*]** calendar quarters commencing with the second calendar quarter of the preceding Commercial Forecast (ii) shall be delivered to Jazz Pharmaceuticals at least **[*]** days prior to the first day of such **[*]** calendar quarter period and (iii) without Jazz Pharmaceuticals' written consent may not forecast an aggregate quantity of Products that is more than **[*]** the aggregate quarterly forecast in the preceding Commercial Forecast. The quantities of Product for the first two calendar quarters of each Commercial Forecast shall be firm and UCB shall be obligated to submit purchase orders in respect thereof ("**Firm Orders**"). The quantities of Product for the remaining **[*]** calendar quarters in each Commercial Forecast shall be non-binding estimates based on UCB's reasonable business judgment.

7.2 Pricing. Subject to Sections 2.1(b) and 2.1(d) hereto, during the Term of this Agreement, UCB shall purchase from Jazz Pharmaceuticals all of its requirements of the Product in the Territory for the Transfer Price, plus any applicable customs duties or VAT.

7.3 Shipments. Shipments of Product shall be made ex-works ("**EXW**") (as such term is defined in INCOTERMS 2000) Jazz Pharmaceuticals' designated supplier unless otherwise mutually agreed to in writing by the parties. Risk of loss or of damage to Product shall remain with Jazz Pharmaceuticals until Product is loaded onto the carrier's vehicle by Jazz Pharmaceuticals' designated supplier for shipment at the shipping point at which time risk of loss or damage shall transfer to the UCB. Jazz Pharmaceuticals shall, in accordance with the UCB's instructions and as agent for UCB, (i) arrange for shipping to be paid by UCB and (ii) at UCB's risk and reasonable expense, obtain any export license or other official authorization necessary to export the Product from the United States once UCB has provided the appropriate import documentation. UCB shall arrange for insurance and shall select the freight carrier used by Jazz Pharmaceuticals to ship Product and may monitor Jazz Pharmaceuticals' shipping and freight practices as they pertain to this Agreement. Jazz Pharmaceuticals shall deliver the Products no later than **[*]** business days after the date(s) indicated in the applicable purchase order and no earlier than **[*]** business days prior to such specified date(s). Jazz Pharmaceuticals shall provide prompt written notice to UCB in the event of any anticipated delays in the scheduled

delivery date and shall cooperate with UCB to reschedule delivery at the earliest possible date so as to minimize the impact on UCB, provided, however, the foregoing shall in no way modify or mitigate Jazz Pharmaceuticals' obligation to supply Product properly ordered in accordance with this Agreement or UCB's rights and remedies under this Agreement in respect of any failure to timely supply, including UCB's right to assert its remedies in respect of a breach hereof and UCB's rights to appoint a Third Party manufacturer in accordance with Section 2.1(b) or to terminate this Agreement in accordance with Section 14.2(b). Jazz Pharmaceuticals shall send UCB on the date of shipment an invoice and shipping notice, in a format to be agreed upon by the parties. All Products shall be properly packaged and shipped in accordance with the Product Specifications and instructions included in the applicable purchase order.

7.4 Purchase Orders.

(a) Content. All purchase orders placed by UCB shall be in writing and shall state the quantity of Product, the delivery date, shipping information and such other similar information as may be reasonably requested by Jazz Pharmaceuticals.

(b) Lead Time. Unless otherwise agreed by Jazz Pharmaceuticals, all purchase orders must be delivered to Jazz Pharmaceuticals at least **[*]** in advance of the requested delivery date(s).

(c) Number of Orders. UCB may submit **[*]** per quarter for Product to be filled by Jazz Pharmaceuticals.

(d) Maximum Quantities. Jazz Pharmaceuticals may in its sole discretion reject Firm Orders that specify a quantity of Product in respect of a particular calendar quarter in excess of **[*]**% of the most recent non-binding Commercial Forecast for such quarter; provided, however, that the maximum quantities that Jazz Pharmaceuticals shall be required to deliver in a particular calendar quarter shall be reduced by the quantity of Product Jazz Pharmaceuticals shall have delivered in the preceding calendar quarter pursuant to paragraph (e) below in excess of the maximum quantities it was required to provide in such preceding calendar quarter as determined pursuant to this paragraph (d).

(e) Miscellaneous. Jazz Pharmaceuticals shall use its Commercially Reasonable Efforts to fill purchase orders that exceed the quantity limits provided in paragraph (d) above or that are delivered to Jazz Pharmaceuticals **[*]** days in advance of the requested delivery date(s) as required by paragraph (b) above in respect of purchase orders to be filled by Jazz Pharmaceuticals. No accepted purchase order may be modified or canceled by either party except as agreed in writing by the parties. UCB's orders (including mutually agreed change orders) shall be subject to the provisions of this Agreement, and any terms or conditions contained therein that conflict with the terms of this Agreement are excluded.

7.5 Transfer Price Variations. At least thirty (30) days prior to the end of each Contract Year or sooner if available, Jazz Pharmaceuticals shall notify UCB of the Transfer Price for the Product for the next Contract Year. Jazz Pharmaceuticals shall reserve the right to increase transfer pricing for any increases in the costs identified in Appendix C imposed on Jazz Pharmaceuticals by its suppliers. Jazz Pharmaceuticals shall reduce transfer pricing for any decreases in the costs referenced in the preceding sentence and for any other reductions in the components of Jazz Pharmaceuticals' standard manufacturing costs as listed on Appendix C (including any reductions that may result from decreases in the required fill volume resulting from improvements in the PIBA). Each such notice shall include all necessary documentation reasonably required for UCB to verify the adjusted Transfer Price; provided, however that notwithstanding Jazz Pharmaceuticals' delivery of such documentation, UCB shall be permitted to conduct inspections and audits during reasonable business hours, to the extent necessary to verify the Transfer Price and adjustments thereto. Such inspections and audits shall be conducted at the request (not to be made more than **[*]**) and expense of UCB by an independent Certified Public Accountant appointed by UCB. Such Certified Public Accountant shall undertake a confidentiality obligation to Jazz Pharmaceuticals permitting it to disclose only to UCB the amount of the Transfer Price and adjustments and the information required to verify such Transfer Price and adjustments, and no other information.

7.6 Payment Terms.

(a) General. Unless otherwise agreed by Jazz Pharmaceuticals in writing, payments for the Product shall be paid net on the last day of the first full calendar month following the date of the invoice therefore, provided that no invoice shall be dated prior to the date of actual shipment of the Product covered by the invoice. All payments shall be made in United States Dollars by wire transfer to a U.S. bank designated by Jazz Pharmaceuticals at least five (5) days prior to the date of payment. Any overdue payment from UCB to Jazz Pharmaceuticals under this Agreement shall accrue interest at **[*]** from time to time in force. Jazz Pharmaceuticals shall have the right to recover its reasonable collection costs and expenses (including attorneys' fees) for late payments. Notwithstanding the above, in the event UCB disputes the amount, or any portion thereof, of any invoice submitted to it by Jazz Pharmaceuticals, UCB shall promptly notify Jazz Pharmaceuticals of the amount and nature of the disagreement. Before relying on the provisions of Section 15.2 hereof, the parties first shall promptly attempt to resolve such disagreement in good faith in a manner provided in Section 7.6(b) and UCB shall make payments with respect to disputed invoices as provided in such Section.

(b) Order and Invoice Non-Conformance.

(i) In the event UCB disputes whether Product supplied by Jazz Pharmaceuticals conforms to an order placed for such Product pursuant to Section

7.4 with respect to quantity, UCB shall provide notice to Jazz Pharmaceuticals in accordance with the provisions relating to apparent non-conformities of Product set forth in Section 7.12. In the case of any such non-conformity which results from delivery of less Product than ordered, Jazz Pharmaceuticals shall supply additional Product promptly. In such case, UCB shall pay for the quantity actually received in accordance with the provisions of Section 7.6(a). In the case of any such non-conformity which results from delivery of more Product than ordered, UCB may in its sole discretion accept any Product in excess of the quantity ordered as against future orders of Product. In such latter case, UCB shall pay for the quantity actually received and accepted in accordance with the provisions of Section 7.6(a) unless otherwise agreed.

(ii) In the event that UCB disputes any invoice due to the price at which any quantity of Product is invoiced as a result of the parties being unable to reach agreement with respect to the calculation of the Transfer Price, UCB shall be obligated to pay the undisputed amount of such invoice in full in accordance with the provisions of Section 7.6(a) pending resolution of the dispute pursuant to Section 15.2.

(iii) In the event that UCB disputes any invoice due to non-conformance of the Product supplied by Jazz Pharmaceuticals with the Product Specifications, such dispute shall be resolved in accordance with Sections 7.11 and 7.12 of this Agreement. Pending resolution of such dispute, UCB shall not be obligated to pay the amount of such invoice that relates to Product alleged to be non-conforming. Upon resolution of any such dispute in favor of Jazz Pharmaceuticals, UCB shall pay the unpaid balance of such invoice within ten (10) days of such resolution.

7.7 Short Supply Allocation. If Jazz Pharmaceuticals is unable to supply all of UCB's orders for Product hereunder in a timely manner, Jazz Pharmaceuticals shall allocate its available sources and supplies among UCB, Jazz Pharmaceuticals and Jazz Pharmaceuticals' other partners (distributors, licensees, agents, etc.) and internal needs in accordance with the **[*]** of each of the parties for that allocation period, provided, however, the foregoing shall in no way modify or mitigate Jazz Pharmaceuticals' obligation to supply Product properly ordered in accordance with this Agreement or UCB's rights and remedies under this Agreement in respect of any failure to timely supply, including in respect of a breach hereof and UCB's rights to appoint a Third Party manufacturer in accordance with Section 2.1(b) or to terminate this Agreement in accordance with Section 14.2(b).

7.8 Product Expiration.

(a) All Product supplied by Jazz Pharmaceuticals shall have a minimum expiration dating **[*]** at the time of its delivery EXW Jazz Pharmaceuticals' designated supplier pursuant to Section 7.3.

(b) In the event the applicable Regulatory Authority grants an expiration date less than **[*]**, Jazz Pharmaceuticals and UCB shall negotiate in good faith a reasonable minimum expiration, taking into account the differing expiration dates set forth herein for Product.

(c) UCB shall not sell any Product beyond its stated expiration date.

7.9 Certificate of Analysis. With each delivery of the Product to UCB, Jazz Pharmaceuticals shall, in accordance with the terms of the Quality Agreement, provide to UCB (i) a Certificate of Analysis and Certificate of Conformity confirming that the Product has been manufactured in accordance with cGMP and the Product Specifications, (ii) a copy of all batch documentation from the Product manufacturer for the first three (3) batches of Product delivered to UCB and (iii) a copy of the annual stability test report, provided that the provision of the certificates and other documents listed in (i)—(iii) above shall not release UCB from any of its obligations hereunder, including, without limitation, its obligation to conduct all necessary release testing to ensure that the Products distributed in the Territory comply with all applicable regulatory requirements in the Territory.

7.10 Storage. Jazz shall comply with the Quality Agreement in relation to the storage of the Product prior to delivery EXW to UCB. UCB shall at its own expense maintain adequate and suitable storage facilities for the storage of Product delivered to UCB in accordance with cGMP, the Marketing Authorizations, the Quality Agreement and all applicable laws and regulations. Jazz Pharmaceuticals or its representative shall have the right no more than twice per calendar year to inspect, during normal business hours, such storage facilities upon sixty (60) days prior written notice.

7.11 Testing of Product Upon Receipt. UCB shall, as soon as practical after receipt of Product, examine the Product for any apparent non-conformance and carry out or have carried out, routine laboratory testing and other chemical analysis of the Product as required by the relevant Marketing Authorizations and/or Regulatory Authority(ies). UCB shall promptly notify Jazz Pharmaceuticals if such examination or testing establishes the basis to reject the Product for non-conformance. Any such notice shall identify the specific claims of non-conformance and include copies of relevant test results or other materials indicating such non-conformance. Upon receipt of a notification of non-conformance, Jazz Pharmaceuticals and UCB shall compare test results obtained during release testing of the Product by Jazz Pharmaceuticals to the results UCB obtained during acceptance testing to evaluate the potential cause of discrepancy. If Jazz Pharmaceuticals confirms such non-conformity, it shall promptly so notify UCB. If Jazz

Pharmaceuticals does not confirm such non-conformity, it shall promptly so notify UCB, and the parties shall submit the disputed Product shipment for testing to an independent testing laboratory or other independent Third Party expert mutually acceptable to the parties. Notwithstanding Section 15.2, the findings of the testing laboratory or Third Party expert shall be binding on the parties. The expenses of such testing shall be borne by Jazz Pharmaceuticals if the non-conformity is confirmed, and otherwise by UCB. Without limiting UCB's other remedies as herein provided, Jazz Pharmaceuticals shall promptly replace properly rejected Product. UCB shall return such Product or, if requested by Jazz Pharmaceuticals, destroy the Product and provide the certification described in Section 7.12.

7.12 Rejection of Shipments For Product Non-Conformance. If UCB rejects a shipment on the determination that such shipment of Product fails to conform to the purchase order therefore or on the grounds that it fails to conform to the Product Specifications, UCB shall give written notice of such rejection to Jazz Pharmaceuticals **[*]** after receipt thereof, in the case of apparent non-conformance, and **[*]** of the receipt of definitive test results obtained pursuant to Section 7.11 in the case of non-conformance established by such tests. Such notice of rejection shall specify the manner in which the Product fails to conform to the relevant purchase order, or otherwise fails to conform to the Product Specifications. If UCB fails to provide Jazz Pharmaceuticals such notice in respect of Product delivered to UCB pursuant to a purchase order within **[*]** as the case may be, of the date of delivery, the Product shall be deemed accepted by UCB; provided, however, that such deemed acceptance shall not (i) impair UCB's right to reject shipment or recover damages in respect of any non-conformance that is not apparent and cannot be determined by such tests or (ii) reduce, diminish or alter UCB's rights to indemnification as specified in Article IX hereof or to terminate this Agreement in accordance with Section 14.2(b). If UCB expects to make a claim against Jazz Pharmaceuticals in accordance with this Section 7.12, UCB shall not dispose or allow the disposal of the Product in question without the express written authorization and instructions of Jazz Pharmaceuticals. Any such instructions from Jazz Pharmaceuticals, or UCB's compliance therewith, shall not relieve UCB of its obligation to dispose of any Product in accordance with all applicable laws and regulations in the relevant country in the Territory. UCB shall not return any rejected Product to Jazz Pharmaceuticals without a Return Material Authorization (**"RMA"**) from Jazz Pharmaceuticals. Jazz Pharmaceuticals shall promptly issue a RMA for any reasonably rejected Product, provided, however, appropriate samples may be retained by UCB as evidence of the basis for such rejection by UCB. Proof of destruction or disposal shall be certified in writing to Jazz Pharmaceuticals by an officer of UCB. Within **[*]** of receipt of a statement detailing and documenting all of UCB's costs and expenses associated with Jazz Pharmaceuticals' delivery of non-conforming Products, including without limitation, any payments made or other Indemnification Amounts arising out of Claims and the return, destruction or disposal of such Product pursuant to this Section 7.12, Jazz Pharmaceuticals shall reimburse UCB for all such amounts. Any disputes between the parties relating to such reimbursement amounts shall be resolved in accordance with the procedures set forth in Section 15.2.

ARTICLE VIII
REPRESENTATIONS AND WARRANTIES

8.1 Jazz Pharmaceuticals Warranties. Jazz Pharmaceuticals represents and warrants to UCB that as of the Effective Date (unless specified otherwise):

(a) As of the Execution Date, it is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware, U.S.A. and has the corporate power to own its assets and properties and to carry on its business as now being and heretofore conducted.

(b) As of the Execution Date, it has all requisite power and authority (corporate and otherwise) to enter into this Agreement and it has duly authorized, by all necessary action, the execution and delivery hereof by the officer or individual whose name is signed on its behalf below. Jazz Pharmaceuticals' execution and delivery of this Agreement does not and will not conflict with or result in a breach of or a default under its organizational documents or any agreement, instrument, order, law or regulation applicable to it or by which it or the Product may be bound. This Agreement has been duly and validly executed and delivered by Jazz Pharmaceuticals and constitutes Jazz Pharmaceuticals' valid and legally binding obligation, enforceable against Jazz Pharmaceuticals in accordance with its terms, except as enforcement may be limited by laws of bankruptcy or insolvency or other laws of general application relating to or affecting the enforcement of creditor's rights and general equitable principles.

(c) At the time of its shipment to UCB, each order of Product shall have been manufactured, stored and shipped in accordance with cGMP, the Product Specifications and the Marketing Authorizations and other applicable laws and regulations, shall be in compliance with the Marketing Authorizations, and shall not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetics Act, as in effect at the time of shipment;

(d) At the time of its shipment to UCB, each order of the Product shall conform to the Product Specifications until the expiration of the shelf life approved by the Regulatory Authorities.

(e) Patent Rights, Trademarks and Other Intellectual Property Rights.

(i) Jazz Pharmaceuticals has good title and ownership or rights to the Licensed Intellectual Property free and clear of all liens. To Jazz

Pharmaceuticals' actual knowledge, it has all intellectual property rights necessary for (A) the manufacture of the Product by Jazz Pharmaceuticals and the distribution, marketing, promotion and sale by UCB of the Product in the Territory in accordance with the terms of this Agreement and (B) the grant by Jazz Pharmaceuticals to UCB of the rights granted under this Agreement.

(ii) Schedule 8.1(e)(ii) hereto contains a true and complete list of all Patent Rights in the Territory and all Trademarks and all other intellectual property rights of Jazz Pharmaceuticals relating to the Product in the Territory, indicating for each whether it is registered or is the subject of a pending application with any patent and/or trademark office with jurisdiction in the Territory, and all licenses and other contracts and similar rights relating thereto.

(iii) Except as set forth on Schedule 8.1(e)(iii), to Jazz Pharmaceuticals' actual knowledge, the Product as manufactured and delivered to UCB by Jazz Pharmaceuticals for distribution in the Territory pursuant to this Agreement, and UCB's use of the Licensed Intellectual Property in the Territory as contemplated hereby, [*].

(f) Contracts; No Default.

(i) Except for those contracts set forth on Schedule 8.1(f)(i) and Schedule 8.1(e)(ii) and except for this Agreement, as of the date hereof, there are no material contracts, agreements, understandings, arrangements or commitments, written or oral, including without limitation, manufacturing, supply, sales agency, sales representative, distributor, dealer, license, supplier, wholesaler, or similar contracts or agreements (**"Contracts"**) of Jazz Pharmaceuticals relating to the Product in the Territory.

(ii) Except as set forth on Schedule 8.1(f)(ii), Jazz Pharmaceuticals and, to Jazz Pharmaceuticals' actual knowledge, each other party to Jazz Pharmaceuticals' Contracts referenced in clause (i) above (other than UCB) has performed in all material respects, and is now performing in all material respects, its obligations under, and is not in material default (and would not by the mere lapse of time or the giving of notice or both be in default) under, or in material breach or violation of any of such Contracts; nor has Jazz Pharmaceuticals received notice of any asserted claim of a default by any other party thereto under, or a breach or violation by such other party of any of such Contracts.

(g) Actions.

(i) Except as set forth on Schedule 8.1(g)(i), there are no Claims pending or, to Jazz Pharmaceuticals' actual knowledge, threatened against Jazz Pharmaceuticals before any court or regulatory authority that (A) question or challenge the validity of this Agreement or any action taken or proposed to be taken by Jazz Pharmaceuticals pursuant hereto or in connection with the transactions contemplated hereby, or (B) relate to the Product or would if adversely determined, singly or in the aggregate, prohibit or materially impair Jazz Pharmaceuticals' or UCB's ability to perform its obligations under this Agreement.

(ii) There are no outstanding judgments, orders, decrees, writs, awards, stipulations, or injunctions of any regulatory authority against or affecting the Product or Jazz Pharmaceuticals with respect to the Product or which would if adversely determined, singly or in the aggregate, prohibit or materially impair Jazz Pharmaceuticals' or UCB's ability to perform its obligations under this Agreement.

(h) Approvals. Except as contemplated by this Agreement or set forth on Schedule 8.1(h) or as shall already have been made, obtained or given, no approval of any regulatory authority or other Person is required to be made, obtained or given by or with respect to Jazz Pharmaceuticals or the Product in connection with the execution or delivery by Jazz Pharmaceuticals of this Agreement, the performance by it of its obligations hereunder or the consummation by it of the transactions contemplated hereby.

8.2 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO THE PRODUCT OR UCB'S SALE AND DISTRIBUTION THEREOF IN THE TERRITORY. The warranties given by each party are for the sole benefit of the other party shall not extend to any Third Party. This provision does not affect the right of any patient to pursue legal remedy in the event Jazz Pharmaceuticals provides Product that is adulterated or misbranded or if Product does not meet Product Specifications. Except as provided in Section 2.1, nothing in this Agreement shall be construed as, and Jazz Pharmaceuticals expressly disclaims, any warranty or agreement to furnish any manufacturing information beyond that required to obtain Registrations for the Product in the Territory. UCB agrees that as between UCB and Jazz Pharmaceuticals, UCB alone shall be liable, to the exclusion of Jazz Pharmaceuticals, for the breach of any warranties given by UCB, its Subdistributors or its Sublicensees to customers or others regarding the Product, provided, however, nothing herein shall reduce, diminish or alter UCB's rights as herein provided including its right to assert claims against Jazz Pharmaceuticals in respect of the same facts that form or might form the basis of Claims against UCB by its Subdistributors or Sublicensees and its or their customers.

8.3 UCB Warranties. UCB represents and warrants to Jazz Pharmaceuticals that as of the Effective Date (unless specified otherwise):

(a) As of the Execution Date, it is a corporation duly organized, validly existing and in good standing under the laws of England and has the corporate power to own its assets and properties and to carry on its business as now being and heretofore conducted.

(b) As of the Execution Date, it has all requisite power and authority (corporate and otherwise) to enter into this Agreement and it has duly authorized, by all necessary action, the execution and delivery hereof by the officers or individuals whose name is signed on its behalf below. UCB's execution and delivery of this Agreement does not and will not conflict with or result in a breach of or a default under its organizational documents or any agreement, instrument, order, law or regulation applicable to it or by which it or the Product may be bound. This Agreement has been duly and validly executed and delivered by UCB and constitutes UCB's valid and legally binding obligation, enforceable against UCB in accordance with its terms, except as enforcement may be limited by laws of bankruptcy or insolvency or other laws of general application relating to or affecting the enforcement of creditor's rights and general equitable principles.

(c) During the term of this Agreement, it shall and shall require its Subdistributors, Sublicensees and Third Party manufacturers to manufacture (if applicable), store, package, label, promote, market, sell and distribute the Product in compliance with this Agreement, the Registrations and all applicable laws and regulations.

(d) Contracts; No Default.

(i) Except for those Contracts set forth on Schedule 8.1(e)(i) and except for this Agreement, as of the date hereof, there are no material Contracts of UCB relating to the Product in the Territory.

(ii) Except as set forth on Schedule 8.1(d)(ii), UCB and, to UCB's actual knowledge, each other party to UCB's Contracts referenced in clause (i) above (other than Jazz Pharmaceuticals) has performed in all material respects, and is now performing in all material respects, its obligations under, and is not in material default (and would not by the mere lapse of time or the giving of notice or both be in default) under, or in material breach or violation of any of such Contracts; nor has UCB received notice of any asserted claim of a default by any other party thereto under, or a breach or violation by such other party of any of such Contracts.

(e) Actions.

(i) Except as set forth on Schedule 8.1(e)(i), there are no Claims pending or, to UCB's actual knowledge threatened against UCB before any court or regulatory authority that (A) question or challenge the validity of this Agreement or any action taken or proposed to be taken by UCB pursuant hereto or thereto or in connection with the transactions contemplated hereby, or (B) would if adversely determined, singly or in the aggregate, prohibit or materially impair Jazz Pharmaceuticals' or UCB's ability to perform its obligations under this Agreement.

(ii) There are no outstanding judgments, orders, decrees, writs, awards, stipulations, injunctions of any regulatory authority against or affecting UCB which would if adversely determined, singly or in the aggregate, prohibit or materially impair UCB's ability to perform its obligations under this Agreement.

(f) Approvals. Except as contemplated by this Agreement or set forth on Schedule 8.1(f) or as shall already have been made, obtained or given, no approval of any regulatory authority or other Person is required to be made, obtained or given by or with respect to UCB or the Product in connection with the execution or delivery by UCB of this Agreement, the performance by it of its obligations hereunder or the consummation by it of the transactions contemplated hereby.

ARTICLE IX
INDEMNIFICATION

9.1 Indemnification by Jazz Pharmaceuticals. Subject to Section 9.2, Jazz Pharmaceuticals shall indemnify and hold harmless UCB and its directors, officers, employees and agents from and against all claims, disputes, actions, arbitrations, mediations, litigations, proceedings, suits and governmental investigations brought by a Third Party and any appeal therefrom (the **"Claims"**) and all liabilities, damages, losses, costs and expenses (including reasonable attorneys' fees and expenses in respect of Claims and to enforce rights to indemnification as herein provided (**"Indemnification Amounts"**)) arising out of (i) a breach by Jazz Pharmaceuticals of any representation, warranty or covenant provided in this Agreement, including, without limitation, the representations and warranties set forth in Section 8.l, (ii) an allegation that bodily injury (including death) or tangible personal property damage was caused by, resulted from or arose out of the use of the Product for a Licensed Indication by whomsoever such Product was sold (including UCB, its Subdistributors and Sublicensees) and regardless of

the legal theory on which such Claim is based, except, however, where such bodily injury and/or property damage is due to (a) a circumstance described in Section 9.2(i) or 9.2(iii) hereof or (b) failure of a Third Party manufacturer appointed by UCB pursuant to Section 2.1 to manufacture, store or ship the Product in accordance with cGMP, the Marketing Authorizations and other applicable laws and regulations or due to the action or inaction of such Third Party manufacturer which causes the Product to be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as in effect at the time of shipment; and (iii) negligence, gross negligence or willful misconduct of or attributable to Jazz Pharmaceuticals, its sublicensees (other than UCB, its Subdistributors, Sublicensees or Third Party manufacturers), contractors, manufacturers and its or their directors, officers, agents, employees, consultants or clinical investigators in connection with the manufacture, storage or supply of API and/or the Product.

9.2 Indemnification by UCB. UCB agrees to indemnify, defend and hold harmless Jazz Pharmaceuticals and its directors, officers, employees and agents from and against all Claims and Indemnification Amounts arising out of (i) a breach by UCB of any representation, warranty or covenant provided in this Agreement, (ii) an allegation that bodily injury (including death) or tangible personal property damage was caused by, resulted from or arose out of the Products sold by UCB, its Subdistributors, Sublicensees or Third Party manufacturers that were used other than for a Licensed Indication, regardless of the legal theory on which such Claim is based, except, however, where such bodily injury and/or property damage is due to a circumstance described in Sections 9.1(i) and 9.1(iii) hereof, (iii) negligence, gross negligence or willful misconduct of or attributable to UCB, its Subdistributors, Sublicenses or Third Party manufacturers and its or their directors, officers, agents, employees, consultants or clinical investigators in connection with the storage, packaging, labeling, promotion, marketing, sale and distribution of the Product in the Territory; and (iv) except to the extent that Jazz Pharmaceuticals indemnifies UCB under Section 9.1, any express or implied warranty, whether oral or written, including any implied warranty or the merchantability or fitness of the Product for a particular purpose asserted by any customer of UCB, its Subdistributors or Sublicensees, if such warranty was extended by or arising from any undertaking, action or inaction of UCB, its Subdistributors or Sublicensees.

9.3 Procedure. A party seeking indemnification (an **"indemnified party"**) shall give the other party (an **"indemnifying party"**) written notice of any Claim promptly upon becoming aware thereof. The indemnifying party shall have sole and exclusive control of the defense of any Claim, including the choice and direction of legal counsel. The indemnified party shall have the right to participate in such defense through its own counsel, at its own expense. Neither party may settle or compromise any Claim for which indemnification is being sought without the written consent of the other party, which may not be unreasonably withheld.

9.4 Insurance. Both parties shall maintain during the Term of this Agreement, and for a reasonable period thereafter, general liability insurance (whether Third Party insurance or self-insurance provided through a captive insurance subsidiary), which insurance shall include product liability coverage and shall be in amounts and of a type customarily maintained by companies similarly situated. Such insurance shall provide at least ten million ($10,000,000) Dollars in coverage per occurrence. Each party shall use commercially reasonable efforts to name the other party as an additional insured on such party's insurance policy(ies). On or prior to the Effective Date, each party shall deliver to the other evidence of its insurance.

ARTICLE X
INTELLECTUAL PROPERTY RIGHTS
PERFECTION AND USE

10.1 License Perfection. In the event that the execution and filing of any document is required in connection with the license granted in Section 2.2 to UCB for the Trademarks or Patent Rights under the laws of any country in the Territory, UCB shall promptly notify Jazz Pharmaceuticals, and Jazz Pharmaceuticals shall cause such document to be executed and filed, and UCB shall sign such document if necessary and otherwise cooperate in the filing thereof.

10.2 Quality Standards. All Products sold and marketed under the Trademarks by UCB or its Subdistributors or Sublicensees, including all related advertising, promotional materials, and all other related uses of the Trademarks shall comply with the reasonable trademark use standards adhered to by Jazz Pharmaceuticals in the manufacture, sale and promotion of the Product, which such standards are set forth in Appendix E. In particular, and without limiting the generality of the foregoing, upon reasonable request by Jazz Pharmaceuticals, UCB shall provide Jazz Pharmaceuticals with samples of Products bearing the Trademarks, as well as copies of all materials, including but not limited to brochures, professional literature, packaging and consumer instructions, which are created or intended for use by UCB, its Subdistributors and/or Sublicensees in the advertising, promotion, marketing or sale or other distribution of the Product in the Territory, for examination and testing to verify compliance with the trademark use standards set forth in Appendix E. UCB shall also permit Jazz Pharmaceuticals, not more than **[*]** and upon thirty (30) days prior written notice and at reasonable times during normal business hours, to examine stocks of the Product held by it or its Subdistributors or Sublicensees to verify compliance with such standards. Jazz Pharmaceuticals shall notify UCB in writing of any noncompliance herewith, and UCB shall use Commercially Reasonable Efforts to correct the problem and bring such Products into compliance with applicable standards.

10.3 Use of Trademarks. UCB shall and shall cause its Subdistributors and Sublicensees to market the Product in the Narcolepsy Indication under the Narcolepsy Trademarks; provided, however that if the Narcolepsy Trademarks are unavailable or unusable in

a particular country in the Territory for the Narcolepsy Indication, the parties shall mutually agree on a suitable alternative. In addition, to the extent permitted by applicable law in each country in the Territory, where that Product has been manufactured by Jazz Pharmaceuticals, all labeling for the Product shall bear a legend, identifying Jazz Pharmaceuticals as the manufacturer of the Product for UCB.

10.4 Narcolepsy: Registration and Approvals. Attached hereto as Appendix B is a list of the registrations and pending applications for registration for the Narcolepsy Trademarks and Patent Rights in the Territory for use in relation to the Narcolepsy Indication. Jazz Pharmaceuticals shall at its sole cost file applications and maintain trademark registrations (including for the Trademarks and any alternative trademarks pursuant to Section 10.3) and patent registrations (including for the Patent Rights) in each country in the Territory including without limitation the registrations and pending applications for the Narcolepsy Trademarks and Patent Rights in each country listed in Appendix B as shall be reasonably useful or necessary to protect UCB's rights under this Agreement; provided, however, that if Jazz Pharmaceuticals shall fail to file a useful or necessary application or maintain a useful or necessary registration for any trademarks, alternative trademarks or patents in a country in the Territory, or to maintain the Trademarks and Patent Rights registrations in each country listed in Appendix B, UCB shall have the right to file such applications and maintain such registrations in each such country in the Territory for such trademarks, alternative trademarks or patents at the expense and in the name and on behalf of Jazz Pharmaceuticals (or in UCB's own name if that is not permitted in the applicable country). Such registration and use of the Trademarks and Patent Rights shall inure to the benefit of and be on behalf of Jazz Pharmaceuticals. On any termination of this Agreement pursuant to Article XIV hereof, UCB shall promptly assign to Jazz Pharmaceuticals registrations and any applications for registration of trademarks, alternative trademarks registered pursuant to Section 10.3 or patents for the Product in the Territory filed in its name pursuant to this Section 10.4.

10.5 Licensed Indications other than the Narcolepsy Indication: Registration and Approvals.

(a) Jazz Pharmaceuticals shall, at least 1 month prior to making an application, consult UCB as to the name(s) and, if applicable, form(s) of the trademark(s) it wishes to apply to register in the Territory for use with the Product in relation to the Licensed Indications other than the Narcolepsy Indication. Jazz Pharmaceuticals agrees to hold good faith discussions with UCB about such applications and to give due consideration to UCB's representations.

(b) Jazz Pharmaceuticals shall at its sole cost file applications and maintain trademark registrations (including the Other Licensed Trademarks and any alternative trademarks pursuant to Section 10.6) and patent registrations (including for the Patent Rights) in

each country in the Territory as shall be necessary to protect UCB's rights under this Agreement; provided, however, that if Jazz Pharmaceuticals shall fail to file a necessary application or maintain a necessary registration for any trademarks, alternative trademarks or patents in a country in the Territory UCB shall have the right to file such applications and maintain such registrations in each such country in the Territory for such trademarks, alternative trademarks or patents at the expense and in the name and on behalf of Jazz Pharmaceuticals (or in UCB's own name if that is not permitted in the applicable country). Such registration and use of the Other Licensed Trademarks and Patent Rights shall inure to the benefit of and be on behalf of Jazz Pharmaceuticals. Appendix B shall be updated by Jazz Pharmaceuticals at least every 12 months to list all registrations and pending applications for registration for the Other Licensed Trademarks and Patent Rights in the Territory for use in relation to the Licensed Indication other than the Narcolepsy Indication.

10.6 Use of the Other Licensed Trademarks. UCB shall and shall cause its Subdistributors and Sublicensees to market the Product in the Licensed Indications other than the Narcolepsy Indication under the Other Licensed Trademarks; provided, however that if the Other Licensed Trademarks are unavailable or unusable in a particular country in the Territory for the Licensed Indications other than the Narcolepsy Indication, the parties shall mutually agree on a suitable alternative. In addition, to the extent permitted by applicable law in each country in the Territory, where that Product has been manufactured by Jazz Pharmaceuticals, all labeling for the Product shall bear a legend, identifying Jazz Pharmaceuticals as the manufacturer of the Product for UCB.

10.7 Reservation of Rights. Except as otherwise provided herein, (i) nothing in this Agreement shall entitle UCB to any right, title or interest in or to any of the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements, and Proprietary Information of Jazz Pharmaceuticals or any associated goodwill, which is and shall remain the sole and exclusive property of Jazz Pharmaceuticals and (ii) UCB shall not take and shall cause its Subdistributors, Sublicensees and Third Party manufacturers to not take any action that might (a) impair any right, title or interest of Jazz Pharmaceuticals in and to the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements and Proprietary Information; or (b) create any right, title or interest in or to such Patent Rights, Know How, Trademarks, Improvements and Proprietary Information in UCB or any other Person. UCB acknowledges Jazz Pharmaceuticals' proprietary rights as provided in the preceding sentence, and hereby waives in favor of Jazz Pharmaceuticals any right UCB may have in and to the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements and Proprietary Information except as herein provided.

ARTICLE XI
INTELLECTUAL PROPERTY INFRINGEMENTS

11.1 Protection of Intellectual Property. UCB shall cooperate with Jazz Pharmaceuticals and take all reasonable actions which Jazz Pharmaceuticals may reasonably request, at Jazz Pharmaceuticals' sole cost and expense, in order to protect and enforce Jazz Pharmaceuticals' intellectual property rights, including, but not limited to, carrying out any act Jazz Pharmaceuticals may reasonably require in connection with any registration, enforcement or protection thereof. UCB shall promptly notify Jazz Pharmaceuticals upon becoming aware of any use in the Territory by a Third Party of the Patent Rights, Know How, Manufacturing Know How, Trademarks, Improvements or Proprietary Information of Jazz Pharmaceuticals related thereto, or any other Jazz Pharmaceuticals intellectual property relating to the Product which may constitute an infringement thereof. Jazz Pharmaceuticals shall have the first right, at its option, to institute proceedings against Third Party infringers in respect of such infringements occurring in the Territory. If Jazz Pharmaceuticals elects not to institute such proceedings within a period of thirty (30) days after its discovery of the infringement, UCB shall have the right at its option to do so. The party instituting proceedings in the Territory pursuant to this Article XI shall bring all such proceedings in the name of both parties. Jazz Pharmaceuticals shall have the exclusive right in its sole discretion to institute proceedings solely in its name against Third Party infringers in respect of infringements occurring outside the Territory. Each party shall cooperate fully with the other party in connection with any such proceedings against third-party infringers. All expenses of any such proceedings shall be borne by the party instituting the proceedings and damages which may be awarded or agreed upon in settlement of such action shall be allocated first to reimburse the documented costs of the proceedings incurred by the party bringing suit, with the balance of such amounts, if any, to be allocated between the parties in accordance with their relative economic loss from such infringement.

ARTICLE XII
IMPROVEMENTS

12.1 Improvements by UCB. Subject to UCB's rights therein as provided elsewhere in this Agreement, including without limitation Section 2.2, UCB hereby irrevocably assigns, releases, and transfers to Jazz Pharmaceuticals its entire right, title and interest in and to any Improvement solely relating to the API and/or a Product (whether patentable or not) made or conceived solely or jointly by UCB employees or contractors.

12.2 Improvements by Jazz Pharmaceuticals. Subject to UCB's rights therein as provided elsewhere in this Agreement, including without limitation Section 2.2, Jazz Pharmaceuticals shall own all right, title and interest in and to any Improvement relating to the API and/or Product (whether patentable or not) made or conceived solely or jointly by Jazz Pharmaceuticals employees or by any Jazz Pharmaceuticals contractor, other than UCB, including, without limitation, any manufacturing or analytical process, procedure or method or any source of synthesis given to UCB.

12.3 Disclosure. UCB shall promptly disclose to Jazz Pharmaceuticals any and all Improvements relating to the API and/or Product by UCB's employees, Subdistributors, Sublicensees or contractors, either alone or together with Jazz Pharmaceuticals' employees or contractors. UCB, its Subdistributors and Sublicensees shall execute at Jazz Pharmaceuticals' expense any assignments, applications or other instruments or documents reasonably requested by Jazz Pharmaceuticals to obtain, maintain, and otherwise to perfect Jazz Pharmaceuticals' interest therein as provided by this Agreement. UCB's obligations hereunder shall survive termination of this Agreement.

ARTICLE XIII
CONFIDENTIALITY

13.1 Proprietary Information. During the Term hereof and for a period of [*] years thereafter, any Proprietary Information disclosed by one party (the **"Disclosing Party"**), directly or indirectly, to the other party (the **"Receiving Party"**) under this Agreement shall be deemed confidential, and trade secret information, whether so designated or not, and shall not be disclosed by the Receiving Party to any Third Party, except as set forth below. Access to such Proprietary Information shall be limited to employees, agents, consultants or contractors of the Receiving Party who reasonably require such Proprietary Information for purposes of performing the Receiving Party's obligations hereunder and who are bound to the Receiving Party by similar obligations in respect of confidentiality and use. Such employees, agents, consultants or contractors shall be advised of the nature and existence of the undertakings in respect of such Proprietary Information pursuant to this Agreement and of the applicability of such undertakings to them. The Receiving Party shall use such Proprietary Information only to carry out its obligations or to exercise its rights hereunder and shall not use such Proprietary Information for its own benefit or for the benefit of others or in any way inconsistent with this Agreement.

13.2 Exclusions. Information shall not be deemed Proprietary Information which:

(a) at the time of disclosure, is already in the public domain or thereafter becomes part of the public domain through no act or omission of the Receiving Party;

(b) was rightfully in the possession of the Receiving Party prior to the time of the disclosure;

(c) is independently disclosed to the Receiving Party by a Third Party who has not violated any confidential obligation owed to the Disclosing Party;

(d) was independently developed by the Receiving Party without any use of or reliance on any Proprietary Information of the Disclosing Party;

(e) is required to be disclosed by legal process, provided that, in each case the party so disclosing information timely informs the other and uses its best efforts to limit the disclosure and maintain confidentiality to the extent possible and permits the other party to attempt by appropriate legal means to limit such disclosure;

(f) is information which is required to be included in patent applications or required to be provided to the FDA or any other Regulatory Authority in the Territory in order that Registrations for the Product can be obtained or otherwise to comply with applicable regulatory requirements; provided, however, that no Proprietary Information of UCB or Jazz Pharmaceuticals shall be disclosed in any such patent application or Registration without the prior written consent of the Disclosing Party, which consent shall not be unreasonably withheld; or

(g) is information which is required to be disclosed to customers, users, and prescribers of the Product or which is reasonably necessary to disclose in connection with the ethical marketing of the Product, if applicable.

13.3 Third Party Disclosure. Disclosure by the Receiving Party to a Third Party shall be made only to the extent necessary to enable the Receiving Party to comply with its contractual obligations to the Disclosing Party, and only if such Third Party has executed a confidentiality agreement containing terms that are at least as protective as the terms of this Agreement.

13.4 Third Party Confidentiality Agreement. Each Third Party to which Proprietary Information is disclosed other than a regulatory authority shall agree in writing prior to such disclosure to keep the Proprietary Information in strict confidence.

13.5 Confidentiality of Agreement. Except as otherwise required by law, applicable regulations or the terms of this Agreement or as mutually agreed upon by the parties hereto, each party shall treat as confidential the terms and conditions of this Agreement.

13.6 Prior Confidentiality Agreement. The Confidentiality Disclosure Agreement between Orphan Medical and Celltech hereto dated 20 November 2002 is hereby superseded and terminated. Any disclosure of Proprietary Information by either Orphan Medical or Celltech pursuant to such Confidentiality Agreement shall be deemed to have been made hereunder and shall be subject to this Article 13.

ARTICLE XIV
TERM AND TERMINATION

14.1 Term. This Agreement shall become effective as of the Effective Date and, subject to earlier termination in accordance with its terms, shall remain in full force and effect until the last of Jazz Pharmaceuticals' Patent Rights to expire or ten (10) years from the date UCB receives approval from the EMEA to commercially promote and distribute Product in the relevant Licensed Indication, whichever is longer. This Agreement will be automatically extended indefinitely thereafter unless and until terminated by UCB upon not less than twelve (12) months written notice to Jazz Pharmaceuticals. All references herein to **"Term"** or **"Term of this Agreement"** shall be deemed to include both the initial and any extended terms.

14.2 Mutual Termination. This Agreement may be terminated prior to its normal Term as follows:

(a) Either party may terminate this Agreement immediately upon notice if the other party files a petition of any type as to its bankruptcy, is declared bankrupt, becomes insolvent, makes an assignment for the benefit of creditors, goes into liquidation or receivership, or otherwise loses legal control of its business involuntarily.

(b) Either party may terminate this Agreement if the other party materially defaults or commits a material breach of this Agreement and has failed to cure such default or breach within ninety (90) days of receipt of written notice thereof from the first party.

(c) Either party may terminate this Agreement in accordance with Section 16.2.

14.3 Termination by Jazz Pharmaceuticals. In addition to its termination rights under Section 14.2, Jazz Pharmaceuticals may terminate this Agreement upon written notice to UCB if any of the following occurs otherwise than due to the default of Jazz Pharmaceuticals and continues uncured for a period of ninety (90) days following receipt of written notice thereof from Jazz Pharmaceuticals:

(a) UCB shall have failed to meet the applicable minimum royalty payment requirements for the Product as provided in Article IV hereof.

(b) UCB ceases to sell the Product throughout the Territory (other than as a result of Jazz Pharmaceuticals' default and/ or where the cessation of selling arises from circumstances contemplated and separately addressed in Section 16.2 (Force Majeure)).

14.4 Termination by UCB. In addition to its termination rights under Section 14.2, UCB may terminate this Agreement upon written notice to Jazz Pharmaceuticals as follows:

(a) on 9 months' written notice, if (i) UCB is entitled to take over the manufacture of the Product or appoint a Third Party manufacturer pursuant to Section 2.1(b), (ii) UCB determines in good faith that there would be a significant impact on UCB's ability to commercialize the Product in the Territory and (iii) UCB reasonably concludes that assuming responsibility for manufacturing itself or transferring the manufacture to a Third Party manufacturer could not be achieved in sufficient time to avoid such significant impact;

(b) immediately, upon withdrawal of all of the Marketing Authorizations for the Product in all of the Major European Countries; or

(c) on 18 months' written notice, for any reason.

14.5 Rights and Obligations on Termination. In the event of termination of the whole of this Agreement for any reason, the parties shall have the following rights and obligations:

(i) Neither party shall be released from the obligation to make payment of all amounts then or thereafter due and payable in respect of the Term prior to such termination as otherwise herein provided.

(ii) Except as provided in Section 14.7, UCB shall cease to market, promote, sell and distribute the Product and shall return to Jazz Pharmaceuticals, at UCB's expense, all copies of promotional and technical materials and artwork provided by Jazz Pharmaceuticals; provided, however, that if this Agreement is terminated in whole by UCB pursuant to Section 14.2(b) or Section 14.4(a) or (b), Jazz Pharmaceuticals shall pay all expenses related to such return of materials and artwork;

(iii) Jazz Pharmaceuticals **[*]**, if UCB **[*]** under Section **[*]**, **[*]** of **[*]** and **[*]** at the **[*]** by UCB **[*]** or direct UCB to **[*]** Third Party or parties selected by Jazz Pharmaceuticals at the **[*]** by UCB; provided, however, that if this Agreement is terminated by UCB pursuant to Section 14.2(b) or Section 14.4(a) or (b), Jazz Pharmaceuticals **[*]** by UCB if UCB **[*]** under Section **[*]**;

(iv) UCB shall return or, if requested by Jazz Pharmaceuticals, destroy all of Jazz Pharmaceuticals' Proprietary Information, including, if applicable, all electronic copies thereof and shall certify in writing that it has done so;

(v) UCB shall comply with the provisions of Section 10.4 regarding the assignment to Jazz Pharmaceuticals of trademark and/or patent rights registrations filed in UCB's name; and

(vi) if UCB has contracted with a Third Party or if UCB and/or its Affiliates have taken over responsibility for the manufacturing of the Product in the Territory, UCB shall continue to manufacture or have manufactured the Product being manufactured by UCB and/or its Affiliates for supply of the Product in the Territory to Jazz Pharmaceuticals during the shorter of (i) the twelve (12) month period following termination and (ii) the period following termination and prior to Jazz Pharmaceuticals' establishment of its own manufacturing capabilities and/or Third Party manufacturing and supply arrangements with respect to the Product for the Territory, provided, however, that:

(a) if this Agreement is terminated by UCB pursuant to Section 14.2(b) or Sections 14.4(a) or 14.4(b), Jazz Pharmaceuticals shall pay UCB for the manufacture of Product **[*]**; or

(b) if this Agreement is terminated by (i) Jazz Pharmaceuticals pursuant to Section 14.2(b) or Sections 14.3(a) or (b) or (ii) UCB pursuant to Section 14.4(b), Jazz Pharmaceuticals shall pay UCB for the manufacture of Product **[*]**; and

(c) UCB shall during such period (i) to the extent legally permissible, assign to Jazz Pharmaceuticals all Third Party manufacturing and supply agreements relating exclusively to the Product in the Territory, (ii) transfer to Jazz Pharmaceuticals all manufacturing know-how in its possession or control, and (iii) provide Jazz Pharmaceuticals with such other assistance, at **[*]** as to **[*]**, as Jazz Pharmaceuticals reasonably requires for the purpose of establishing its own manufacturing capabilities and/ or Third Party manufacturing and supply arrangements with respect to the Product in the Territory.

14.6 Partial Termination. In the event that a cause of termination shall relate solely to any country not subject to regulation by the EMEA, then termination of this Agreement shall be limited and applied only to such country or portion of the Territory.

14.7 Sell-Off Period. Notwithstanding anything to the contrary in Section 14.4 hereto, upon expiration or termination of this Agreement, UCB shall have the right to continue to distribute its existing inventory of non-expired Product for a period of six (6) months after the effective

date of expiration or the effective date of termination of this Agreement as the case may be. Any such continued distribution shall be in accordance with all applicable laws and regulations and the terms of this Agreement.

14.8 Survival. The provisions of Articles I (Definitions), VIII (Representations & Warranties), IX (Indemnification), XIII (Confidentiality), XIV (Term and Termination), XV (Arbitration), and XVII (Miscellaneous), as well as the provisions of Articles III (Compliance with Laws and Regulations), XI (Intellectual Property Infringement), XII (Improvements) Article XIII (Confidentiality), Article XIV (Termination), Article XV (Arbitration), Article XVII (Miscellaneous) and the other provisions hereof which by their terms are intended to survive the expiration or termination of this Agreement (including without limitation, Section 4.9 (Books and Records)) shall survive any termination or expiration of this Agreement.

14.9 Assignment of Authorizations. As soon as possible following the expiration or earlier termination of this Agreement, UCB shall take all necessary steps to ensure expeditious assignment of all Marketing Authorizations and Orphan Drug Designations which are in UCB's name to Jazz Pharmaceuticals. If an assignment to Jazz Pharmaceuticals is prohibited under the laws of a country in the Territory, UCB agrees to and hereby grants Jazz Pharmaceuticals authorization to distribute the Product under such Marketing Authorization until Jazz Pharmaceuticals or its designee has obtained Marketing Authorizations and Orphan Drug Designations in its own name for the Product in that country; provided that Jazz Pharmaceuticals shall defend, indemnify and hold harmless UCB from and against all Claims and Indemnification Amounts of whatsoever kind or nature that result from, arise out of or relate to Jazz Pharmaceuticals' distribution of the Product under the Marketing Authorizations and Drug Designations continuing in UCB's name as contemplated by this Section 14.9.

14.10 Rights on Termination for Cause. In the event of termination of this Agreement by Jazz Pharmaceuticals pursuant to the provisions of Sections 14.2(a) or (b) or 14.3 (a) – (b), UCB shall provide to Jazz Pharmaceuticals, at no expense to Jazz Pharmaceuticals, its then current list of prospects and customers, including company name, contact, address and telephone number.

14.11 No Compensation. In the event of any expiration or termination of this Agreement for any reason, neither party shall owe any compensation to the other party for lost profits, lost opportunities, good will, or any other loss or damage in respect of future periods as a result of or arising from such termination or expiration.

ARTICLE XV
ARBITRATION

15.1 Litigation Rights Reserved. If any dispute arises with respect to the unauthorized use of Proprietary Information by either Party or, Jazz Pharmaceuticals' Trademarks, Patent Rights, Know How, Manufacturing Know How, and Improvements by UCB, or with respect to acts or omissions of UCB or Jazz Pharmaceuticals relating to the Product which in the good faith discretion of Jazz Pharmaceuticals or UCB, as the case may be, negatively impact the safety of the public, Jazz Pharmaceuticals or UCB, as the case may be, may seek any available equitable remedy from a court of competent jurisdiction.

15.2 Arbitration. Except as provided in Sections 7.11, 15.1 and subject to Section 15.3, all disputes arising between the parties in connection with this Agreement shall be settled as follows:

(a) initially, through discussion between the parties;

(b) if no resolution can be reached through such discussions, then either party may request that the matter be referred to the parties' respective Chief Executive Officers for resolution by same; and

(c) if no resolution can be reached by the parties' respective Chief Executive Officers within thirty (30) days of referral to them under Section 15.2(b) then the dispute shall be submitted to arbitration for settlement. The arbitration shall take place in New York, New York, and be conducted by the American Arbitration Association in accordance with the commercial arbitration rules thereof (the **"Rules"**) except as modified hereby. All necessary determinations, including the arbitration decision, shall be made by a panel of three arbitrators (the **"Panel"**). Within ten (10) days after delivery of a notice of arbitration, each of the two parties shall select one arbitrator as a member of the Panel. The two parties shall select as the third member of the Panel an independent arbitrator with no past or current business affiliations with either party, and if the parties cannot agree on such independent arbitrator within ten (10) days after delivery of a notice of arbitration, such independent arbitrator shall be selected in accordance with the Rules. The Panel shall establish a schedule of discovery and hearing such that the Panel's final written decision shall be issued within one hundred and twenty (120) days after selection of the independent arbitrator serving on the Panel. Each party must produce all relevant non-privileged documents requested by the other party within thirty (30) days after the request therefore. The Panel's decision must be in writing and shall set forth the reasons therefore. Such decision shall be conclusive determination of the matter and binding on the parties, shall have the effect of an arbitration award, and shall not (to the extent permitted by applicable law) be contested by any of them. The fees and expenses of an arbitrator selected by a party shall be borne by such party. The fees and expenses of the third independent arbitrator shall initially be borne equally by the parties, and shall be allocated between the parties in accordance with the final decision of the Panel, which decision shall allocate such fees between the parties as determined by the Panel.

15.3 Governing Law. This Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the State of New York, U.S.A., excluding (i) its choice of law rules and (ii) the United Nations Convention on the International Sale of Goods, provided that enforcement and operation of the arbitration agreement contained in Section 15.2 hereof, and the enforcement of any award rendered pursuant thereto, shall be governed by United States federal law to the exclusion of State law.

ARTICLE XVI
FORCE MAJEURE

16.1 Events of Force Majeure. Anything in this Agreement to the contrary notwithstanding, neither party shall be liable or responsible for any failure or delay in performance (excluding [*]) due to causes affecting such party and, in the case of Jazz Pharmaceuticals, its designated suppliers, and, in the case of UCB, its Subdistributors, Sublicensees and Third Party manufacturers, beyond the reasonable control of such party, including, without limitation, any act of God; regulation or law of any government or an agency thereof, excluding, however, if a regulatory authority enjoins manufacture of the Product or otherwise closes the Product manufacturing facilities due to Jazz Pharmaceuticals' failure to comply with cGMP or any other breach by Jazz Pharmaceuticals of its obligations under this Agreement; war; terrorism; insurrection or civil commotion; earthquake, tornado, fire, flood or storm; epidemic; or failure of public utilities or common carriers. Such excuse shall continue as long as the condition preventing the performance continues. Upon cessation of such condition, such party shall promptly resume performance hereunder.

16.2 Notice. A party affected by an event of force majeure shall give the other party prompt written notice of the occurrence of any event of force majeure and the nature and duration thereof. An affected party shall use all Commercially Reasonable Efforts to resume performance as quickly as possible and to give the other party prompt written notice when it is again fully able to perform such obligations. If such event of force majeure continues for more than one hundred eighty (180) days, either party may terminate this Agreement by giving ten (10) days written notice to the other party. If UCB is the affected party, such notice of resumption of performance shall state the quantities of Product Jazz Pharmaceuticals needs to ship to enable UCB to resume performance of obligations.

ARTICLE XVII
MISCELLANEOUS

17.1 Notices. All notices to the parties shall be made at the following addresses (or at such other address as shall be specified by it by like notice):

To: Jazz Pharmaceuticals, Inc.
Attention: Chief Executive Officer
3180 Porter Drive
Palo Alto, California 94304
United States
Copy: General Counsel
Fax: +1 650 496 3781

To: UCB Pharma Limited
Attention: Vice President, Legal Affairs
208 Bath Road
Slough
Berkshire
SL1 3WE
Fax: +44 (0) 1753 447859

Notices permitted or required to be given hereunder shall be deemed sufficient if given by (a) overnight express mail via an internationally-recognized carrier, (b) private courier service or (c) facsimile transmission with electronic confirmation of receipt. Notices so given shall be effective (1) upon receipt by the party to whom notice is given, or (2) on the second (2nd) day following delivery to the international carrier or courier, as may be the case, whichever occurs first.

17.2 Waiver. No failure by either party to take any action or assert any right hereunder shall be deemed to be a waiver of such right in the event of the continuation or repetition of the circumstances giving rise to such right.

17.3 Entire Agreement. This Agreement, the Schedules and Appendices, the Quality Agreement and the Pharmacovigilance Agreement hereto constitute the entire agreement of the parties with respect to the subject matter hereof, and supersede all previous agreements by and between the parties as well as all proposals, oral or written, and all negotiations, conversations or discussions heretofore had between the parties related to this Agreement, including (without limitation) the Prior Agreement.

17.4 Conflicts. In the event of any conflict between the terms of this Agreement, the Quality Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall prevail.

17.5 Amendment. No modification or amendment of this Agreement shall be binding unless in writing and signed by both parties.

17.6 Headings. Article, section and paragraph headings used in this Agreement are for convenience only, have no legal significance, and in no way change the construction or meanings of the terms hereof.

17.7 Relationship of the Parties. The parties shall be deemed independent contractors of each other and, as such, they shall not be entitled to any benefits applicable to employees of the other party. Nothing contained in this Agreement shall be construed or implied to create an agency, partnership, or employer and employee relationship between Jazz Pharmaceuticals and UCB. At no time shall one party make commitments or incur any charges or expenses for or in the name of the other party except as specifically provided herein.

17.8 Assignment. Neither party may assign this Agreement without the prior written consent of the other party except that either Jazz Pharmaceuticals or UCB may assign this Agreement (a) to an Affiliate or (b) in connection with a merger, stock sale, or the sale or transfer of all or substantially all of the assets of such party or the division of such party manufacturing or marketing the Product, as the case may be, provided, however, any permitted assignee shall assume all obligations of its assignor under this Agreement and in the case of clause (a), the assigning party shall remain primarily liable for the performance of such Affiliate. Any purported assignment in violation of the foregoing sentence shall be null and void. No assignment shall relieve either party of responsibility for the performance of any accrued obligation under this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of UCB and Jazz Pharmaceuticals, respectively.

17.9 Severability. If any term or condition of this Agreement is found by a court of competent jurisdiction to violate the provisions of any applicable statute, law or regulation, the remainder of this Agreement shall remain in full force and effect. The parties shall then negotiate in good faith to modify this Agreement, to the extent necessary to make the affected term or condition of this Agreement valid and enforceable, having full regard for the original intent of the parties.

17.10 Publicity. This Agreement is confidential and neither party shall issue press releases or engage in other types of publicity of any nature (whether written or oral) dealing with the existence or details of this Agreement without the other party's prior written approval, which

approval shall not be unreasonably withheld; provided that, approval of such disclosure shall be deemed to be given to the extent such disclosure is required to comply with governmental rules, regulations or requirements. In such event, the disclosing party shall furnish a copy of such disclosure to the other party.

17.11 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. This Agreement may be executed and delivered via facsimile transmission with the same force and effect as if it were executed and delivered in writing. In making proof of this Agreement, it shall not be necessary to produce or account for more than one fully executed counterpart.

17.12 LIMITATION OF DAMAGES. NEITHER JAZZ PHARMACEUTICALS NOR UCB SHALL HAVE ANY LIABILITY OF ANY KIND TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES, EVEN IF JAZZ PHARMACEUTICALS OR UCB, AS THE CASE MAY BE, SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL LOSS OR DAMAGE BY THE OTHER PARTY. FOR PURPOSES OF THE LIMITATION OF LIABILITY IN THE IMMEDIATELY PRECEDING SENTENCE, (i) LEGAL FEES AND EXPENSES THAT ARE RECOVERABLE AS PROVIDED IN ARTICLE IX SHALL NOT BE CONSIDERED INDIRECT DAMAGES, (ii) INDIRECT DAMAGES PAYABLE BY AN INDEMNIFIED PARTY TO A THIRD PARTY THAT WOULD BE RECOVERABLE UNDER THE INDEMNITY PROVISIONS IN ARTICLE IX BUT FOR SUCH LIMITATION OF LIABILITY SHALL BE RECOVERABLE NOTWITHSTANDING SAID LIMITATION OF LIABILITY AND (III) **[*]** SHALL NOT BE DEEMED TO BE SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES EXCEPT IN RESPECT OF **[*]** IN ACCORDANCE WITH THE TERMS HEREOF.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement by their respective duly authorized representatives as of the Effective Date.

UCB PHARMA LIMITED

By: /s/ Robert J. Trainor
Name: Robert J. Trainor
Title: Executive Vice President and General Counsel

By: /s/ William J. Robinson
Name: William J. Robinson
Title: Executive Vice President Global Operations

JAZZ PHARMACEUTICALS, INC.

By: /s/ Robert M. Myers
Name: Robert M. Myers
Title: President

By: /s/ Matthew K. Fust
Name: Matthew K. Fust
Title: Chief Financial Officer

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APPENDIX A

TERRITORY

[*]

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APPENDIX B

TRADEMARK

Xyrem®

[*]

N/A = Not Available

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PATENT RIGHTS

[*]

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APPENDIX C

COMPONENTS OF STANDARD MANUFACTURING COST
AND
TRANSFER PRICE FOR CONTRACT YEAR 2006

Direct Manufacturing Costs	Per Unit/Orders of One Batch	
API @ $**[*]**/ kg	$**[*]**	
Bulk Pack and Fill	$**[*]**	
Stability Testing	$**[*]**	
Release Testing	$**[*]**	
Set-up Fee @ $**[*]** Flat Rate	$**[*]**	Per campaign of less than **[*]** lots of bulk unlabeled/DSM
Subtotal Product	$**[*]**	
Manufacturing Cost Markup @ **[*]**	$**[*]**	
Transfer Price	**$[*]**	

Assumptions:

1. Total Direct Manufacturing Costs above based on production of one (1) lot of approximately **[*]** bottles.
2. API is manufactured per the terms of the contract between Lonza and Jazz Pharmaceuticals.
3. Product is manufactured per the terms of the contract between DSM and Jazz Pharmaceuticals.
4. Set-up fee and **[*]** markup on the set-up fee to be deleted if **[*]** more lots of bulk unlabeled Product are run in a campaign.

APPENDIX D

REGULATORY ASSISTANCE

1. Marketing Authorizations and Registrations

In connection with UCB's acquisition of the Marketing Authorizations and Registrations and in addition to Jazz Pharmaceuticals' obligations set forth elsewhere in this Agreement, Jazz Pharmaceuticals will, **[*]** (but subject to the limitations set forth in Section 3.2), take the following actions:

[*]

2. Training, Sales and Technical Literature.

In addition to the materials that Jazz Pharmaceuticals is to provide UCB pursuant to Section 6.5 of this Agreement, Jazz Pharmaceuticals shall also provide to UCB in accordance with Section 6.5, the following materials:

[*]

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APPENDIX E

TRADEMARK USE STANDARDS

See attached.

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The trademark use standards below are minimum requirements to ensure consistent and appropriate use of the Xyrem® trademark. The consistent application of the Xyrem® trademark standards arc essential to conveying a common image to reinforce consumer awareness and recognition of the Xyrem® trademark.

Use Requirements:

The Xyrem® trademark should always be displayed in its entirety will the word and design elements used together. To maintain a consistent presentation of the Xyrem® trademark, the word elements should never be separated from the design portion or otherwise manipulated. Such prohibited manipulation includes, but is not limited to, changes in the stylization, font, proportions, and spacing of the word elements.

In order to help preserve the visual impact of the Xyrem® trademark, a minimum amount of clear space should surround the Xyrem® trademark to separate the trademark from other elements such as headlines, text, and other imagery. In addition, the ® symbol should always be displayed with the Xyrem® trademark in its proper position following the last letter within the Xyrem® trademark in those countries in which the mark is registered. Otherwise, the TM symbol should be used.

Color Requirements:

Two color Xyrem logo: The Xyrem® trademark should be presented in Pantone Match System Blue PMS 287 and Orange PMS 144 and black.

Four color print to match Xyrem logo: The Xyrem® trademark is made up of print to match orange PMS 144, yellow PMS 123, blue PMS 287 and Black.

Black and White Xyrem logo: The Xyrem® trademark is made up of Black and White.

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Schedule 8.1(e)(ii)
Patent Rights, Trademarks and Other Intellecutal Property
Relating to the Product in the Territory

[*]

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Schedule 8.1(e)(iii)
Infringement or Conflict

None

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Schedule 8.1(f)(i)
Contracts

[*]

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Schedule 8.1(f)(ii)
Default, Breach or Violation

None

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Schedule 8.1(g)(i)
Claims

None

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Schedule 8.1(h)
Required Approvals

None

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EXHIBIT 10.42

Execution Copy Confidential

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LICENSE AGREEMENT

by and between

SOLVAY PHARMACEUTICALS, INC.

and

JAZZ PHARMACEUTICALS, INC.

relating to

LUVOX®-IR (fluvoxamine) and LUVOX®-ER (fluvoxamine extended release)

Dated January 31, 2007

LICENSE AGREEMENT

This License Agreement (the "Agreement") is made and entered into as of the 31st day of January, 2007 ("Effective Date"), by and between SOLVAY PHARMACEUTICALS, INC., a Georgia corporation having its principal office at 901 Sawyer Road, Marietta, Georgia 30062 ("Solvay") and JAZZ PHARMACEUTICALS, INC., a Delaware corporation, having its principal offices at 3180 Porter Drive, Palo Alto, California 94304 ("Jazz Pharmaceuticals"). Solvay and Jazz Pharmaceuticals are referred to herein on occasion separately as a "Party" or together as the "Parties".

WHEREAS, each of Solvay and Jazz Pharmaceuticals is engaged in the business of developing, manufacturing, distributing and selling pharmaceuticals; and

WHEREAS, Solvay is the owner or exclusive licensee of certain assets related to the Products (as hereinafter defined); and

WHEREAS, Solvay has developed and currently has filed an NDA (as hereinafter defined) for each of the Products;

WHEREAS, Solvay has agreed to transfer, assign and/or license to Jazz Pharmaceuticals, as hereinafter set forth, certain rights and interests relating to the Products, and Jazz Pharmaceuticals has agreed to acquire such rights and interests, all as set forth in this Agreement; and

WHEREAS, the Parties will enter into the following agreements related to the Products at the Time of Closing (as hereinafter defined) under this Agreement, the Trademark License and the Supply Agreement (each, as hereinafter defined).

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth in this Agreement, the Parties agree as follows:

1. Definitions

The capitalized terms used in this Agreement shall have the meanings specified below or as otherwise set forth in this Agreement.

1.1 "Affiliate" of an entity means any person or entity controlling, controlled by or under common control with such entity for so long as such control exists. As used herein, "control" means ownership, directly or indirectly, of at least fifty (50%) percent of the common stock or voting ownership interests of the entity in question. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of Jazz Pharmaceuticals, such as financial institutions, venture capital funds and private equity investors, will not be "Affiliates" of Jazz Pharmaceuticals for purposes of this Agreement.

1.2 "API" means fluvoxamine maleate, the active pharmaceutical ingredient in the Products.

1.3 "API Information" means the **[*]** the API.

1.4 "Closing Date" means January 31, 2007 or such other time as Solvay and Jazz Pharmaceuticals shall mutually agree.

1.5 "FDA" means the United States Food and Drug Administration, and any successor entity thereto.

1.6 "IND" means any Investigational New Drug Applications relating to the Products.

1.7 "Elan" means Elan Pharma International Limited, a company incorporated in Ireland, and its affiliates.

1.8 "Elan Agreement" means the License Agreement by and between Solvay and Elan dated December 22, 1997, as amended up to and including the Closing Date. A copy of the Elan Agreement, as amended up to and including the Effective Date, is attached hereto as Exhibit A.

1.9 "First Commercial Sale" of a Product means the first invoiced commercial sale by Jazz Pharmaceuticals or its Affiliates or sublicensees (excluding, however, sales made by one such entity to another such entity) to a Third Party for commercial purposes in the Territory after receipt of appropriate NDA approval for such Product.

1.10 "Laws and Regulations" means all applicable laws, statutes, licensing requirements, rules, regulations and judicial or administrative decisions applicable to the Products in the Territory and the development, use, sale, import, marketing, promotion, distribution or manufacture thereof in the Territory.

1.11 "Milestones" means the events identified in Sections 3.1 (b) through (k).

1.12 "Milestone Payments" means the payments to be made by Jazz Pharmaceuticals to Solvay pursuant to Sections 3.1 (b) through (k).

1.13 "NDAs" means the New Drug Applications for approval to market the Products submitted to the FDA, as amended or supplemented from time to time, as listed on Schedule 1.13. The NDA currently filed with the FDA relating to LUVOX-IR **[*]** will be referred to individually as the "LUVOX-IR NDA" and the NDA currently filed with the FDA relating to LUVOX-ER **[*]** will be referred to individually as the "LUVOX-ER NDA". The LUVOX-IR NDA and the LUVOX-ER NDA will be referred to collectively as the "Current NDAs."

1.14 "Net Sales" means the gross amounts invoiced by Jazz Pharmaceuticals and its Affiliates and sublicensees on all sales of the Products to independent unrelated Third Parties in bona fide arms' length transactions (including, but not limited to, hospital sales, mail orders, retail sales, and sales to federal or state governments, wholesalers, medical institutions, etc.) in the Territory, less (a) transportation and freight charges, including insurance and handling, to the extent that such charges are included in the gross amounts invoiced in connection with the transport of the Products; (b) sales, use and excise taxes, value added taxes, and duties which fall

due and are paid as a consequence of such sales by Jazz Pharmaceuticals or its Affiliates or sublicensees and any other governmental charges imposed upon the importation, use or sale of the; and (c) the following deductions actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to Jazz Pharmaceuticals or its Affiliates**:**

(i) trade, quantity and cash discounts;

(ii) allowances or credits on account of rejection, defects, recall or return of the Products or on account of retroactive price reductions or wholesaler chargebacks affecting such Products; and

(iii) rebates, refunds, reductions and charge backs specifically related to Products including those granted to insurers, buying groups, government agencies or similar bodies.

"Net Sales" shall not include any sales among Jazz Pharmaceuticals and its Affiliates and sublicensees.

1.15 "Products" means the pharmaceutical preparations owned or controlled by Solvay and/or developed on behalf of Solvay under the Elan Agreement containing the API, referred to and defined below as LUVOX-IR (fluvoxamine maleate) and LUVOX-ER (fluvoxamine maleate extended release), which are the subject of, and are further described in, the Current NDAs. LUVOX®-IR (fluvoxamine maleate) will be referred to individually as "LUVOX-IR" and LUVOX®-ER (fluvoxamine maleate extended release) will be referred to individually as "LUVOX-ER".

1.16 "Product Experience Data" means all adverse event information and all product complaints, both technical and medical, concerning the Products in Solvay's possession or control.

1.17 "Regulatory Materials" means all regulatory submissions and filings or registrations, including any INDs, NDAs, certifications or approvals, made with or received from the FDA and all correspondence and material communications related thereto, together with all other reports or correspondence provided to or received from the FDA, in each case which primarily relate to the API or any Product.

1.18 "Solvay Know-How" means all data (including all clinical, adverse event and product complaint data), information, specifications, methods, processes, techniques, compositions, technology, discoveries, inventions, assays, designs for and results of experiments, tests and studies, study materials, information contained in submissions to and information from the FDA, and statistical and other analyses, in each case related to one or both of the Products or otherwise required for or useful to the development, manufacture, use or sale of one or both Products in the Territory, whether patented or unpatented, which are, at the Time of Closing, owned or controlled by Solvay, including, without limitation, pharmacology, toxicology, clinical and non-clinical safety and efficacy data and quality control and quality assurance data, expressly excluding, however, API Information**.**

1.19 "Territory" means, in the case of LUVOX-IR, the United States of America, its territories and possessions, including Puerto Rico and the U.S Virgin Islands (collectively, the "United States") and, in the case of LUVOX-ER, the United States and any country(ies) for which Jazz Pharmaceuticals exercises its right of first offer described in Section 2.8 below.

1.20 "Third Party" means any person or entity other than Solvay or Jazz Pharmaceuticals or each of their respective Affiliates or, in the case of Jazz Pharmaceuticals, its sublicensees.

1.21 "Time of Closing" means 11:00 A.M. (Pacific Daylight Time) on the Closing Date or such other time and date as the Parties mutually agree in writing at which time the Parties are to deliver the closing documents and other deliverables described in Article 8.

1.22 "Trademark" means LUVOX® and all trademarks, service marks, logos, slogans, and trade names (whether or not registered), including all variations, derivations, combinations, registrations and applications for registration or renewals of the foregoing and all goodwill associated therewith to the extent of any interest owned, controlled or licensed by Solvay.

2. Assignment and License Grants

2.1 License to Solvay Know-How. Solvay hereby grants to Jazz Pharmaceuticals, and Jazz Pharmaceuticals hereby accepts, an exclusive, royalty bearing license, with the right to sublicense, to use Solvay Know-How to use, sell, have sold, offer to sell, import, market, promote and distribute the Products solely in the Territory, and to make or have made the Products inside or outside the Territory (subject to the terms of the Supply Agreement) solely for use, sale, marketing, promotion or distribution in the Territory, and for no other purpose whatsoever, in accordance with and subject to the terms and conditions of this Agreement, the Supply Agreement and the Elan Agreement.

2.2 Assignment of Elan Agreement. Pursuant to the terms and conditions of the assignment and assumption agreement attached hereto as Exhibit D ("Assignment and Assumption Agreement"), Solvay shall assign to Jazz Pharmaceuticals, and Jazz Pharmaceuticals shall assume, in each case as of Time of Closing, all of Solvay's rights and obligations under the Elan Agreement**.** Solvay will not enter into any amendment to, or otherwise agree to any modification of, the Elan Agreement in the form attached hereto as Exhibit A between the Effective Date and the Closing Date without the prior written consent of Jazz Pharmaceuticals.

2.3 Trademark License. The Parties agree to enter into, at the Time of Closing, a Trademark License Agreement dated as of the Closing Date in the form attached as Exhibit B hereto (the "Trademark License") whereby Solvay grants to Jazz Pharmaceuticals an exclusive license to use the Trademark in the Territory in connection with the Products. In addition, Solvay agrees to apply for any additional trademarks in the Territory containing the term LUVOX® (the "Additional Trademarks) as may be requested by Jazz Pharmaceuticals **[*]** and such Additional Trademarks will be included in the definition of (i) Trademark for purposes of this Agreement and (ii) Licensed Mark (as defined in the Trademark License) for purposes of the Trademark License without any further action required by either Party. For the avoidance of doubt, any Additional Trademark shall be the **[*]**.

2.4 Supply Agreement. The Parties agree to enter into, at the Time of Closing, a supply agreement dated as of the Closing Date for supply of API in the form attached hereto as Exhibit C (the "Supply Agreement"), pursuant to which Solvay will manufacture Jazz Pharmaceuticals' requests of API for Jazz Pharmaceuticals during the term thereof. The Parties further agree to enter into a Quality Agreement promptly after the Closing Date defining each Party's responsibilities with respect to quality matters in connection with the Supply Agreement.

2.5 Sublicense to Solvay. Jazz Pharmaceuticals agrees to grant to Solvay an exclusive royalty-free sublicense, outside the LUVOX-ER Territory, under all of the rights assigned and licenses granted hereunder, to use, sell, have sold, offer to sell, import, market, promote and distribute LUVOX-ER outside the LUVOX-ER Territory subject to the Parties negotiating and entering into an agreement within **[*]** days after the Time of Closing providing for (a) the grant of such royalty-free sublicense rights as described above (and no additional payments will be due to Jazz Pharmaceuticals from Solvay for such sublicense rights); (b) an appropriate apportionment of any payments due to Elan under the Elan Agreement with respect to sales outside the LUVOX-ER Territory; (c) arrangements whereby Solvay will provide Jazz Pharmaceuticals with reports and other information regarding its activities as a sublicensee sufficient to allow Jazz Pharmaceuticals to satisfy its obligations to Elan under the Elan Agreement; (d) Solvay to be bound by terms required to be passed through to a sublicense under the Elan Agreement; (e) Jazz Pharmaceuticals to supply LUVOX-ER to Solvay for sale outside the LUVOX-ER Territory for a price equal to the price that Jazz Pharmaceuticals pays to Elan for LUVOX-ER **[*]** (**[*]**%) percent of such price to cover administrative costs; (f) arrangements whereby Jazz Pharmaceuticals will provide Solvay with all necessary access to the NDA dossier for use outside of the Territory; and (g) such other provisions as the Parties deem appropriate. The Parties will negotiate and execute such an agreement promptly and in good faith within **[*]** days after the Time of Closing.

2.6 No Sales By Solvay Inside the Territory. Solvay, its Affiliates and any successors or assigns of Solvay or its Affiliates shall not, and shall not at any time during the term of this Agreement enter into an agreement whereby it will: (a) sell, market, promote or distribute, directly or indirectly, LUVOX-ER in the Territory; (b) sell, market, promote or distribute, directly or indirectly, a fluvoxamine product in the United States; or (c) sell or distribute the Products to any person outside the Territory if Solvay has knowledge that such person intends to sell such Products in the United States. To the extent permitted by law, such agreement shall secure from such Third Party its obligation to abide by the restrictions relating to inside the Territory contained in this Agreement, including refraining from knowingly engaging, directly or indirectly, in parallel importation or dealing in "grey market" products in connection with its sale and distribution of the Products.

2.7 No Sales By Jazz Pharmaceuticals Outside the Territory. Jazz Pharmaceuticals, its Affiliates and any successors or assigns of Jazz Pharmaceuticals or its Affiliates shall not at any time during the term of this Agreement enter into an agreement whereby it will: (a) sell, market, promote or distribute, directly or indirectly, LUVOX-ER outside the Territory; or (b) sell or distribute LUVOX-ER to any person inside the Territory if Jazz Pharmaceuticals has knowledge that such person intends to sell such LUVOX-ER outside the Territory. To the extent permitted by law, such agreement shall secure from such Third Party its obligation to abide by the restrictions

relating to sales outside the Territory contained in this Agreement, including refraining from knowingly engaging, directly or indirectly, in parallel importation or dealing in "grey market" products in connection with its sale and distribution of LUVOX-ER.

2.8 Right of First Offer. In the event (a), (b) or (c) below occurs, Solvay hereby grants to Jazz Pharmaceuticals a right of first offer to acquire the exclusive license or right to commercialize LUVOX-ER in the applicable country outside the Territory:

(a) Within **[*]** months following the **[*]** in a country, Solvay has not **[*]** LUVOX-ER;

(b) Within **[*]** months following the **[*]** in a country, Solvay has not **[*]** LUVOX-ER; or

(c) Solvay wishes to sublicense, assign or otherwise transfer the rights to LUVOX-ER in a country outside the Territory to any Third Party during the term of this Agreement.

If Solvay (i) fails to **[*]** stated in (a) or (b) above or (ii) wishes to transfer the rights to LUVOX-ER as set forth in (c) above, Solvay will provide prompt written notice of the same to Jazz Pharmaceuticals. Jazz Pharmaceuticals shall have **[*]** following the date of Solvay's written notice within which to deliver written notice to Solvay of its election to acquire the exclusive license or right to commercialize LUVOX-ER in such country. In the event Solvay does not receive such notice within this **[*]** period, the failure shall be deemed to be Jazz Pharmaceuticals' election not to acquire the exclusive license or right for such country. In the event Solvay receives such notice within this **[*]** period, the parties will negotiate in good faith the terms upon which Jazz Pharmaceuticals will acquire this right in such country.

3. Compensation

3.1 Upfront Payment and Milestone Payments. As consideration for the license granted by Solvay to Jazz Pharmaceuticals hereunder, Jazz Pharmaceuticals will make the following upfront and milestone payments to Solvay:

(a) Two million ($2,000,000.00) dollars to be paid as a non-refundable payment at the Time of Closing (the "Upfront Payment");

(b) Two million ($2,000,000.00) dollars within fifteen (15) days of the First Commercial Sale of LUVOX-IR, supplied by or on behalf of Solvay, by Jazz Pharmaceuticals;

(c) [*] dollars within fifteen (15) days of receipt of FDA approval of the first indication for the LUVOX-ER NDA (which is either an indication for the treatment of obsessive compulsive disorder ("OCD") or an indication for the treatment of generalized social anxiety disorder ("SAD"));

(d) [*] dollars within fifteen (15) days of receipt of FDA approval of a second indication for the LUVOX-ER NDA (which is either an indication for the treatment of OCD or an indication for the treatment of SAD);

(e) [*] dollars within fifteen (15) days of receipt of FDA approval of LUVOX-ER for OCD or SAD with a label that includes expiration dating of at least eighteen (18) months;

(f) [*] dollars within fifteen (15) days of the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals after FDA approval of the first indication for LUVOX-ER (which is either an indication for the treatment of OCD or an indication for the treatment of SAD); provided, however, if the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals occurs more than sixty (60) days following approval of the first indication due to Solvay's failure to supply API or Elan's failure to supply Product, the milestone payment payable pursuant to this Section 3.1(f) shall be reduced to [*] ($[*]) dollars;

(g) [*] dollars within fifteen (15) days of the First Commercial Sale of LUVOX-ER (regardless of indication) by Jazz Pharmaceuticals after FDA approval of the second indication for LUVOX-ER (which is either an indication for the treatment of OCD or an indication for the treatment of SAD); provided, however, if the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals after the FDA approval of the second indication for LUVOX-ER (which is either an indication for the treatment of OCD or an indication for the treatment of SAD) occurs more than sixty (60) days following approval of the second indication, due to Solvay's failure to supply API or Elan's failure to supply Product, the milestone payment payable pursuant to this Section 3.1(g) shall be reduced to [*] ($[*]) dollars;

(h) [*] dollars payable as set forth in Section 3.5 after twelve (12) months of uninterrupted supply of Jazz Pharmaceuticals' requirements of LUVOX-ER by Elan to Jazz Pharmaceuticals in accordance with the terms and conditions of the Elan Agreement as measured from the date of the First Commercial Sale of LUVOX-ER by Jazz Pharmaceuticals;

(i) [*] dollars payable as set forth in Section 3.5 when Net Sales of LUVOX-ER first reach one hundred million ($100,000,000.00) dollars in a single twelve month period;

(j) [*] dollars payable as set forth in Section 3.5 when Net Sales of LUVOX-ER first reach two hundred million ($200,000,000.00) dollars in a single twelve month period; and

(k) [*] dollars payable as set forth in Section 3.5 when Net Sales of LUVOX-ER first reach four hundred million ($400,000,000.00) dollars in a single twelve month period.

Each Milestone Payment shall be made only once, regardless of how many times each related Milestone is achieved. No payment shall be owed for a Milestone which is not reached. In the event that more than one Milestone is achieved at one time, then all applicable payments under Section 3.1 shall be made.

For the sake of clarity, it is acknowledged and understood that in the event both OCD and SAD indications are approved by the FDA at the same time, the payments in 3.1(c) and 3.1(d) will be due and payable at the same time and the payments in 3.1(f) and 3.1(g) will be due and payable at the same time.

3.2 Reimbursement by Solvay. Solvay will reimburse Jazz Pharmaceuticals for any amounts paid by Jazz Pharmaceuticals to Elan under Sections **[*]** of the Elan Agreement within thirty (30) days of Jazz Pharmaceuticals' written notice to Solvay that such amounts have been paid.

3.3 Royalty Payments. In addition to the Upfront Payment and Milestone Payments set forth in Section 3.1 above, as further consideration for the transactions contemplated hereunder, including without limitation the license granted by Solvay to Jazz Pharmaceuticals hereunder, Jazz Pharmaceuticals shall pay to Solvay the following royalty payments on Net Sales of LUVOX-ER in each calendar year during the term of the Agreement until such time as **[*]**, excluding **[*]** (a) **[*]** percent of LUVOX-ER Net Sales up to and including **[*]** dollars in such calendar year, and (b) **[*]** percent of LUVOX-ER Net Sales in excess of **[*]** dollars in such calendar year. If Jazz Pharmaceuticals (i) is required, by a final court order from which no appeal can be taken, to obtain a royalty-bearing license from a Third Party under any patent which would be infringed by the manufacture, use, offer for sale, sale or import of LUVOX-ER by Jazz Pharmaceuticals or its Affiliates or sublicensees in the Territory or by the manufacture of LUVOX-ER outside the Territory solely for use, sale, marketing, promotion or distribution in the Territory, or (ii) in the exercise of its reasonable judgment, Jazz Pharmaceuticals believes that a license from such Third Party is necessary, then royalty payments due to Solvay under this Section 3.3 will be reduced by an amount equal to **[*]** by Jazz Pharmaceuticals to such Third Party under such license, provided, however, that in no event will the royalty payments otherwise due under this Section 3.3 be so reduced by more than **[*]** percent of the amount that would otherwise be calculated under this Section 3.3.

3.4 Records. Jazz Pharmaceuticals shall keep complete and accurate records of all sales of LUVOX-ER in the applicable Territory and the calculation of Net Sales of LUVOX-ER. Solvay shall have the right, at Solvay's expense and after thirty (30) days' prior written notice to Jazz Pharmaceuticals, through an independent certified public accountant, on a mutually agreeable date, to examine such records at any time within **[*]** after the due date of the royalty payments to which such records relate (but no more than **[*]**) during regular business hours, during the life of this Agreement and for **[*]** after its expiration or termination, in order to verify the accuracy of the reports to be made under Section 3.5 hereunder. The results of such examination will be made available to Jazz Pharmaceuticals. If, thereafter, Jazz Pharmaceuticals disputes in good faith the accuracy of the results of such examination, the parties will retain a second independent certified public accountant whose examination will be binding upon both parties. **[*]**.

3.5 Reports. Within forty-five (45) days after the end of each calendar quarter during the term of this Agreement, Jazz Pharmaceuticals shall provide Solvay with a written report of Net Sales of LUVOX-ER during such quarter. Simultaneously with the submission of such report, Jazz Pharmaceuticals shall pay to Solvay all royalty payments due to Solvay under Section 3.3 hereof and the milestone payments due under Sections 3.1(h), (i), (j) and (k), if applicable. Interest, at a rate of **[*]** percent (**[*]**%) per annum, or at the highest legal rate if less than **[*]**%, shall be payable for any late payments.

3.6 Payment Mechanics, Taxes. All payments will be made by wire transfer to an account designated by Solvay to Jazz Pharmaceuticals in writing. All undisputed payments not made when due hereunder will bear interest at the rate stated in Section 3.5 on the date the payment became due. Jazz Pharmaceuticals shall be responsible for the payment of, and shall promptly pay, all federal, state, and local transfer, sales, and other taxes, if any, levied or imposed on Jazz Pharmaceuticals as a result of the transactions contemplated by this Agreement, including without limitation sales and use taxes but excluding any tax payable on any income or gain of Solvay or related to any Upfront Payment, Milestone Payment or royalty payable to Solvay hereunder, for which Solvay shall be responsible and shall pay. All sums payable to Solvay hereunder shall be paid net of any required withholding taxes. Jazz Pharmaceuticals shall submit to Solvay proof of payment of any taxes withheld in accordance with the preceding sentence.

4. Representations and Warranties of Solvay. The only representations and warranties of Solvay are those contained in this Article 4. Solvay hereby represents and warrants to Jazz Pharmaceuticals as follows as of the Effective Date and again as of the Time of Closing:

4.1 Organization; Standing. Solvay is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation, and has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted, including the performing of all the obligations set forth in this Agreement.

4.2 Authorization; Binding Effect. The execution and delivery by Solvay of this Agreement, the performance by Solvay of its obligations hereunder and the consummation by

Solvay of the transactions contemplated hereby have been duly authorized by all necessary action on the part of Solvay. This Agreement has been duly executed and delivered by a duly authorized representative of Solvay and constitutes the valid and legally binding obligation of Solvay enforceable against Solvay in accordance with its terms.

4.3 No Conflict; No Consents Required. The execution, delivery and performance of this Agreement by Solvay will not (a) violate or result in the breach of, constitute a default under, or accelerate the performance required by, any term of any covenant, agreement or understanding to which Solvay is a party, or any judgment, order, decree, law, rule or regulation to which Solvay entities or is subject, or (b) violate or constitute a breach of or default under the articles of incorporation or bylaws of Solvay. Except as provided in Article 7 and other than any consent required from Elan under the terms of the Elan Agreement as well as any standard corporate proceedings required to be taken by Solvay in connection with the transactions contemplated hereby, no authorization, consent, approval, license, exemption of or filing or registration with any Third Party is or will be necessary for, or in connection with, the execution of this Agreement, the Trademark License or the Supply Agreement by Solvay or the performance of Solvay's obligations thereunder.

4.4 Title; Liens and Encumbrances. Solvay has good and marketable title, free of any mortgage, charge, lien, security interest, restriction, encumbrance or pledge of any nature, to the rights being transferred or licensed to Jazz Pharmaceuticals hereunder. Solvay has the lawful right to grant the licenses as described herein and to assign the Elan Agreement as assigned herein.

4.5 Claims; Litigation. Except as described in Schedule 4.5 attached hereto, there is no action, claim, suit, arbitration, or other legal or administrative proceeding, pending, or, to the knowledge of Solvay or its Affiliates, threatened against, Solvay or its Affiliates pertaining to the API or either or both Products or the development, use, sale, import, marketing, promotion, distribution or manufacture of any thereof, the NDAs or the Elan Agreement and, to Solvay's or its Affiliates' knowledge, no governmental investigation pertaining to any of the foregoing is pending or threatened. There is no judgment, decree, injunction, rule or order of any court, governmental department, commission, agency, instrumentality or arbitrator or other similar ruling outstanding against Solvay or its Affiliates relating to the API or the Products or the development, use, sale, import, marketing, promotion, distribution or manufacture thereof, the NDAs or the Elan Agreement.

4.6 No Broker. Solvay has not engaged any corporation, firm or other person who is entitled to any fee or commission as a finder or broker as a result of the negotiation or consummation of the transactions contemplated by this Agreement.

4.7 Disclosure. Solvay has, to the best of its knowledge, provided or made available to Jazz Pharmaceuticals all relevant and material documents in Solvay's and its Affiliates' possession or control, in each case relating to the Solvay Know-How, the API and the Products and the development, use, sale, import, marketing, promotion, distribution or manufacture thereof in the Territory, the NDAs and the Elan Agreement, including without limitation all agreements with Third Parties set forth on Schedule 4.7 attached hereto related to the development, use, sale, import, marketing, promotion, distribution or manufacture of the API or Products in the Territory

(collectively, the "Third Party Agreements"), and all Product Experience Data and Regulatory Materials. No representations or warranties of Solvay in this Agreement, and no statement contained in any document, certificate or other writing furnished, or to be furnished, to Jazz Pharmaceuticals pursuant hereto contains any untrue statement of a material fact, or omits to state any material fact, which would, in light of the circumstances under which it was made, make such representations, warranties or statements not misleading.

4.8 Compliance with Laws and Regulations. To Solvay's knowledge, Solvay and its Affiliates have complied and are in compliance with all Laws and Regulations and all laws, statutes, licensing requirements, rules, regulations, and judicial or administrative decisions applicable to the API, the Current NDAs and the Elan Agreement. Without limiting the foregoing, in Solvay's good faith belief without further investigation (a) no statement contained in any IND, Current NDA or other Regulatory Materials related to the API and the Products contains any untrue statement of a material fact, or omits to state any material fact, which would, in light of the circumstances under which it was made, make any statement of a material fact misleading, and (b) there is no relevant material clinical trial data, CMC information, Product Experience Data or other data or information that should have been disclosed to the FDA in connection with the filing of any IND, Current NDA or Regulatory Materials which has not been so disclosed to the FDA.

4.9 Other Fluvoxamine Products. Solvay and its Affiliates do not **[*]**, including any combination product, **[*]**.

4.10 Contracts. Solvay is not in material breach of or default under the Elan Agreement or any other Third Party Agreements and, to Solvay's knowledge, no event has occurred which with the passage of time or giving of notice or both would constitute such a default. To Solvay's knowledge, there is no existing material breach or default by Elan under the Elan Agreement or by any Third Party under any Third Party Agreement and, in each case, no event has occurred which with the passage of time or giving of notice or both would constitute such a default. Solvay has not received any notice from Elan that it intends to terminate or is threatening to terminate or to breach the Elan Agreement or that Solvay is in breach of the Elan Agreement. Solvay has not received any notice from any Third Party that it intends to terminate or is threatening to terminate or to breach any Third Party Agreement or that Solvay is in breach of any Third Party Agreement.

4.11 Patents. The patents and patent applications listed on Schedule 4.11 are the only patents or patents applications owned, controlled or licensed by Solvay or its Affiliates or, to Solvay's knowledge, owned, controlled or licensed by Elan relating to the Products in the applicable Territory.

4.12 Claims of Infringement. Neither Solvay nor any of its Affiliates has received any notice of any claims by any Third Party asserting that the API or the Products, or the development, use, sale, import, marketing, promotion, distribution or manufacture thereof as contemplated herein, infringes or will infringe or misappropriates or will misappropriate any patent rights or other intellectual property rights of any Third Party or require any payments to any Third Party; **[*]** with regard to **[*]**.

4.13 Third Party Intellectual Property Rights. To the best of Solvay's and its Affiliates' knowledge after reasonable inquiry, no Third Party patent rights or other intellectual property rights are necessary for the development, use, sale, import, marketing, promotion, distribution or manufacture of the Products as contemplated herein, except those rights assigned to Jazz Pharmaceuticals hereunder under Elan Agreement.

4.14 No Conflicting Rights. Solvay has not granted, and will not grant during the term of this Agreement, any right to any Affiliate or Third Party which would conflict with the rights granted to Jazz Pharmaceuticals hereunder. Solvay will not take, or cause or permit any Affiliate or Third Party to take, any action that will conflict with, contravene or otherwise limit or restrict the rights of Jazz Pharmaceuticals hereunder or the right of Jazz Pharmaceuticals to enjoy the benefits of this Agreement.

4.15 Elan Agreement. The copy of the Elan Agreement attached hereto as Exhibit A is a true, correct and complete copy of the Elan Agreement as in effect as of the Effective Date.

5. Representations and Warranties of Jazz Pharmaceuticals. The only representations and warranties of Jazz Pharmaceuticals are those contained in this Article 5. Jazz Pharmaceuticals hereby represents and warrants to Solvay as follows as of the Effective Date and again as of the Time of Closing:

5.1 Organization; Standing. Jazz Pharmaceuticals is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation, and has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted, including the performing of all the obligations set forth in this Agreement.

5.2 Authorization; Binding Effect. The execution and delivery by Jazz Pharmaceuticals of this Agreement, the performance by Jazz Pharmaceuticals of its obligations hereunder and the consummation by Jazz Pharmaceuticals of the transactions contemplated hereby have been duly authorized by all necessary action on the part of Jazz Pharmaceuticals. This Agreement has been duly executed and delivered by a duly authorized officer of Jazz Pharmaceuticals and constitutes the valid and legally binding obligation of Jazz Pharmaceuticals enforceable against Jazz Pharmaceuticals in accordance with its terms.

5.3 No Conflict; Consents. The execution, delivery and performance of this Agreement by Jazz Pharmaceuticals will not (a) violate or result in the breach of, constitute a default under, or accelerate the performance required by, any term of any covenant, agreement or understanding to which Jazz Pharmaceuticals is a party, or any judgment, order, decree, law, rule or regulation to which Jazz Pharmaceuticals is subject and (b) violate or constitute a breach of or default under the certificate of incorporation or bylaws of Jazz Pharmaceuticals. Except as provided in Article 7 as well as any standard corporate proceedings required to be taken by Jazz Pharmaceuticals in connection with the transactions contemplated hereby, no authorization, consent, approval, license, exemption of or filing or registration with any Third Party is or will be necessary for, or in connection with, the execution of this Agreement, the Trademark License or the Supply Agreement by Jazz Pharmaceuticals or the performance of Jazz Pharmaceuticals' obligations thereunder.

5.4 No Broker. Jazz Pharmaceuticals has not engaged any corporation, firm or other person who is entitled to any fee or commission as a finder or broker as a result of the negotiation or consummation of the transactions contemplated by this Agreement.

5.5 Disclosure. No representations or warranties of Jazz Pharmaceuticals in this Agreement, and no statement contained in any document, certificate or other writing furnished, or to be furnished, to Solvay pursuant hereto contains any untrue statement of a material fact, or omits to state any material fact, which would, in light of the circumstances under which it was made, make such representations, warranties or statements not misleading.

6. Regulatory Matters.

6.1 Transfer of Current NDAs. Within **[*]** business days of Solvay's receipt of notification of FDA approval of the LUVOX-IR NDA, Solvay shall transfer and assign ownership and responsibility of such NDA and corresponding INDs to Jazz Pharmaceuticals. Within **[*]** business days of Solvay's receipt of notification of FDA approval of the LUVOX-ER NDA, Solvay shall transfer and assign ownership and responsibility of the LUVOR-ER NDA and corresponding INDs to Jazz Pharmaceuticals.

6.2 Transfer of Regulatory Responsibilities. Until the transfer of each respective Current NDA (and corresponding INDs) to Jazz Pharmaceuticals, Solvay shall remain responsible, at its sole expense, for all regulatory responsibilities as holder of such NDA and corresponding INDs and all other responsibilities under applicable Laws and Regulations. Subject to Solvay's indemnification obligations hereunder and any other obligations and/or rights of Solvay contained in this Agreement and the Supply Agreement, effective upon the transfer and assignment of each respective Current NDA, all of Solvay's obligations and responsibilities as the holder of such Current NDAs shall be assumed in their entirety by Jazz Pharmaceuticals; provided, however, that Solvay will remain responsible for any liability incurred or obligation breached under each NDA which is not a Current NDA and corresponding INDs; provided further that Solvay will remain responsible for any liability incurred or obligation breached under each Current NDA and corresponding INDs prior to the effective date of the transfer and assignment to Jazz Pharmaceuticals of such Current NDA and corresponding INDs. Upon transfer of each respective Current NDA (and the corresponding INDs) to Jazz Pharmaceuticals, Jazz Pharmaceuticals shall assume, at its sole expense, all regulatory responsibilities as holder of such Current NDA and corresponding INDs and all other responsibilities under applicable Laws and Regulations in the applicable Territory, reporting and otherwise, in connection with each of the Products in the applicable Territory. These responsibilities shall include, without limitation, those responsibilities related to (i) the marketing and promotion by Jazz Pharmaceuticals and its Affiliates and sublicensees of the Product in the Territory; (ii) reporting Product Experience Data relating to the Products to the FDA; (iii) if applicable, the filing of additional new drug applications and/ supplements to NDAs for product line extensions, extensions of the expiry date and additional product claims or additions to the labeling of the Products; and (iv) any ongoing and future commitments to the FDA applicable to the holder of the Current NDAs.

6.3 Regulatory Materials. Solvay has provided Jazz Pharmaceuticals and will continue to provide Jazz Pharmaceuticals with full access to all Regulatory Materials and

Product Experience Data. Upon the transfer and assignment of each respective Current NDA and corresponding INDs, Solvay will provide Jazz Pharmaceuticals with all Regulatory Materials and copies of Product Experience Data related thereto (including without limitation any and all electronic databases related thereto); provided that Solvay may retain an archival copy of the Regulatory Materials, including supplements and records that are required to be kept under 21 C.F.R. §314.81.

6.4 Communications with Regulatory Agencies. Prior to the transfer of the Current NDAs to Jazz Pharmaceuticals, Solvay shall have primary responsibility for communications with the FDA; provided, however, that (a) Solvay will promptly provide Jazz Pharmaceuticals with copies of all correspondence (and summaries of all communications) from or to the FDA with respect to the API and the Products and the Current NDAs, (b) Jazz Pharmaceuticals will have the right to review and comment upon any filings and correspondence from Solvay to the FDA with respect to the API, the Products and the Current NDAs prior to filing and Solvay will include any changes reasonably requested by Jazz Pharmaceuticals; (c) Jazz Pharmaceuticals will have the right to participate in all meetings and significant telephone calls with the FDA with respect to the API, the Products and the Current NDAs and (d) Solvay will not make any agreements with, or commitments to, the FDA or otherwise in connection with the API, the Products or the Current NDAs between the Effective Date and the Closing Date, and thereafter until the effective date of the transfers of the Current NDAs, without the prior written consent of Jazz Pharmaceuticals, which consent shall not be unreasonably delayed or withheld. After the transfer of the each Current NDA (and the corresponding INDs), Jazz Pharmaceuticals shall have responsibility for all communications with the FDA with respect matters relating to the Products and the Current NDAs and corresponding INDs. To the extent reasonably requested by Jazz Pharmaceuticals, Solvay will cooperate with and assist Jazz Pharmaceuticals in its communications with the FDA relating to the Products and the Current NDAs and corresponding INDs for a reasonable transition period after the effective date of the transfers of the Current NDAs.

6.5 Post-Transfer Activities. The Parties agree to enter into a Pharmacovigilance Agreement promptly after the Closing Date, defining each Party's responsibilities with respect to drug safety and communications relating thereto after the transfer of each Current NDA and the corresponding INDs to Jazz Pharmaceuticals.

6.6 Additional Regulatory Commitments. In the event that, in connection with or as a condition of the approval of either of the Current NDAs, the FDA requires the conduct of additional post-approval studies or activities, Solvay will reimburse Jazz Pharmaceuticals for **[*]** percent (**[*]**%) of all amounts expended by Jazz Pharmaceuticals and submitted to Solvay prior to the **[*]** anniversary of the date upon which such NDA approval or conditional approval is granted on the preparation for and conduct of such studies or other activities and related filings with regulatory authorities**[*]**.

7. HSR Filing

7.1 Filing. Solvay and Jazz Pharmaceuticals shall file, prior to, on or promptly after the Effective Date of this Agreement, with the Federal Trade Commission ("FTC") and the Antitrust Division of the United States Department of Justice ("Antitrust Division"), the notification and

report form (the "Report") required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR Act"), with respect to the transactions contemplated under this Agreement. The Parties shall cooperate with each other to proceed to obtain any necessary approvals under the HSR Act, including, without limitation, the expiration or, if requested by Jazz Pharmaceuticals, the earlier termination of any and all applicable waiting period required by the HSR Act. Each Party will be responsible for its own costs and expenses associated with any filing under the HSR Act and the Parties will share equally the filing fee due to the FTC for filing of the Report.

7.2 HSR Cooperation. Solvay and Jazz Pharmaceuticals shall each use diligent efforts to eliminate any concern on the part of any court or government authority regarding the legality of the proposed transaction, including, if required by federal or state antitrust authorities, promptly taking steps to secure government antitrust clearance, including, without limitation, cooperating in good faith with any government investigation.

7.3 HSR Termination. In the event that the FTC, the Antitrust Division or any U.S. court or government authority of competent jurisdiction shall issue a final determination to the Parties that the transactions contemplated under this Agreement are illegal and/or violative of U.S. federal antitrust laws, then either Party shall at any time thereafter have the right to terminate and rescind this Agreement by notifying the other Party to that effect. Upon mutual agreement, the Parties may also elect to contest such determination and shall coordinate such efforts with each Party bearing its own expenses in connection therewith. Upon receipt of notice of termination and rescission by a Party pursuant to this Section 7.3, this Agreement shall be rescinded and of no further force or effect and the Parties shall fully cooperate to return all rights, assignments and other interests and/or property exchanged or transferred by one Party to the other pursuant to this Agreement or otherwise in connection with the completion of the transactions contemplated hereunder, including all amounts paid by Jazz Pharmaceuticals hereunder.

8. Closing.

8.1 Conditions Precedent to Jazz Pharmaceuticals' Obligations. Each and every obligation of Jazz Pharmaceuticals to be performed on the Closing Date shall be subject to the satisfaction prior to or on the Closing Date of each of the following conditions, any or all of which may be waived by Jazz Pharmaceuticals in writing:

(a) Representations and Warranties True on the Closing Date. Each of the representations and warranties made by Solvay in this Agreement shall be true and correct in all material respects when made and shall be true, complete and correct in all material respects at and as of the Closing Date as though such representations and warranties were made or given on and as of the Closing Date.

(b) Compliance with Agreement. Solvay shall have in all material respects performed and complied with all of its agreements and obligations under this Agreement which are to be performed or complied with by Solvay prior to or on the Closing Date.

(c) Consents and Approvals. Solvay has received all approvals, consents and waivers that are required to effect the transactions contemplated hereby and copies of such documents

which are in Solvay's possession shall have been received by Jazz Pharmaceuticals on or prior to the Closing Date. Any necessary approvals under the HSR Act shall have been received, including, without limitation, the expiration or, if requested by Jazz Pharmaceuticals (or Solvay, at Jazz Pharmaceuticals' request), the earlier termination of any and all applicable waiting period required by the HSR Act.

8.2 Conditions Precedent to Solvay's Obligations. Each and every obligation of Solvay to be performed on the Closing Date shall be subject to the satisfaction prior to or on the Closing Date of each of the following conditions, any or all of which may be waived by Solvay in writing:

(a) Representations and Warranties True on the Closing Date. Each of the representations and warranties made by Jazz Pharmaceuticals in this Agreement shall be true, complete and correct in all material respects when made and shall be true and correct in all material respects at and as of the Closing Date as though such representations and warranties were made or given on and as of the Closing Date.

(b) Compliance with Agreement. Jazz Pharmaceuticals shall have in all material respects performed and complied with all of its agreements and obligations under this Agreement which are to be performed or complied with by Jazz Pharmaceuticals prior to or on the Closing Date.

(c) Consents and Approvals. Jazz Pharmaceuticals has received all approvals, consents and waivers that are required to effect the transactions contemplated hereby and copies of such documents which are in Jazz Pharmaceuticals' possession shall have been received by Solvay on or prior to the Closing Date. Any necessary approvals under the HSR Act shall have been received, including, without limitation, the expiration or, if requested by Jazz Pharmaceuticals, the earlier termination of any and all applicable waiting period required by the HSR Act.

8.3 Deliveries at Closing.

(a) Solvay Deliveries. At or prior to the Time of Closing, Solvay shall have delivered or caused to be delivered to Jazz Pharmaceuticals, any or all of which may be waived by Jazz Pharmaceuticals in writing:

(i) physical possession (or the implementation of arrangements reasonably satisfactory to both Parties of transfer and delivery of physical possession) of all tangible personal property (or copies thereof) concerning the Products, including all tangible personal property included in the Solvay Know-How, with as much as possible in electronic form;

(ii) a certificate, dated the Closing Date and signed by its President or any Vice President, to the effect that all corporate proceedings required to be taken by Solvay in connection with the transactions contemplated hereby have been taken and that all representations and warranties are true, complete and correct as of the Closing Date;

(iii) a duly executed Trademark License;

(iv) a duly executed Supply Agreement;

(v) a true, correct and complete copy of the Elan Agreement as in effect as of the Closing Date, accompanied by a certificate, dated the Closing Date and signed by Solvay's President or any Vice President, to that effect;

(vi) a written consent of Elan, in a form acceptable to Jazz Pharmaceuticals, to Solvay's assignment of the Elan Agreement hereunder;

(vii) a duly executed Assignment and Assumption Agreement relating to the Elan Agreement; and

(viii) such other documents, instruments and certificates as Jazz Pharmaceuticals and Solvay may mutually agree upon.

(b) Deliveries by Jazz Pharmaceuticals. At or prior to the Time of Closing, Jazz Pharmaceuticals shall deliver or cause to be delivered to Solvay, any or all of which may be waived by Solvay in writing:

(i) the Upfront Payment;

(ii) a duly executed Trademark License;

(iii) duly executed Supply Agreement;

(iv) a certificate, dated the Closing Date and signed by its Chief Executive Officer, to the effect that all corporate proceedings required to be taken by Jazz Pharmaceuticals in connection with the transactions contemplated hereby have been taken and that all representations and warranties are true, complete and correct as of the Closing Date;

(v) a duly executed Assignment and Assumption Agreement relating to the Elan Agreement; and

(vi) such other documents, instruments and certificates as Jazz Pharmaceuticals and Solvay may mutually agree upon.

9. Cooperation; Further Assurances.

9.1 Proceedings Relating to the Products. Each Party covenants and agrees as to any suit, action, arbitration or judicial proceeding or any governmental investigation or inquiry, relating to the API, either of the Products or the NDAs, being prosecuted or defended by the other Party, to cooperate in making records available to such other Party and to provide such access to, and use of, such information and data as reasonably requested by such other Party in connection therewith. Each Party will reimburse the Party providing such cooperation for its reasonable out-of-pocket expenses incurred in connection with its obligations hereunder.

9.2 Information. From time to time after the Closing Date, the Parties hereto shall deliver to each other such information and data concerning the transactions contemplated hereby as either Party may reasonably request including that required in order to enable such Party to complete and file all national, state and local forms which may be required to be filed by it and to complete all customary tax and accounting procedures and otherwise to enable such Party to satisfy its internal accounting, tax and other requirements.

9.3 Further Assurances. From time to time after the Closing Date, without further consideration, Solvay shall perform all such other actions and shall execute, acknowledge and deliver all such assignments, transfers, consents and other documents as Jazz Pharmaceuticals or its counsel may reasonably request with respect to, and for the purpose of carrying out or evidencing, any of the transactions contemplated hereby.

10. Indemnification; Insurance.

10.1 Survival. All representations and warranties of Solvay and Jazz Pharmaceuticals contained herein will survive for a period of **[*]** after the Time of Closing. The covenants and agreements of the parties hereto contained in this Agreement will survive and remain in full force for the applicable periods described therein or, if no such period is specified, **[*]**. Any right of indemnification pursuant to this Article 10 with respect to a claimed breach of a representation, warranty or covenant will expire at the date of termination of the representation, warranty or covenant claimed to be breached, unless on or prior to such date the party from whom indemnification is sought will have received notice in accordance with the provisions of Section 10.5 hereof.

10.2 Indemnification by Solvay. Solvay hereby agrees to indemnify Jazz Pharmaceuticals and its Affiliates and their respective officers, directors and employees (the "Jazz Pharmaceuticals Indemnified Parties") from and against all claims, disputes, actions, arbitrations, mediations, litigations, proceedings, suits and governmental investigations brought by a Third Party and any appeal therefrom (the "Claims"), and agrees to hold them harmless from, any costs, expenses, damages, and loss, including reasonable attorneys fees in respect of such Claims and to enforce rights to indemnification as herein provided ("Losses") to the extent such Losses arise from or in connection with the following:

(i) any breach by Solvay of any representation or warranty made by it contained in this Agreement, provided Solvay receives notice of the same within **[*]** after the Time of Closing;

(ii) any breach by Solvay of any of its covenants contained in this Agreement;

(iii) any and all liabilities and obligations of Solvay to Elan, any Affiliates of Elan or any other Third Party which liabilities or obligations either (A) accrued to Solvay prior to the Time of Closing, (B) relate to events occurring prior to the Time of Closing or (C) accrue to or from Solvay under any sublicense rights granted to Solvay by Jazz Pharmaceuticals under Section 2.5 of this Agreement;

(iv) the manufacture, sale, marketing or distribution of the API or Products outside the Territory by Solvay or its Affiliates or sublicensees, and the operation of the business of Solvay or its Affiliates or sublicensees related to the API or the Products at any time after the Closing Date;

(v) the negligence or willful misconduct of any of the Solvay Indemnified Parties (as defined below);

provided, however, that in each case Solvay will not be obligated to indemnify any Jazz Pharmaceuticals Indemnified Parties with respect to, and to the extent of, any Losses for which Jazz Pharmaceuticals is obligated to indemnify Solvay pursuant to Section 10.3.

Notwithstanding anything to the contrary, the indemnifications in favor of the Jazz Indemnified Parties contained in this Section 10.2: (a) **[*]**; (b) and **[*]**.

Jazz Pharmaceuticals acknowledges and agrees that the indemnification provided in this Section 10.2 **[*]**.

10.3 Indemnification by Jazz Pharmaceuticals. Jazz Pharmaceuticals hereby agrees to indemnify Solvay and its officers, directors and employees (the "Solvay Indemnified Parties") against, and agrees to hold them harmless from, any Claims and Losses to the extent such Losses arise from or in connection with the following:

(i) any breach by Jazz Pharmaceuticals of any representation or warranty made by it contained in this Agreement;

(ii) any breach by Jazz Pharmaceuticals of any of its covenants contained in this Agreement;

(iii) the manufacture, sale, marketing or distribution of the Products in the Territory by Jazz Pharmaceuticals or its Affiliates or sublicensees after the Closing Date, and the operation of the business of Jazz Pharmaceuticals or its Affiliates or sublicensees related to the Products at any time after the Closing Date; or

(iv) the negligence or willful misconduct of any of the Jazz Pharmaceuticals Indemnified Parties;

provided, however, that in each case Jazz Pharmaceuticals will not be obligated to indemnify any Solvay Indemnified Parties with respect to, and to the extent of, any Losses for which Solvay is obligated to indemnify Jazz Pharmaceuticals pursuant to Section 10.2.

Solvay acknowledges and agrees that the indemnification provided in this Section 10.3 will **[*]**.

10.4 No Incidental Damages. In no event will either Party be liable to the other Party for incidental, indirect, punitive, exemplary, special or consequential damages, such as losses of revenues or profits, whether based upon a claim or action of contract, warranty, negligence, strict liability or other tort, a product claim, or otherwise arising out of or related to this Agreement; provided, however, that the foregoing limitation shall not apply to damages due to a third party which are the subject of a valid claim for indemnification hereunder.

10.5 Procedure. In order for an indemnified party under this Article 10 (an "Indemnified Party") to be entitled to any indemnification provided for under this Agreement, such Indemnified Party will, promptly following the discovery of the matters giving rise to any

Loss, notify the indemnifying party under this Article 10 (the "Indemnifying Party") in writing of its claim for indemnification for such Loss, specifying in reasonable detail the nature of such Loss and the amount of the liability estimated to accrue therefrom, if known; provided, however, that failure to give such prompt notification will not affect the indemnification provided hereunder except to the extent the Indemnifying Party will have been actually prejudiced as a result of such failure (except that the Indemnifying Party will not be liable for any expenses incurred during the period in which the Indemnified Party failed to give such notice). Thereafter, the Indemnified Party will deliver to the Indemnifying Party, within ten (10) business days after the Indemnified Party's receipt of such request, all information and documentation reasonably requested by the Indemnifying Party with respect to such Loss.

10.6 Third Party Claims. If the indemnification sought pursuant hereto involves a claim made by a third party against the Indemnified Party (a "Third Party Claim"), the Indemnifying Party will be entitled to participate in the defense of such Third Party Claim and, if it so chooses, to assume the defense of such Third Party Claim with counsel selected by the Indemnifying Party; provided, however, that the Indemnifying Party shall not be entitled to assume control of such defense and shall pay the reasonable fees and expenses of counsel retained by the Indemnified Party if the Third Party Claim relates to or arises in connection with any criminal proceeding, action, indictment, allegation or investigation. Should the Indemnifying Party be permitted and so elect to assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof unless and to the extent that a conflict arises between the interests of the Parties. If the Indemnifying Party assumes such defense, the Indemnified Party will have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnifying Party, it being understood that the Indemnifying Party will control such defense. The Indemnifying Party will be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party for any period during which the Indemnifying Party has not assumed the defense thereof (other than during any period in which the Indemnified Party will have failed to give notice of the Third Party Claim as provided above) or in the event of a conflict of interest between the Parties. If the Indemnifying Party chooses to defend or prosecute a Third Party Claim, each of the Parties hereto will cooperate in the defense or prosecution thereof. Such cooperation will include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party of records and information which are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will agree to any settlement, compromise or discharge of such Third Party Claim which the Indemnifying Party may recommend and which by its terms obligates the Indemnifying Party to pay the full amount of the liability in connection with such Third Party Claim; provided, however, that the Indemnified Party shall have the right to consent to any such settlement, compromise or discharge that (x) would materially adversely affect the rights granted to the Indemnified Party hereunder, (y) would materially conflict with the terms of this Agreement or (z) would materially adversely affect the Products outside the Territory. Whether or not the Indemnifying Party will have assumed the defense of a Third Party Claim, the Indemnified Party will not admit any liability with respect to, or settle, compromise or discharge, such Third Party Claim without the Indemnifying Party's prior written consent.

11. Term and Termination.

11.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue in effect until terminated in accordance with the terms hereof.

11.2 Termination for Breach. This Agreement may be terminated by either Party in the event the other Party breaches its obligation(s) under this Agreement and does not cure the same within sixty (60) days following written notice of such breach; provided, however, that if the breach is of such a nature that it can not be cured within sixty (60) days, then the time to cure shall be extended until such breach can reasonably be cured.

11.3 Termination by Either Party. If the FTC and/or the Antitrust Division has not made a determination regarding the validity or legality of the transactions contemplated herein within six (6) months following the Effective Date, then either of the Parties may terminate this Agreement, in which case the Parties shall fully cooperate to return all rights, assignments and other interests and/or property exchanged or transferred by one Party to the other pursuant to this Agreement, including all amounts paid by Jazz Pharmaceuticals hereunder; provided, however, that a Party shall not be permitted to terminate this Agreement in the event that the failure of the FTC and/or the Antitrust Division to make a determination regarding the validity or legality of the transactions contemplated herein within six (6) months following the Effective Date is a result of such Party's failure to cooperate with respect to the Report in accordance with the terms of Article 7. In addition, this Agreement may be terminated by either Party in accordance with the terms of Section 7.3 and/or Section 13.9.

11.4 Termination by Jazz Pharmaceuticals. If either (a) the FDA has not approved the LUVOX-IR NDA by April 1, 2008 or (b) the FDA has not approved the LUVOX-ER NDA by April 1, 2008, then Jazz Pharmaceuticals shall have the right to terminate this Agreement with written notice to Solvay, in which case the Parties shall fully cooperate to return all rights, assignments and other interests and/or property exchanged or transferred by one Party to the other pursuant to this Agreement, including all amounts paid by Jazz Pharmaceuticals hereunder (expressly excluding the Upfront Payment).

12. Confidentiality.

12.1 "Confidential Information" means the existence of this Agreement, information relating to the terms of this Agreement, the products, services, business, personnel, research, development, manufacturing or commercial activities of a Party, including, but not restricted to, unpublished patent applications, formulae, compilations, programs, devices, concepts, tests, results, inventions, designs, methods, techniques, marketing and commercial strategy and information, processes, data concepts, and unique combinations of separate items which individually may or may not be confidential, which information is not generally known to the public and either derives economic value, actual or potential, from not being generally known or has a character such that the Party has a legitimate interest in maintaining its secrecy. Confidential Information will not include information which, as demonstrated by competent evidence: (i) was known to the receiving Party prior to the disclosure; (ii) was generally available to the public at the time of disclosure or becomes available to the public after disclosure other than through any act or omission of the receiving Party in breach of this Agreement; or (iii) becomes known to the receiving Party as the result of disclosure

from a third party under no obligation of secrecy to the disclosing Party. If Confidential Information is required to be disclosed by law or pursuant to the disclosure requirements of a governmental agency, the Party ordered to disclose the Confidential Information shall notify the disclosing Party which owns or supplied the Confidential Information sought to be disclosed pursuant to such request, requirement or order in sufficient time to allow such disclosing Party to oppose such request, requirement or order.

12.2 Confidentiality Obligation. The Parties shall each keep in strictest confidence all Confidential Information and shall not disclose such Confidential Information to any third person except employees, consultants or other agents who need to receive such Confidential Information for the purpose of achieving an objective of this Agreement and who are bound by obligations of confidentiality with respect thereto, as necessary in connection with the transactions provided for or contemplated hereby, or as may otherwise be required by law and to the extent related to the exploitation of the Products, including such disclosures to licensees, sublicensees or assigns as may be reasonably required to permit the exploitation of the Products. Each such licensee, sublicensee or assignee shall be obligated to by an agreement of confidentiality binding such licensee, sublicensee or assignee to the same extent to which the Party from which it received the Confidential Information is bound. The Parties shall exercise all necessary precautions to safeguard the secrecy of Confidential Information and to prevent the unauthorized disclosure thereof. Except as otherwise provided herein, the obligations of this Article 12 shall survive for a period of **[*]** years from the **[*]**.

13. Miscellaneous.

13.1 Force Majeure. If any Party is prevented from complying, either totally or in part, with any of the terms or provisions of this Agreement, by reason of force majeure, including, but not limited to fire, flood, earthquake, explosion, storm, strike, lockout or other labor trouble, riot, war, rebellion, accidents, acts of God and/or any other cause or externally induced casualty beyond its reasonable control, whether similar to the foregoing matters or not, then, upon written notice by the Party liable to perform to the other Party, the requirements of this Agreement or such of its provisions as may be affected, and to the extent so affected, shall be suspended during the period of such disability; provided that the Party asserting force majeure shall bear the burden of establishing the existence of such force majeure by clear and convincing evidence; and provided further, that the Party prevented from complying shall use its best efforts to remove such disability within thirty (30) days, and shall continue performance with the utmost dispatch whenever such causes are removed, and shall notify the other Party of the force majeure event not more than five (5) working days from the time of the event. When such circumstances arise, the Parties shall discuss what, if any, modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

13.2 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

13.3 Headings. Section headings are inserted for convenience of reference only and do not form a part of this Agreement, and no construction or inference shall be derived from them.

13.4 Counterparts. This Agreement may be executed simultaneously in two counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.5 Entire Agreement. This Agreement and the Exhibits attached hereto, together with the Trademark License, Assignment and Assumption Agreement and the Supply Agreement, set forth the entire agreement and understanding of the Parties regarding the subject matter.

13.6 Amendment; Waiver, Etc. This Agreement may be amended, modified, superseded or canceled, and any of its terms may be waived, only by a written instrument executed by both Parties or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of any Party at any time or times to require performance of any provision shall in no manner affect the rights of such Party at a later time to enforce the same. No waiver by any Party of any condition or of the breach of any term contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such breach or the breach of any other term of this Agreement.

13.7 No Third Party Beneficiaries. No person or entity not a Party to this Agreement, including any employee of any Party to this Agreement, shall have or acquire any rights by reason of this Agreement, nor shall either Party have any obligations or liabilities to such other person or entity by reason of this Agreement.

13.8 Assignment and Successors. This Agreement may not be assigned by either Party to any Third Party without the prior written consent of the other Party; except that either Party may assign this Agreement, without the prior written consent of the other Party, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation with or into such corporation. In the event of any such assignment, the assignee shall expressly assume in writing the performance of all the terms and conditions of this Agreement and all of the obligations to be performed by the assignor. Any assignment not in accordance with this Agreement will be void.

13.9 Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance will, to any extent, be held to be invalid or unenforceable, then (i) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, will not be affected thereby and each term, covenant or condition of this Agreement will be valid and be enforced to the fullest extent permitted by law; and (ii) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated; provided, however, that if a provision is stricken so as to significantly alter the economic arrangements of this Agreement, the Party adversely affected may terminate this Agreement upon sixty (60) days' prior written notice to the other Party.

13.10 Notices. All notices shall be mailed via certified mail, return receipt requested, by nationally recognized overnight courier or by facsimile transmission (receipt verified), addressed as follows, or to such other addresses as may be designated from time to time by notice given in the manner provided in this Section 13.10:

If to Solvay:
SOLVAY PHARMACEUTICALS, Inc.
901 Sawyer Road
Marietta, Georgia 30062
ATTN: Office of the President
CC: General Counsel
Facsimile: 770-578-5749

If to Jazz Pharmaceuticals:
JAZZ PHARMACEUTICALS, Inc.
3180 Porter Drive
Palo Alto, CA 94304
Attn: General Counsel
Facsimile: 650-496-3781

13.11 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed in accordance with the laws of the State of New York, without regard to principles of conflicts of law.

13.12 Publicity. The Parties will agree upon the contents of a joint press release or a Jazz Pharmaceuticals press release to be made promptly after the Closing Date or, if requested by Jazz Pharmaceuticals, at a later date chosen by Jazz Pharmaceuticals. Except for information in such press release, neither Party will make any public announcement concerning, or otherwise publicly disclose, the existence of this Agreement, any information with respect to the transactions contemplated by this Agreement, the performance under it or any of the terms and conditions hereof without the prior written consent of the other Party hereto. Notwithstanding the foregoing, either Party may make any public disclosure concerning the transactions contemplated hereby that in the opinion of such Party's counsel may be required by law or the rules of any stock exchange on which such Party's or its Affiliates' securities trade; provided, however, the Party making such disclosure will provide the non-disclosing Party with a copy of the intended disclosure reasonably, and to the extent practicable, prior to public dissemination, and the Parties hereto will coordinate with one another regarding the timing, form and content of such disclosure.

13.13 Consent/Approval. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval will not unreasonably be withheld, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval will not unreasonably be exercised.

13.14 Independent Contractors. Nothing herein will be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Except as otherwise expressly provided in this Agreement, neither Party assumes or will assume, either directly or indirectly, any liability or obligations of or for the other Party, whether past, present or future. Neither Party will have the authority to bind or obligate the other Party and neither Party will represent that it has such authority.

13.15 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing Party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such Party may be entitled.

13.16 Specific Performance. The Parties hereto agree that irreparable damage would occur in the event any provision of this Agreement was not performed in accordance with the terms hereof and that the Parties shall be entitled to seek specific performance of the terms hereof in addition to any other remedy at law or in equity.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

JAZZ PHARMACEUTICALS, INC.		**SOLVAY PHARMACEUTICALS, INC.**	
By:	/s/ Samuel R. Saks, M.D.	By:	/s/ Laurence J. Downey, M.D.
Print Name:	Samuel R. Saks, M.D.	Print Name:	Laurence J. Downey, M.D.
Title:	Chief Executive Officer	Title:	President and Chief Executive Officer
Date:	January 22, 2007	Date:	January 26, 2007

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

Exhibit A
Elan Agreement

{This Exhibit A has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

Exhibit B
Form of Trademark License Agreement

{This Exhibit B has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

Exhibit C
Form of Supply Agreement

{This Exhibit C has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

Exhibit D
Assignment and Assumption Agreement

{This Exhibit D has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

Schedule 1.13

There have been three NDAs filed related to LUVOX-IR or its predecessor products:

[*] (withdrawn in September 1994)
[*] (withdrawn in May 2002)
[*] (pending with the FDA)

There have been two NDAs filed related to LUVOX-ER or its predecessor products:

[*] (withdrawn in June 2001)
[*] (pending with the FDA)

Schedule 4.5

Solvay has been contacted regarding a **[*]** resulting from **[*]**. To Solvay's knowledge and belief, **[*]**.

Schedule 4.7

None.

Schedule 4.11

Elan has the following patents and patent applications:

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

EXHIBIT 10.46

.As executed

This Agreement is made the 22nd day of December 1997

BY AND BETWEEN

ELAN CORPORATION, plc

An Irish company, of Lincoln House, Lincoln Place, Dublin 2, Ireland.

AND

SOLVAY PHARMACEUTICALS, INC.

An American company, of 901 Sawyer Road, Marietta, Georgia, United States of America.

RECITALS

WHEREAS

- ELAN is beneficially entitled to the use of various patents, including the ELAN PATENT RIGHTS, which have been granted or are pending under the International Convention in relation to the development and production of drug specific dosage forms for pharmaceutical products and process, and
- ELAN is knowledgeable in the development of drug specific dosage forms and has developed a unique range of delivery systems designed to provide newer and better formulations of medicaments, and
- COMPANY wishes to have ELAN develop a new, improved dosage form or forms of the COMPOUND and ELAN is willing to use its technology to develop an improved dosage form or dosage forms of the COMPOUND.
- COMPANY is desirous of entering into a licensing agreement with ELAN by virtue of which COMPANY will be free to have manufactured the PRODUCT in accordance with the terms of this Agreement and COMPANY will be granted an exclusive world-wide licence to market the PRODUCT in the TERRITORY without infringing any of the ELAN PATENT RIGHTS or ELAN KNOW-HOW rights held by ELAN, and
- ELAN is prepared to develop and license the marketing and sales rights, including the ELAN PATENT RIGHTS and ELAN KNOW-HOW for the PRODUCT in the TERRITORY to COMPANY and ELAN is prepared to supply the PRODUCT to COMPANY.

NOW IT IS HEREBY AGREED AS FOLLOWS:

ARTICLE I : DEFINITIONS

1.1. In the present Agreement and any further agreements based thereon between the parties hereto, the following definitions shall prevail:

1. AFFILIATE shall mean any corporation or entity controlling, controlled by or under the common control of ELAN or COMPANY as the case may be.
2. cGCP, cGMP, cGLP shall mean current Good Clinical Practice, current Good Manufacturing Practice and current Good Laboratory Practices as defined in the Code of Federal Regulations 21 as issued by the FDA, as amended from time to time.

3. CMC SECTION shall mean the chemistry, manufacturing, and controls section of an NDA as defined in 21 CFR Section 314.50 (D)(1) & (E) and its equivalent in other registration applications.

4. COMPANY shall mean Solvay Pharmaceuticals, Inc. and any of its AFFILIATES.

5. COMPANY KNOW-HOW shall mean all knowledge, information trade secrets, data and expertise owned or licensed by COMPANY or to be developed by COMPANY during the term of this Agreement relating to the COMPOUND which is not generally known to the public, whether or not covered by any patent, copyright, design or other industrial or intellectual property rights and all clinical data relevant to the COMPOUND (excluding any such data which is relevant solely to **[*]**) generated by **[*]** during the PROJECT.

6. COMPANY PATENT RIGHTS shall mean all patents and patent applications listed in Appendix A, Part II. COMPANY PATENT RIGHTS shall also include all continuations, continuations-in-part, divisionals and re-issues of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder. Extensions of patents shall include: a) extensions under the U.S. Patent Term Restoration Act, b) extension of patents under the Japanese Patent Law, and c) Supplementary Protection Certificates for members of the European Patent Convention and other countries in the European Economic Area.

7. COMPOUND shall mean the active substance Fluvoxamine maleate, hereafter called Fluvoxamine.

8. COMPOUND SPECIFICATIONS shall mean the specifications for the COMPOUND as approved by the FDA under COMPANY's Drug Master File or equivalent licence in the United States of America and any further specifications which may be agreed by the parties in writing.

9. ELAN shall mean Elan Corporation, plc and any of its AFFILIATES.

10. ELAN KNOW-HOW shall mean all knowledge, information, trade secrets, data and expertise owned or licensed by ELAN or to be developed by ELAN whether before or during the term of this Agreement relating to the PRODUCT, whether or not covered by any patent, copyright, design, trademark or other industrial or intellectual property rights.

11. ELAN PATENT RIGHTS shall mean all patents and patent applications listed in Appendix A, Part I. ELAN PATENT RIGHTS shall also include all continuations, continuations-in-part, divisionals and re-issues of such patents and patent applications and any patents issuing thereon and extensions of any patents licensed hereunder. Extensions of patents shall include: a) extensions under the U.S. Patent Term Restoration Act, b) extension of patents under the Japanese Patent Law, and c) Supplementary Protection Certificates for members of the European Patent Convention and other countries in the European Economic Area.

    ELAN PATENT RIGHTS shall further include any patents or patent applications covering any improved methods of making or using the PRODUCT acquired by ELAN, whether before or during the term of this Agreement, and under which ELAN has a right to grant a licence to COMPANY hereunder; provided that ELAN is not obliged to pay a royalty or any other consideration to a third party in connection with such licence. In the event that ELAN acquires or merges with a third party entity, ELAN PATENT RIGHTS shall not include any patent rights to the extent that such patent rights relate to a product containing the COMPOUND which has been approved for marketing or is in development by the said third party entity.

12. EX WORKS shall have the meaning as such term is defined in the ICC Incoterms, 1990, International Rules for the Interpretation of Trade Terms, ICC Publication No. 460.

13. FCA shall have the meaning as such term is defined in the ICC Incoterms, 1990, International Rules for the Interpretation of Trade Terms, ICC Publication No. 460.

14. FDA shall mean the United States Food and Drug Administration or any other successor agency whose approval is necessary to market the PRODUCT in the United States of America and/or its foreign equivalents in the other countries of the TERRITORY.

15. IN MARKET shall mean the sale of the PRODUCT by COMPANY or its AFFILIATE (or where applicable by a permitted sub-licensee) to an unaffiliated third party such as a wholesaler, distributor, managed care organisation, hospital or pharmacy and shall exclude the transfer pricing of the PRODUCT by COMPANY to an AFFILIATE or a permitted sub-licensee.

16. MANUFACTURING COST shall mean the cost to ELAN for the manufacture of the PRODUCT which is calculated by the method described in Appendix D hereto.

17. NDA shall mean the New Drug Application or any other application for regulatory approval which COMPANY intends to file, including any supplements or amendments thereto which COMPANY may file, for the PRODUCT in the United States of America and the other countries of the TERRITORY.

18. NDA APPROVAL shall mean the final approval to market the PRODUCT in the relevant country of the TERRITORY.

19. NSP shall, subject to the provisions of Article V paragraphs 3.5., mean in the case of any PRODUCT sold by COMPANY or AFFILIATE or a permitted sub-licensee, that sum determined by deducting from the aggregate gross IN MARKET sales proceeds billed for the PRODUCT the following deductions:

    (a) any sales or other taxes (excluding income or corporation taxes), assessments, charges or fees, including customs tax, imposed by any government authority which are paid, directly or indirectly, by COMPANY or its AFFILIATES or permitted sub-licensees as applicable, as directly relates to the sale of the PRODUCT;

    (b) a discount from the gross sales proceeds to cover such normal costs as are imposed on COMPANY or its AFFILIATES or permitted sub-licensees as applicable, in respect of freight, postage, and shipping insurance;

    (c) a discount from the gross sales proceeds to cover such costs as are imposed on COMPANY or its AFFILIATES or permitted sub-licensees as the case may be, in respect of quantity or cash discounts actually taken or allowed, including Medicaid rebates, said discounts being consistent with normal practices applied by COMPANY in relation to its other branded products;

    (d) a maximum deduction of **[*]** to cover amounts repaid or credited by COMPANY or its AFFILIATES or its permitted sub-licensees as the case may be, by reason of rejections, return of goods and retroactive price reductions directly relating to the PRODUCT;

    (e) a **[*]** discount from the gross sales proceeds in each country of the TERRITORY to cover **[*]** price reductions initiated by COMPANY in response to the **[*]**.

20. PRODUCT shall depending upon the context mean one or more of the oral controlled release dosage forms being developed by ELAN during the course of the PROJECT containing the COMPOUND as its sole active ingredient.

21. PRODUCT SPECIFICATIONS shall mean the specifications for the PRODUCT to be agreed by the parties hereto, which shall be consistent with the specifications to be determined by FDA in the NDA APPROVAL, and which shall be attached as Appendix C, as well as such other specifications such as interim specifications which may be required during the PROJECT and which may be agreed upon by the parties in writing.

22. PROJECT shall mean all activity in order to develop the PRODUCT(S) in accordance with the plan shown in Appendix B.

23. PROJECT TEAM shall mean the group to be established pursuant to Article IX.

24. QUALITY PROCEDURES shall mean the technical and quality procedures specified in Appendix E hereto and which may be amended by agreement of the parties from time to time

25. STAGE I, STAGE II, STAGE III and STAGE IV shall mean the stages as set out in Appendix B.

26. TERRITORY shall mean all of the countries of the world.

27. $ shall mean United States Dollars.

1.2 In this Agreement

1.2.1. the singular includes the plural and vice versa, the masculine includes the feminine and vice versa and references to natural persons include corporate bodies, partnerships and vice versa.

1.2.2. any reference to an Article or Appendix shall, unless otherwise specifically provided, be to an Article or Appendix of this Agreement.

1.2.3. the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.

1.2.4. all references to “days” in this Agreement shall mean calendar days.

ARTICLE II : THE LICENCE

Licence to COMPANY

1. ELAN shall remain proprietor of all ELAN PATENT RIGHTS and ELAN KNOW-HOW and all other intellectual property relating thereto, as well as products derived therefrom, but shall grant to COMPANY for the term of the Agreement an exclusive licence pursuant to the ELAN PATENT RIGHTS and ELAN KNOW-HOW, to have manufactured, package, use and sell the PRODUCT as a prescription medicine in the TERRITORY under the terms and conditions set out herein.

2. Subject to the provisions of the following sentence, COMPANY hereby accepts such licence and confirms that COMPANY and its AFFILIATES **[*]** during the Initial Period and for one year thereafter. Should COMPANY **[*]** in the countries of the European Union and/or in the European Economic Area, ELAN reserves the right to **[*]**.

3. COMPANY shall remain the sole owner of all COMPANY PATENT RIGHTS and COMPANY KNOW-HOW. ELAN shall remain the sole owner of all ELAN PATENT RIGHTS and ELAN KNOW-HOW.

4. ELAN shall be entitled to use the ELAN PATENT RIGHTS and ELAN KNOW-HOW, including all improvements and other intellectual property thereto, generated by ELAN pursuant to this Agreement in connection with **[*]**, and in connection with **[*]** or following termination of this Agreement.

5. COMPANY shall market the PRODUCT in the TERRITORY under COMPANY's trademark.

6. COMPANY shall submit copies of all trade package cartons and labels and other printed materials to ELAN once commercial sale of the PRODUCT commences. When packaged, and to the extent permitted by law, a product label shall include an acknowledgement that the PRODUCT is made under licence from ELAN. Such acknowledgement shall take into consideration regulatory requirements and COMPANY's commercial requirements. COMPANY shall wherever possible give due acknowledgement and recognition to ELAN in all printed promotional and other material regarding the PRODUCT such as stating that the PRODUCT is manufactured by, ELAN.

7. Where appropriate, COMPANY shall mark or have marked the patent number on all PRODUCT labelling, or otherwise reasonably communicate to the trade concerning the existence of any ELAN PATENT RIGHTS for the countries within the TERRITORY in such a manner as to ensure compliance with, and enforceability under, applicable laws.

8. For the avoidance of doubt, ELAN acknowledges that it has exclusively licensed the ELAN PATENT RIGHTS and ELAN KNOW-HOW to COMPANY to have manufactured, package, use and sell the PRODUCT as a prescription medicine in the TERRITORY. This exclusivity shall not restrict ELAN from licensing any other product containing the COMPOUND which is not a **[*]** solid oral dosage form of the COMPOUND or any **[*]**. In the event that ELAN subsequently develops a product containing the COMPOUND ("Developed Product") in accordance with this paragraph and intends to licence the Developed Product to a third party, then subject to any pre-existing contractual obligations, ELAN shall

grant to COMPANY a right of first refusal to licence such Developed Product for a licence royalty to be negotiated. Said right of first refusal shall expire **[*]** days after the Developed Product has been offered to COMPANY. Subject to any confidentiality restraints, ELAN shall notify COMPANY in the event that ELAN commences development of any other product containing the COMPOUND during the term of this Agreement. In the event that ELAN acquires or merges with a third party entity, this provision **[*]** by the said third party entity. ELAN shall not use the ELAN PATENT RIGHTS, ELAN KNOW-HOW, COMPANY PATENT RIGHTS or COMPANY KNOW-HOW to **[*]**.

Sub-licence

9. COMPANY may grant a sub-licence to use and sell the PRODUCT in one or more countries of the TERRITORY, provided that COMPANY not grant a sub-licence to **[*]**. Sub-licenses hereunder shall be in the same terms mutatis mutandis as the terms of this Agreement insofar as they are applicable, but excluding the right to grant a sub-license or a production licence. COMPANY shall remain responsible for all acts and omissions of such sub-licensees as though such acts and omissions were by COMPANY.

10. Any sub-license permitted by Article II, paragraph 9 shall automatically and immediately terminate if the country or countries for which the sub-licensee has rights are terminated in accordance with this Agreement (so that a sub-license shall only terminate for such country or countries if the Agreement has been terminated for the country or countries concerned). For the avoidance of doubt, the parties agree that any such sub-license agreement shall not be capable of surviving the termination of this Agreement and that **[*]** by the sub-licensee shall be included **[*]**, whether under paragraph **[*]** of this Agreement. COMPANY shall use its reasonable endeavours to ensure that ELAN shall have the same rights of audit and inspection vis a vis a sub-licensee, as ELAN has pursuant to this Agreement concerning COMPANY.

Licence to ELAN

11. In the event that COMPANY

    11.1. exercises its right to terminate the PROJECT in accordance with Article III, paragraph 4 or Article XII, paragraph 5.3.; or

    11.2. fails to file the NDA for the PRODUCT in any country of the TERRITORY within eighteen (18) months from the conclusion of the Phase III clinical trial program and the collation of all data and reports as are appropriate for the filing of the NDA in such country of the TERRITORY; or

    11.3. fails to commercialise the PRODUCT within twelve (12) months from the date of receipt of final approval, including reimbursement and pricing approvals where applicable, to market the PRODUCT in any country of TERRITORY; or

11.4. notifies ELAN that it does not wish to commercialise the PRODUCT in any country of the TERRITORY;

then, ELAN shall have the right to terminate the licence granted to COMPANY pursuant to Article II, paragraph 1 for the whole of the TERRITORY (pursuant to paragraph 11.1.) or for any such country or countries of the TERRITORY (pursuant to paragraphs 11.2., 11.3. and 11.4.), as appropriate. Thereafter, ELAN shall be entitled to research, develop and commercialise the PRODUCT in the countries of the TERRITORY in which the license has been so terminated. If ELAN should require a licence to the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in order to research, develop and/or commercialise the PRODUCT in the TERRITORY, COMPANY shall grant ELAN a licence to such COMPANY PATENT RIGHTS and COMPANY KNOW-HOW for a term of **[*]** starting from the date of the launch of the PRODUCT by ELAN or up to the expiration of the life of the last to expire patent included in the COMPANY PATENT RIGHTS, whichever is longer, in consideration of the payment of a royalty by ELAN in accordance with Article V, paragraph 3.7.

12. ELAN may grant a sub-licence to such COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in one or more countries of the TERRITORY mutatis mutandis with the terms of Article II, paragraphs 9 and 10. In consideration for the royalty which may be payable under Article V, paragraph 3.8., COMPANY shall transfer to ELAN or ELAN's designee without charge any and all pending or granted NDA APPROVALS for the PRODUCT for such country or countries of the TERRITORY

ARTICLE III: DEVELOPMENT OF THE PRODUCT

1. ELAN shall develop the PRODUCT in accordance with the PROJECT.
2. ELAN shall apply its technical skill and expertise, including the ELAN PATENTS and ELAN KNOW-HOW, in the development of the PRODUCT on behalf of COMPANY. However, it is acknowledged that pharmaceutical research and development incorporates inherent risk in terms of outcomes and, save for acts of negligence or omission by ELAN, ELAN shall have no liability to COMPANY as a result of any failure or delay of the PRODUCT to achieve one or more of the milestones set out in the PROJECT and/or to obtain the NDA APPROVAL in one or more of the other countries of the TERRITORY.
3. ELAN and COMPANY hereby confirm that each shall undertake its respective part of the PROJECT as a collaborative effort and that the provisions of this Agreement requires that each party diligently carries out those tasks assigned to it under the PROJECT and as otherwise agreed during the course of the PROJECT. Each party

shall co-operate with the other in good faith particularly with respect to unknown problems or contingencies and shall perform its obligations in good faith and in a commercially reasonable, diligent and workmanlike manner.

4. COMPANY may evaluate the reports furnished by ELAN at the end of STAGES I, II and III of the PROJECT for the PRODUCT for the purpose, inter alia, of deciding whether or not to proceed further with the PROJECT for the PRODUCT. COMPANY shall use its reasonable efforts to review the content of the said reports in a timely fashion and shall promptly undertake such discussions it requires with ELAN on the future conduct and direction of subsequent stages of the PROJECT.

5. Within thirty (30) days of the execution of this Agreement, COMPANY shall impart to ELAN a full package of physicochemical, pharmacokinetic and clinical data regarding the COMPOUND, including the COMPOUND SPECIFICATIONS, and current marketed versions thereof as it might be reasonably expected shall be required by ELAN to successfully undertake the PROJECT. The foregoing data shall include, but shall not be limited to, **[*]**. ELAN shall not be required to commence the PROJECT until it has received such data and information. For the avoidance of doubt, all confidential information disclosed by COMPANY in accordance with this paragraph shall be considered COMPANY KNOW-HOW for the purposes of this Agreement.

6. For so long as this Agreement is in effect and COMPANY is participating in the PROJECT, COMPANY will supply ELAN with all of ELAN's requirements of COMPOUND **[*]** to enable ELAN to carry out the PROJECT. For the avoidance of doubt, ELAN shall not be required to commence or to continue with any STAGE of the PROJECT in the event that ELAN is not in receipt of appropriate quantities of the COMPOUND. In such an event, appropriate adjustment will be made by ELAN and COMPANY to extend the time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V for the achievement by ELAN of the tasks set out therein.

7. With reference to the strict time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V for the achievement of the tasks set out therein by ELAN and the potential financial implications for ELAN in the event that any of such tasks are not achieved within the time period set out in paragraphs 2.1.2. and 2.1.3. of Article V, the parties recognise that the timely supply by COMPANY to ELAN of the information, data, materials and COMPOUND in accordance with Article III on an ongoing basis throughout the PROJECT is fundamental to the successful completion of the PROJECT and to ELAN's successful attainment of the tasks within the time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V. Accordingly, in addition to the other provisions of Article II, COMPANY shall:-

   7.1. ensure that all information and data, materials and COMPOUND, which are required by ELAN from COMPANY are supplied to ELAN within the timeframe so requested by ELAN and agreed with COMPANY;

7.2. in the event that there are delays in the supply of any information, data, materials or COMPOUND by COMPANY to ELAN, or delays by any government agency or authority (which delays by any such agency or authority are not attributable to any act or omission of ELAN) which will materially affect ELAN's ability to achieve the tasks and/or successfully complete the PROJECT within the time schedules set out in paragraphs 2.1.2. and 2.1.3. of Article V, the parties shall agree in good faith an appropriate mechanism to remedy any such delays by COMPANY or any government agency or authority and amend paragraphs 2.1.2. and 2.1.3. of Article V, in particular to extend the dates set out therein for the achievement of the tasks by ELAN to ensure that any such delays by COMPANY or any government agency or authority will not adversely affect the payment of the full amount of any licence royalty to ELAN under paragraphs 2.1.2. and 2.1.3. of Article V.

8. COMPANY shall inform ELAN as to its choice of initial developmental dosage strengths within thirty (30) days of the execution of this Agreement and ELAN shall promptly inform COMPANY as to the suitability of such dosage strengths for development. Pursuant to the PROJECT, ELAN shall then develop up to **[*]** unit dosage strengths of the PRODUCT after the preferred dosage form (SODAS or HYDAS) has been chosen by COMPANY. In the event that ELAN informs COMPANY that one or more of the dosage strengths is unsuitable for development, the parties shall agree on a suitable alternative dosage strength(s).

9. In the event that COMPANY wishes to have more than **[*]** dosage strengths developed pursuant to this Agreement, the parties shall negotiate in good faith as to the additional costs to be paid to ELAN for such development and such amendments as are required to the PROJECT and the timeframe for the PROJECT, including the time periods set out in paragraphs 2.1.2. and 2.1.3. of Article V. The parties agree that ELAN's charges to COMPANY for any such work shall be as set out in Article V, paragraph 4 of the Agreement.

10. ELAN shall conduct the pilot and pivotal Phase I pharmacokinetic studies and associated bio- and statistical analysis in human volunteers in accordance with the PROJECT **[*]**. The design **[*]** of such studies and associated analytical testing shall be as set out in the PROJECT, provided however, that the **[*]** of such studies shall **[*]**, as appropriate, in the event of a **[*]** of the studies. The design **[*]** of such studies shall be finalised with COMPANY prior to commencement of each such study. The parties agree that **[*]** shall be as set out in **[*]** of the Agreement. ELAN shall furnish a full and detailed report to COMPANY on the results of all such pharmacokinetic studies. **[*]**. ELAN undertakes that it shall carry out all such pharmacokinetic studies to prevailing cGCP and cGLP and most specifically in accordance with FDA standards and guidelines.

11. COMPANY shall be responsible for carrying out **[*]** the efficacy clinical studies programme in human patients. The objective of the programme so conducted shall be to assist in obtaining NDA APPROVAL. COMPANY agrees to carry out and complete the clinical efficacy programme to an FDA approvable standard and to a standard and timeframe that COMPANY would otherwise find acceptable for one of its major branded products. COMPANY shall keep ELAN informed as to the progress of the studies and on completion, shall impart summary reports on the studies. COMPANY undertakes that it shall carry out all such clinical studies to prevailing cGCP and cGLP and most specifically in accordance with FDA standards and guidelines.

12. During the PROJECT, the parties shall review and agree on interim specifications for the PRODUCT and shall also agree on the final PRODUCT SPECIFICATIONS following the filing of the NDA in the United States of America, which shall at that time be attached to this Agreement as Appendix C. The PRODUCT SPECIFICATIONS may thereafter be amended as agreed by the parties or as may otherwise be requested or mandated by the regulatory authorities in the TERRITORY, most specifically the FDA.

13. For the avoidance of doubt, the parties hereby confirm that the primary objective of the PROJECT is to generate the NDA and secure NDA APPROVAL for the PRODUCT in the United States of America. As of the date of this Agreement, it is the parties' expectation that the body of data so generated in the PROJECT will also be used to support such applications for regulatory approval that COMPANY, its AFFILIATES or permitted sub-licensees shall make in the other countries of the TERRITORY.

14. In the event however that such expectation proves unfounded or incorrect and further data is required to obtain such other NDA APPROVAL as are pursued by COMPANY in the other countries of the TERRITORY, COMPANY shall determine the viability of proceeding further with the regulatory application and generation of the further data requirements. In the event that COMPANY elects to continue, the parties shall agree on the programme of work to be undertaken to generate such additional data and the apportioning of tasks and costs therefor. COMPANY shall reimburse ELAN for all such additional work which it requires ELAN to carry out in accordance with ELAN's charges as set out in Article V, paragraph 4 of the Agreement.

ARTICLE IV : SUPPLY OF THE PRODUCT

1. Except as otherwise herein provided, ELAN shall produce and supply to COMPANY its entire requirements of the PRODUCT. ELAN shall be the sole

and exclusive supplier of the PRODUCT to COMPANY in the TERRITORY and COMPANY will purchase the PRODUCT exclusively from ELAN in the TERRITORY. COMPANY may qualify a second site for the manufacture of PRODUCT for the purposes of Article IV paragraphs 14 and 15.

2. The PRODUCT to be supplied to COMPANY by ELAN shall be in the form of bulk capsules or tablets (as will be agreed by the parties during the PROJECT) complying with the PRODUCT SPECIFICATIONS. ELAN shall deliver the PRODUCT to COMPANY and/or any party designated by COMPANY in proper packaging so as to permit safe storage and transport. COMPANY shall be responsible for the packaging of the PRODUCT into final market packaging, whether such packaging is conducted by COMPANY or by a sub-contractor which it may nominate, but whose final selection will be subject to ELAN's prior written agreement, which agreement will not be unreasonably withheld or delayed.

3. In the event that ELAN appoints a third party manufacturer, then ELAN shall be solely responsible and liable to COMPANY for the performance of the said manufacturer and ELAN shall ensure that the said manufacturer's facility is an FDA approved facility and that such facility complies with all relevant FDA and other relevant governmental and regulatory requirements and that all accepted practises of cGMP are adhered to. For the avoidance of doubt, the parties agree that in the event ELAN does not itself wish to manufacture the PRODUCT, then it shall offer to COMPANY a production licence as outlined in paragraph 14.1 below first before appointing a third party manufacturer. Should COMPANY decline such production license, then ELAN shall be free to appoint a third party manufacturer for the PRODUCT. The parties confirm that the provisions of Article V paragraph 3.1 shall apply to the sale of PRODUCT manufactured by COMPANY or by a third party manufacturer, whether appointed by ELAN or COMPANY in accordance with this paragraph.

4. No later than sixty (60) days after the date of filing of the NDA, COMPANY will provide ELAN with a forecast of COMPANY's requirements for the PRODUCT for the twelve (12) month period following NDA APPROVAL. The said forecast will be updated quarterly until NDA APPROVAL of the PRODUCT. Except as otherwise provided herein, all forecasts made hereunder shall be made to assist ELAN in planning its production and COMPANY in planning marketing and sales. Such forecasts shall not be binding purchase orders, and shall be without prejudice to COMPANY's subsequent firm orders for the PRODUCT in accordance with the terms of this Agreement.

5. The parties acknowledge that it is in their mutual interest that launch of the PRODUCT shall be effected in the United States of America and in the remainder of the TERRITORY on a country by country basis as soon as possible following

NDA APPROVAL, for which purpose the parties shall in advance of the NDA APPROVAL discuss and agree upon the manufacture and purchase of specific quantities of launch stocks of the PRODUCT for commercial sale and promotional sampling ("Launch Stocks"). For the avoidance of doubt, the parties hereby confirm that ELAN's manufacturing obligations shall only arise on receipt of firm purchase orders. ELAN shall deliver the PRODUCT to COMPANY within **[*]** days of the receipt of a firm purchase order. During the period in which ELAN is manufacturing Launch Stocks, the foregoing period of **[*]** days shall be increased to **[*]** days. In any event and notwithstanding any firm purchase orders for such Launch Stocks which COMPANY has already placed with ELAN, COMPANY will notify ELAN within five (5) working days of its receipt from the FDA of an approvable letter, or a pre-approval letter, for the NDA from the FDA. COMPANY will within fifteen (15) days of such notification place a firm purchase order with ELAN for Launch Stocks, unless such a purchase order has already been submitted to ELAN prior to that date. COMPANY will use its reasonable efforts to provide forecasts for deliveries for the balance of the year in which the NDA is approved which it requires in addition to the Launch Stocks.

6. Within fifteen (15) days of NDA APPROVAL and at the beginning of each calendar month thereafter, COMPANY will provide a rolling month by month forecast for the **[*]** month period beginning on the first day of the calendar month following the calendar month in which the forecast is made and the **[*]** of such forecast shall be a binding purchase commitment of COMPANY.

7. Subject to the agreement of ELAN, the forecasts (other than for Launch Stocks) shall not vary from **[*]** by more than **[*]** per cent (**[*]**%) in terms of volume of PRODUCT ordered. Notwithstanding the foregoing provision, ELAN will use its reasonable efforts to fulfil COMPANY's requirements in excess of forecasted amounts, but shall not be obliged to meet such requirements if it is not reasonably practicable to do so provided that ELAN shall supply the PRODUCT so ordered but not immediately available as soon thereafter as reasonably practicable.

8. The parties shall agree upon a minimum batch and order size for the manufacture and supply of the PRODUCT.

9. ELAN **[*]**.

10. All quantities of the PRODUCT delivered by ELAN hereunder shall conform to the PRODUCT SPECIFICATIONS and all prevailing legislative and regulatory requirements of the TERRITORY and the country where the PRODUCT is manufactured. ELAN shall furnish the appropriate certificate of analysis with each delivery of PRODUCT. Furthermore, ELAN shall manufacture and supply the PRODUCT and shall provide supporting and accompanying documentation and information in compliance with the QUALITY PROCEDURES.

11. All claims for failure of any shipment of the PRODUCT to conform to PRODUCT SPECIFICATIONS must be made by COMPANY to ELAN in writing within **[*]** following delivery. Failure to make timely claims in the manner prescribed shall constitute acceptance of the shipment except in the case of latent defects. Claims for latent defects, not discovered during the routine testing protocol to be agreed upon by COMPANY and ELAN, shall be made by COMPANY to ELAN in writing within **[*]** days of discovery. PRODUCT which has been delivered and which has been shown within the designated period not to conform to PRODUCT SPECIFICATIONS shall be replaced at ELAN's cost within **[*]** days of the receipt by ELAN of the failed PRODUCT except where such non-conformance is as the result of the supply of defective COMPOUND by COMPANY to ELAN. COMPANY shall bear sole responsibility for all costs associated with the supply of defective COMPOUND to ELAN.

12. In the event of an unresolved dispute as to conformity of PRODUCT supplied with PRODUCT SPECIFICATIONS, the parties shall nominate an independent first class laboratory to undertake the relevant testing. Its findings shall be conclusive and binding upon the parties. All costs relating to this process shall be borne exclusively by the unsuccessful party. Should the parties fail to agree upon a mutually acceptable independent laboratory then the **[*]** shall be entrusted with appointing such an independent laboratory.

13. Save as otherwise agreed between the parties, delivery of consignments of PRODUCT shall be effected by ELAN EX WORKS the manufacturing facility designated by ELAN and all risks therein shall pass to COMPANY when each such consignment of the PRODUCT is loaded onto the vehicle of COMPANY's agent on which it is to be dispatched from ELAN's designated facility. COMPANY shall fully insure or procure the insurance of all consignments of the PRODUCT when risk passes as aforesaid and shall produce such insurance documentation supporting same as and when requested by ELAN.

14. In the event that (i) ELAN fails to supply PRODUCT which has been ordered by COMPANY for a period exceeding **[*]** days from the receipt of a firm purchase order or (ii) there are delays in filling **[*]** successive orders which delays cumulatively exceed **[*]** days when each delay is measured beginning on the **[*]** day from receipt of the corresponding firm purchase order or (iii) there is a shortfall **[*]** successive orders delivered by ELAN which on a cumulative basis, exceeds **[*]** of the total amount of said **[*]** orders; and unless such failure, delay or shortfall is caused by the COMPANY **[*]**, then ELAN shall, upon written notice from COMPANY remedy the failure, delay or shortfall within a further period of **[*]** days from said notice and in the event of ELAN's failure to do so, ELAN shall immediately, upon written request from COMPANY, for so long as such conditions exist:

14.1. grant to COMPANY a production licence in the TERRITORY so that COMPANY may manufacture the relevant PRODUCT without infringing any of ELAN's patent and/or any other industrial property rights (including the ELAN PATENT RIGHTS and ELAN KNOW-HOW). Any such licence shall apply only in regard to the relevant PRODUCT as well as to the applications of technology derived from the ELAN PATENT RIGHTS related to its use with such PRODUCT. In the event that COMPANY is unable or unwilling to itself undertake manufacture of the PRODUCT under any of the circumstances envisaged here, and ELAN is itself unable to offer a third party sub-contractor to manufacture and supply PRODUCT to COMPANY, then COMPANY may assign this production license to a third party sub-contractor which it may nominate, but whose final selection will be subject to ELAN's prior written agreement, which agreement will not be unreasonably withheld or delayed. For the avoidance of doubt, the parties confirm that the provisions of Article V paragraph 3.5 shall apply to the sale of PRODUCT manufactured by COMPANY or its sub-contractor appointed in accordance with this paragraph.

14.2. unless already provided under Article IV paragraph 19, provide COMPANY with any technical data necessary for the carrying of this into effect. To this end, ELAN shall impart to COMPANY the documentation constituting the required material support, more particularly practical performance advice, shop practice, specifications as to materials to be used and control methods.

14.3. unless already carried out under Article IV paragraph 19., assist COMPANY for the working up and use of the technology necessary to manufacture the relevant PRODUCT as well as for the training of COMPANY's personnel. For this purpose, ELAN shall receive COMPANY's scientific staff in its premises for periods the term of which shall be decided by common consent.

15. In the event of such a transfer of manufacture the parties shall, if appropriate, agree on a reasonable period of time within which said transfer is to be made and ELAN shall continue to supply COMPANY with the PRODUCT until such transfer is fully effected so that COMPANY's supply of the PRODUCT shall be continuous and uninterrupted until COMPANY receives all necessary regulatory approvals.

16. When ELAN has remedied the situation that prevented ELAN from satisfying COMPANY's requirements and is once again able to fulfil its obligations to

supply the PRODUCT as provided for in this Agreement, COMPANY shall cease manufacturing the PRODUCT and shall resume purchasing the PRODUCT from ELAN pursuant to the terms of this Agreement; provided that COMPANY shall be entitled to manufacture the PRODUCT for the period necessary so as to enable COMPANY to recoup those fixed and unrecoverable commercial costs expended by COMPANY in establishing its manufacturing capability for the PRODUCT prior to commercial production of the PRODUCT. If ELAN wishes COMPANY to cease manufacturing the PRODUCT prior to the expiration of this period but in no event within **[*]** months from the grant of the production licence to COMPANY, ELAN shall be entitled to re-commence manufacturing the PRODUCT and reimburse COMPANY in respect of such costs by means of a cash payment or a deduction from royalty payments, or by means of a combination of the foregoing (not to exceed **[*]** percent (**[*]**%) of royalty payments payable by COMPANY to ELAN) or otherwise howsoever at the discretion of ELAN provided that:

16.1. prior to discharge of any such costs by ELAN by whatever means, COMPANY shall provide ELAN with a detailed breakdown of such costs, together with a detailed explanation of the bases upon which the breakdown has been calculated and

16.2. to the extent that such costs include the cost of fixed capital items which can be transferred to ELAN, and provided that COMPANY agrees to sell the assets, ELAN shall have an option to take delivery of such fixed capital item(s), the costs of such delivery to be for the account of ELAN.

17. For so long as ELAN or its appointed sub-contractor is manufacturing the PRODUCT, ELAN, its AFFILIATES or subcontractors shall be responsible for all process and equipment validation required by the FDA and other relevant regulatory agency and the regulations thereunder and shall take all steps reasonably necessary to pass government inspection by the FDA or other regulatory agency. In the event that COMPANY or its appointed sub-contractor commences manufacture of the PRODUCT in accordance with the terms of this Agreement, COMPANY shall be responsible for all process and equipment validation required by the FDA and other relevant regulatory agency and the regulations thereunder and shall take all steps reasonably necessary to pass government inspection by the FDA or other regulatory agency. ELAN shall have no liability to COMPANY for any PRODUCT which is manufactured by COMPANY or any sub-contractor appointed by COMPANY.

18. At any time during the term of this Agreement, ELAN shall be entitled to notify COMPANY of its intention to cease manufacture of the PRODUCT due to poor economic return on the PRODUCT. In such an event, ELAN shall grant COMPANY a production licence in accordance with Article IV paragraphs 14 and 15, which license shall be assignable in the manner provided for in Article IV, paragraph 14.1. In such an event the parties confirm that the provisions of Article V, paragraph 3.6 shall apply to the sale of PRODUCT manufactured by COMPANY or its permitted sub-contractor.

19. Upon acceptance of the filing of the NDA by the FDA in the United States of America, COMPANY may, at its option, request ELAN to assist it in the working up and use of the technology necessary to manufacture the PRODUCT so as to qualify COMPANY as a second supporting site of manufacture. **[*]** involved in the set-up and qualification of manufacture at its designated site in the United States of America, **[*]**. **[*]**. For the avoidance of doubt, the qualification of COMPANY as a second supporting site of manufacture as envisaged herein shall not constitute or be interpreted as the granting to COMPANY of a production license.

20. In the event that COMPANY is at any stage the manufacturer of the PRODUCT in accordance with Article IV, paragraphs 3, 14 or 18 or Article XII, paragraph 5.1, then COMPANY shall supply PRODUCT to ELAN for sale in any country of the TERRITORY which ceases to be a part of the TERRITORY in accordance with Article II, paragraph 11 or where ELAN has a non-exclusive licence in accordance with **[*]**. Subject to the following sentence, the terms of this Agreement shall apply mutatis mutandis to the manufacture and supply of PRODUCT by COMPANY to ELAN. The price of the PRODUCT for commercial sale and free-of-charge promotional samples to be charged to ELAN shall be negotiated by the parties at terms substantially similar to Article V, paragraph 5 of the Agreement and ELAN shall pay COMPANY a royalty equal to **[*]**.

Supply of the COMPOUND

21. COMPANY shall supply to ELAN such quantities of COMPOUND **[*]** as ELAN requires for the manufacture and supply of PRODUCT to COMPANY for commercial sale or promotional samples. COMPANY shall be responsible for ensuring that ELAN receives delivery of COMPOUND in such quantities and at such times so as to ensure that ELAN has sufficient stocks of the COMPOUND to meet COMPANY's firm purchase orders and supply the PRODUCT to COMPANY. COMPANY shall furnish the appropriate certificate of analysis with each delivery of COMPOUND. The parties agree that adequate quantities of COMPOUND shall be delivered by COMPANY to ELAN in accordance with orders submitted by ELAN and at least **[*]** days in advance of the date on which the delivery of PRODUCT is scheduled to be made to COMPANY. During the period in which ELAN is manufacturing Launch Stocks, the foregoing period of **[*]** days shall be increased to **[*]** days. For the avoidance of doubt, COMPANY shall not be obligated to supply COMPOUND **[*]** to ELAN for the manufacture of PRODUCT which shall not be sold by COMPANY, its AFFILIATES or permitted sub-licensees, in the TERRITORY. Where ELAN, its AFFILIATES or

permitted sub-licensees are selling PRODUCT in the TERRITORY in consideration for the payment of a royalty to COMPANY in accordance Article V, paragraph 3.7. of the Agreement, then COMPANY shall supply COMPOUND to ELAN at a price to be negotiated in good faith. The terms of this paragraph regarding appropriate certificates of analysis and a **[*]** day delivery period shall also apply to the delivery of such COMPOUND to ELAN.

22. Prior to the end of STAGE III the parties shall negotiate in good faith to conclude a technical agreement regulating the parties' respective obligations from a technical and quality perspective for the supply of the COMPOUND by COMPANY to ELAN and the supply of PRODUCT by ELAN to COMPANY. In no event shall the terms of said technical agreements overrule the terms of this Agreement.

23. All quantities of the COMPOUND delivered by COMPANY hereunder shall conform to the COMPOUND SPECIFICATIONS and all prevailing legislative and regulatory requirements of the country where the COMPOUND is manufactured.

24. Save as otherwise agreed between the parties, delivery of consignments of COMPOUND shall be effected by COMPANY, FCA the manufacturing facility designated by ELAN, and all risks therein shall pass to ELAN when each such consignment of the COMPOUND is delivered to ELAN's designated facility. ELAN shall fully insure or procure the insurance of all consignments of the COMPOUND when risk passes as aforesaid and shall produce such insurance documentation supporting same as and when requested by COMPANY. For purposes of inventory control and/or reconciliation, ELAN will provide an accurate account of inventory levels of COMPOUND to COMPANY on a monthly basis, at the end of each calendar month.

25. Title to the COMPOUND supplied to ELAN by COMPANY shall at all times remain in COMPANY. ELAN shall clearly mark such COMPOUND as the property of COMPANY and keep such COMPOUND separate and apart from other raw materials. ELAN shall not at any time sell or offer for sale, assign, mortgage, pledge, or allow any lien to be created upon the COMPOUND provided by COMPANY, or any portion thereof. At the termination of this Agreement, ELAN shall surrender to COMPANY all useable COMPOUND in ELAN's possession. In the alternative and at the option of ELAN, ELAN may purchase such useable COMPOUND at the cost incurred by COMPANY for the manufacture and delivery of such COMPOUND.

26. All claims for failure of any shipment of the COMPOUND to conform to the COMPOUND SPECIFICATIONS must be made by ELAN to COMPANY in writing within **[*]** following delivery except in the case of latent defects. Claims

for latent defects, not discovered during the routine testing protocol to be agreed upon by COMPANY and ELAN, shall be made by ELAN to COMPANY in writing within **[*]** days of discovery. Failure to make timely claims in the manner prescribed shall constitute acceptance of the shipment. COMPOUND which has been delivered and which has been shown within the designated period not to conform to COMPOUND SPECIFICATIONS shall be replaced at COMPANY's cost within **[*]** days of the receipt by COMPANY of the failed COMPOUND.

27. In the event that the COMPOUND supplied by COMPANY is not in compliance with the COMPOUND SPECIFICATIONS, or is otherwise adulterated, misbranded or defective, ELAN shall immediately notify COMPANY and shall follow all reasonable instructions of COMPANY regarding, and be responsible, at the **[*]**, for re-analysis, sampling, processing, return, disposal or destruction, including certification of destruction, of such non-conforming bulk COMPOUND. In addition, **[*]** shall be responsible for all costs borne by ELAN in the processing of the COMPOUND.

28. In the event of an unresolved dispute as to conformity of the COMPOUND with the COMPOUND SPECIFICATIONS, the parties shall nominate an independent first class laboratory to undertake the relevant testing. Its findings shall be conclusive and binding upon the parties. All costs relating to this process shall be borne exclusively by the unsuccessful party. Should the parties fail to agree upon a mutually acceptable independent laboratory then the **[*]** shall be entrusted with appointing such an independent laboratory.

ARTICLE V : FINANCIAL PROVISIONS

1. **Development Royalties**

1.1. In consideration for the development of the PRODUCT by ELAN under this Agreement, as further described in the PROJECT plan in Appendix B hereto, but specifically excluding the **[*]** envisaged therein, COMPANY shall pay to ELAN amounts as are set out below :

1.1.1. $**[*]** on commencement of STAGE I;

1.1.2. $**[*]** on commencement of STAGE II;

1.1.3. $**[*]** on commencement of STAGE III; and

1.1.4. $**[*]** on commencement of STAGE IV.

1.2. The programme of **[*]** which the parties envisage will be necessary for the development and registration of the PRODUCT is also described in the PROJECT plan in Appendix B, along with projected study designs and budgeted costs and schedules, which costs include bioanalysis, statistical analysis and report generation. However, the final design and corresponding cost for each **[*]** to be carried out by ELAN in the PROJECT shall be agreed with COMPANY in advance of carrying out the study **[*]** (to a standard agreed in advance of the commencement of the study by the PROJECT TEAM) for said study.

1.3. Additional development royalty payments agreed to in advance by the parties in writing shall be payable if COMPANY requires ELAN to carry out work or tasks relating to the development and registration of the PRODUCT which are not included in the PROJECT, including but not limited to, **[*]**. ELAN's charges for such work shall be as set out in Article V, paragraph 4 of the Agreement.

2. **Licence Royalties**

2.1. In consideration of the licence of the ELAN PATENT RIGHTS granted to COMPANY by virtue of this Agreement, COMPANY shall pay to ELAN the following amounts **SUBJECT ALWAYS** to the provisions of Article III, paragraph 7 (which outlines the effect of any delays by COMPANY, or delays of government agencies which are not attributable to acts or omissions of ELAN, which materially affect ELAN's ability to achieve the tasks within the time periods set out in paragraphs 2.1.2. and 2.1.3.) :

2.1.1. $**[*]** upon the execution of this Agreement;

2.1.2. $**[*]** due upon the **[*]** day inclusive following the designated start date being the receipt by ELAN of the written confirmation by COMPANY to ELAN as to COMPANY's agreement to **[*]**.

In the event that **[*]**, then the licence royalty to be paid to ELAN under this paragraph 2.1.2. shall **[*]**. Thus for example, if **[*]**.

However, in the event that such **[*]** day, then the $**[*]** license royalty payable here shall **[*]**. Thus, for example, if **[*]**. COMPANY's obligation to pay a license fee to ELAN under this 2.1.2. shall expire on the **[*]** day of the specified period if no such **[*]** as envisaged here is effected by that date.

2.1.3. $**[*]** due upon **[*]** day inclusive following the designated start date, being the date of **[*]**.

In the event that **[*]** as envisaged herein in this 2.1.3. prior to the specified **[*]** day, then the royalty to be paid to ELAN under this paragraph 2.1.2. shall **[*]**. Thus for example, if **[*]**.

However, in the event that such **[*]** day, then the $**[*]** license royalty payable here shall **[*]**. Thus, for example, if **[*]**. COMPANY's obligation to pay a license fee to ELAN under this 2.1.3. shall expire on the **[*]** day of the specified period if no such **[*]** as envisaged here is effected by that date.

2.1.4. $**[*]** upon either the **[*]** or the **[*]**;

2.1.5. $**[*]** due upon **[*]**; and

2.1.6. $**[*]** due upon **[*]**.

2.2. COMPANY shall be entitled to recover **[*]** percent (**[*]**%) of the licence royalties payable in accordance with paragraphs **[*]** against the royalty payable by COMPANY to ELAN in accordance with either **[*]**, whichever is applicable, following the **[*]**. COMPANY shall be entitled to withhold **[*]** percent (**[*]**%) of the royalty calculated as payable on NSP to ELAN in each quarter following first launch of PRODUCT until such time as total royalty withholdings reach said **[*]** percent (**[*]**%) of such licence royalties, at which point this recovery provision shall cease.

3. <u>Royalty on Sales</u>

3.1. Subject to paragraph 3.6 below, in consideration of the license of the ELAN PATENT RIGHTS to COMPANY, the royalty payable by COMPANY to ELAN on NSP of the PRODUCT by COMPANY, its AFFILIATES or its permitted sub-licensees shall be:

(i) **[*]** percent (**[*]**%) on the first $**[*]** sales of PRODUCT, calculated as NSP value, in any one calendar year; and

(ii) **[*]** percent (**[*]**%) on sales of PRODUCT, calculated as NSP value, in excess of $**[*]** in any one calendar year.

The parties agree that for the purposes of the interpretation of this paragraph 3.1, the parties' intention as regards the operation of this paragraph 3.1 should be clearly stated in this Agreement and the parties further agree that this will best be achieved by way of a hypothetical example set out below.

EXAMPLE: If in any one year period following the first launch of the PRODUCT, the annual NSP were $**[*]**, the royalty payable to ELAN shall be calculated as follows:

[*]

3.2. Within thirty days of the end of each quarter, COMPANY shall notify ELAN of the NSP of PRODUCT for that preceding quarter. Payments shown by each calendar quarter report to have accrued but which have not yet been paid shall be due on the date such report is due.

3.3. Payment of royalties shall be made quarterly within thirty (30) days after the expiry of the quarter.

3.4. All payments due hereunder shall be made in U.S. Dollars ($).

3.5. In the event that COMPANY or any AFFILIATE or a permitted sub-licensee shall sell the PRODUCT together with other products of COMPANY to third parties in any country of the TERRITORY by the tying of a discount on the gross selling price of the PRODUCT to a volume commitment of another product to the same customer in such country, and the price attributable to the PRODUCT is less than **[*]** percent (**[*]**%) of the average price of "arms length" sales for the reporting period in which sales occur in such country (such sales to be excluded from the calculation of the average price of "arms length" sales), the NSP for any such sales shall be **[*]** during the reporting period in which such sales occur in such country of the TERRITORY.

3.6. In the event that a production licence is granted to COMPANY in accordance with Article IV, paragraph 14 or ELAN exercises its option to cease manufacturing the PRODUCT in accordance with Article IV, paragraph 18, then in consideration of the license of the ELAN PATENT RIGHTS to COMPANY, the royalty payable by COMPANY to ELAN in accordance with paragraph 3.1. above, on PRODUCT manufactured by COMPANY or its permitted sub-contractor on sales of the PRODUCT by COMPANY, its AFFILIATES or its permitted sub-licensees shall be reduced to:

(i) **[*]** percent (**[*]**%) on the first $**[*]** sales of PRODUCT, calculated as NSP value, in any one calendar year; and

(ii) **[*]** percent (**[*]**%) on sales of PRODUCT, calculated as NSP value, in excess of $**[*]** in any one calendar year.

Any royalty payable by COMPANY to ELAN under this paragraph shall replace the royalty payable by COMPANY in accordance with paragraph 3.1 above on sales of PRODUCT manufactured by COMPANY or its permitted sub-contractor. Any such royalty shall be calculated and paid mutatis mutandis as the terms of this Agreement.

3.7. In consideration of the licence to the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in accordance with Article II, paragraph 11, ELAN shall pay a royalty by COMPANY on NSP of the PRODUCT on sales by ELAN, its AFFILIATES or its permitted sub-licensees as follows :

(i) **[*]** percent (**[*]**%) on the first $**[*]** sales of PRODUCT, calculated as NSP value, in any one calendar year; and

(ii) **[*]** percent (**[*]**%) on sales of PRODUCT, calculated as NSP value, in excess of $**[*]** in any one calendar year.

Any such royalty payable by ELAN to COMPANY shall be calculated and paid mutatis mutandis as the terms of this Agreement.

4. **Additional Expenses**

4.1. COMPANY shall reimburse ELAN for cost of any **[*]** or any other type of work requested by COMPANY which is not included in the PROJECT at the following charges:

4.1.1. any such work which is necessary in order to obtain NDA APPROVAL in **[*]** shall be charged at **[*]**;

4.1.2. any such work which is necessary in order to **[*]**; and

4.1.3. all other such work, **[*]**, shall be charged at terms to be negotiated in good faith by ELAN and COMPANY.

5. **Price of PRODUCT**

5.1. The price of the PRODUCT to be charged to COMPANY shall be **[*]** percent (**[*]**%) of MANUFACTURING COST which price shall apply to bulk capsules or tablets (as determined during the PROJECT) of PRODUCT supplied EX WORKS ELAN's manufacturing facility to COMPANY. For the avoidance of doubt, the price of the PRODUCT shall not include the cost of any COMPOUND used in the manufacture of the PRODUCT provided that such COMPOUND was supplied **[*]** by COMPANY to ELAN.

5.2. The price of the PRODUCT to be charged to COMPANY for supplies for

distribution as free-of-charge promotional samples in its marketing of the PRODUCT shall be **[*]** percent (**[*]**%) of MANUFACTURING COST which price shall apply to bulk capsules or tablets (as determined during the PROJECT) of PRODUCT supplied EX WORKS ELAN's manufacturing facility to COMPANY. COMPANY shall inform ELAN when placing an order for PRODUCT that the PRODUCT is for distribution as free-of-charge promotional samples in its marketing of the PRODUCT.

5.3. The price of the PRODUCT shall be reviewed on an annual basis and shall be fixed for the following twelve (12) month period. Notwithstanding the foregoing, at the end of each such twelve (12) month period, ELAN shall retrospectively determine the exact amount of MANUFACTURING COST for the preceding twelve (12) month period. In the event that the sums payable to ELAN pursuant to paragraph 5.1. and 5.2. above are less than **[*]** percent (**[*]**%) and **[*]** percent (**[*]**%) of MANUFACTURING COST respectively, COMPANY shall pay the difference to ELAN.

5.4. Payment for all PRODUCT supplied to COMPANY shall be effected in U.S. Dollars ($) within thirty (30) days of the date of the relevant invoice.

6. **Performance by COMPANY**

6.1. Within **[*]** of the filing of the NDA the COMPANY will determine the preliminary structure of the promotional activities to be carried out by COMPANY for the period up to launch of the PRODUCT in the United States of America and for a period of one year after launch of the PRODUCT in that market. COMPANY shall both prior to and subsequent to the launch of the PRODUCT communicate with ELAN regarding its objectives for and performance of the PRODUCT in the TERRITORY.

6.2. COMPANY shall effect the first full scale commercial launch of the PRODUCT in the United States of America within **[*]** of NDA APPROVAL, provided that COMPANY shall have received the agreed quantities of Launch Stocks at least **[*]** in advance of the launch date (provided that such Launch Stocks have been ordered pursuant to firm purchase orders placed in accordance with the terms of this Agreement). It is agreed that with respect to each of the other countries of the TERRITORY, COMPANY will effect a national commercial launch of the PRODUCT within **[*]** after the necessary regulatory approvals and provided that COMPANY shall also have received the agreed quantities of Launch Stocks for each country of the TERRITORY at least **[*]** in advance of the launch date (provided that such Launch Stocks have been ordered by COMPANY pursuant to firm purchase orders placed in accordance with the terms of this Agreement). In the event that COMPANY does not make a national commercial launch within

the **[*]** period, or such longer period as may be agreed between the parties, the licences granted to COMPANY hereunder for such country or countries of the TERRITORY shall become non-exclusive and ELAN shall have the right to commercialise the PRODUCT in such country or countries.

6.3. Should COMPANY fail to effect a national commercial launch of the PRODUCT in the said non-exclusive country or countries within a further **[*]** of the license becoming non-exclusive], then ELAN may, at its option, terminate the non-exclusive licenses granted to COMPANY for such country or countries. In such events none of the monies paid by COMPANY to ELAN shall be repayable.

6.4. COMPANY shall control the format of the promotional campaign to be submitted to the FDA. COMPANY shall use reasonable efforts to obtain approval by the FDA of the promotional campaign for the PRODUCT.

6.5. The parties intend that the PRODUCT will be marketed and promoted by the COMPANY as the flagship brand under COMPANY's prevailing trademark(s) for the COMPOUND in the United States of America. Wherever regulatory and commercially feasible, the parties also intend that the PRODUCT will be marketed and promoted as the flagship brand by the COMPANY, its AFFILIATES and permitted sub-licensees, under COMPANY's prevailing trademark(s) for the COMPOUND in all other countries of the TERRITORY. However, COMPANY may continue to sell the existing formulation(s) of the COMPOUND, including the formulation marketed and promoted in the United States of America as Luvox®, in each country of the TERRITORY following the launch of the PRODUCT PROVIDED ALWAYS that any such sale of such products by COMPANY shall at all times be subject to the parties' agreement hereunder that the PRODUCT will be the flagship brand and in addition to the parties' intention to maximise the sales potential of the PRODUCT.

6.6. Subject to paragraph 6.5. above, COMPANY shall use reasonable efforts consistent with its normal business practices to market and promote the PRODUCT throughout the TERRITORY. In doing so COMPANY will use the same level of effort as with its other similar products of similar sales potential.

ARTICLE VI: REGISTRATION OF THE PRODUCT

1. In respect of the PRODUCT, COMPANY shall be responsible for the filing of the NDA with the FDA and all other relevant regulatory agencies in the TERRITORY and shall consult with ELAN in this regard. COMPANY shall use its commercially reasonable efforts to obtain and maintain NDA APPROVAL for the PRODUCT in each country of the TERRITORY.

2. COMPANY shall notify ELAN of the date of submission of any NDA for the PRODUCT in the TERRITORY and shall also notify ELAN of the NDA APPROVAL of any registration application as soon as is reasonably possible following said approval. COMPANY shall allow ELAN access to the NDA for the United States of America and other registration applications as may be required. COMPANY shall also furnish ELAN with a copy of any further regulatory filings and submissions and its correspondence with the FDA relevant to the PRODUCT.

3. Each party shall notify the other as soon as possible of any notification received by that party from the FDA, or any other regulatory authority to conduct an inspection of its manufacturing or other facilities used in the manufacturing, packaging, storage or handling of the PRODUCT. Copies of all correspondence relevant to the PRODUCT with the regulatory authority will be provided to the other party.

4. COMPANY and ELAN shall discuss on an ongoing basis the regulatory status of the PRODUCT in the TERRITORY whether at meetings of the PROJECT TEAM or otherwise.

5. COMPANY shall be responsible for obtaining all FDA, and other approvals necessary for COMPANY to package the PRODUCT into final marketing packaging and for obtaining all applicable state and local regulatory approvals for the distribution of the PRODUCT in the TERRITORY. ELAN shall co-operate with COMPANY in obtaining such approvals.

6. ELAN shall provide to COMPANY scientific data from the works performed during its development of the PRODUCT which comprises the CMC SECTION and the biopharmaceutics package corresponding to the data as specified in Appendix B. COMPANY shall undertake to protect the confidentiality of ELAN's formulation, engineering and manufacturing processes for the PRODUCT in its dealings with permitted sub-licensees or approved sub-contractor and shall where possible refrain from transmitting such information within the CMC SECTION to permitted sub-licensees.

7. Save as otherwise outlined in this Agreement, the costs and expenses of any filings and proceedings made by ELAN at the request of COMPANY to the FDA, or any other governmental authority in respect of the PRODUCT hereunder shall be paid by **[*]**.

8. COMPANY shall indemnify and hold harmless ELAN, its agents and employees from and against all claims, damages, losses, liabilities and expenses to which ELAN, its agents, and employees may become subject related to or arising out of COMPANY's bad faith, negligence or intentional misconduct in connection with the filing or maintenance of the NDA in the TERRITORY.

9. It is hereby acknowledged that there are inherent uncertainties involved in the research, development and registration of pharmaceutical products with the FDA and other regulatory agencies insofar as obtaining approval is concerned and such uncertainties form part of the business risk involved in undertaking the form of commercial collaboration as set forth in this Agreement. Therefore, save for using their reasonable efforts, ELAN and COMPANY shall have no liability to the other solely as a result of any failure of the PRODUCT to successfully achieve approval of the FDA or any other regulatory body in the TERRITORY.

10. Notwithstanding the foregoing provisions of Article VI, COMPANY may call upon ELAN to carry out all or part of the work necessary to obtain regulatory approval in the TERRITORY. [*].

11. COMPANY may conduct any pharmacokinetic, clinical, non-clinical safety studies, pharmacoeconomic, or any other market analysis, study or test on the PRODUCT without first informing ELAN. In the event that COMPANY does conduct such analysis, study or test, COMPANY shall own said data and information which shall thereafter form part of the COMPANY KNOW-HOW. COMPANY shall provide ELAN with a copy of any such analysis, study or test performed by COMPANY.

12. Subject to Article II, paragraph 11, ELAN shall be entitled to file for NDA APPROVAL for the PRODUCT in any country which ceases to be a part of the TERRITORY, or in the TERRITORY in the event of termination of this Agreement or in any country where COMPANY has a non-exclusive licence in accordance with Article V paragraph 6.2. Where a royalty is payable by ELAN to COMPANY in accordance with Article V. paragraph 3.7 of the Agreement, COMPANY shall permit ELAN or ELAN's designee without charge to conduct sufficient cross-referencing to, any and all pending NDAs or NDA APPROVALS for the PRODUCT for the relevant country or countries of the TERRITORY.

ARTICLE VII: WARRANTY AND INDEMNITY.

1. ELAN represents and warrants that it has the sole, exclusive and unencumbered right to grant the licences and rights herein granted to COMPANY, and that it has not granted any option, licence, right or interest in or to the ELAN PATENT RIGHTS or ELAN KNOW-HOW to any third party which would conflict with the rights granted by this Agreement. ELAN agrees to hold COMPANY harmless from any and all costs, expenses and damages (including reasonable attorneys' fees) incurred or sustained by COMPANY as the result of any third party's challenges to ELAN's right to grant the rights and licences herein granted to COMPANY.

2. ELAN represents and warrants that the execution of this Agreement and the full

performance and enjoyment of the rights of COMPANY under this Agreement will not breach or in any way be inconsistent with the terms and conditions of any licence, contract, understanding or agreement, whether express, implied, written or oral between ELAN and any third party.

3. ELAN represents and warrants that, once successfully developed, the PRODUCT supplied to COMPANY by ELAN under this Agreement shall conform to the PRODUCT SPECIFICATIONS and in accordance with all regulations and requirements of the FDA and other relevant regulatory agencies including the then cGMP regulations which apply to the manufacture and supply of the PRODUCT. Except as expressly stated in this Article VI, all other warranties, conditions and representations, express or implied, statutory or otherwise, including a warranty as to the quality or fitness for any particular purpose of the PRODUCT are hereby excluded and ELAN shall not be liable in contract, tort or otherwise for any loss, damage, expense or injury of any kind whatsoever, consequential or otherwise, arising out of or in connection with the PRODUCT or any defect in the PRODUCT or from any other cause.

4. ELAN is or will become fully cognisant of all applicable statutes, ordinances and regulations of the TERRITORY with respect to the manufacture of the PRODUCT including, but not limited to, the U.S. Federal Food, Drug and Cosmetic Act and regulations thereunder, cGLP and cGMP. ELAN shall manufacture or procure the manufacture of the PRODUCT in conformity with the PRODUCT SPECIFICATIONS and the relevant NDA or Drug Master File in the countries where such activities takes place or have effect and in a manner which fully complies with such statutes, ordinances, regulations and practices.

5. COMPANY is or will become fully cognisant of all applicable statutes, ordinances and regulations of the TERRITORY with respect to the promotion, marketing and sale of the PRODUCT and COMPANY shall comply with all such statutes, ordinances and regulations of the countries where such activities take place or have effect.

6. ELAN certifies to the best of its knowledge that as of the date of this Agreement neither ELAN or any person employed by ELAN has been debarred under Section 306 (a) or 306 (b) of the Federal Food, Drug and Cosmetic Act and that no debarred person will in the future be employed by ELAN to perform any services in connection with any application for approval of the PRODUCT by the FDA. ELAN certifies to the best of its knowledge that neither ELAN nor any person employed by ELAN has a conviction on their record for which a person can be debarred as described in Section 306 (a) or 306 (b) of the Federal Food, Drug and Cosmetic Act. ELAN further certifies that should ELAN or any person employed by ELAN be convicted in the future, of any act for which a person can be debarred as described in Section 306 (a) or 306 (b) of the Federal Food Drug and Cosmetic Act, ELAN shall immediately notify COMPANY of such conviction.

7. ELAN shall assume the sole and entire responsibility and shall indemnify and save harmless COMPANY from any and all claims, liabilities, expenses, including reasonable attorney's fees, responsibilities and damages by reason of any claim, proceedings, action, liability or injury arising out of any faults of the PRODUCT resulting from the preparation, manufacture, packaging, storage, or handling of the PRODUCT by ELAN, (including the distribution, marketing or sale of the PRODUCT if ELAN or any sub-licensee appointed by ELAN is marketing the PRODUCT) to the extent that it was caused by the negligence or wrongful acts or omissions on the part of ELAN or any sub-contractor appointed by ELAN.

8. COMPANY shall assume the sole and entire responsibility and shall indemnify and save harmless ELAN from any and all claims, liabilities, expenses, including reasonable attorney's fees, responsibilities and damages by reason of any claim, proceedings, action, liability or injury arising out of any faults of the PRODUCT resulting from the transport, packaging, storage, handling, distribution, regulatory filing, marketing or sale of the PRODUCT by COMPANY (including the preparation or manufacture of the PRODUCT if COMPANY or any sub-contractor appointed by COMPANY is manufacturing the PRODUCT), to the extent that it was caused by the negligence or wrongful acts or omissions on the part of COMPANY or any sub-contractor appointed by COMPANY.

9. As a condition of obtaining an indemnity in the circumstances set out in this Agreement, the party seeking an indemnity shall:

    9.1. fully and promptly notify the other party of any claim or proceeding, or threatened claim or proceeding;

    9.2. permit the indemnifying party to take full care and control of such claim or proceeding;

    9.3. assist in the investigation and defence of such claim or proceeding;

    9.4. not compromise or otherwise settle any such claim or proceeding without the prior written consent of the other party, which consent shall not be unreasonably withheld; and

    9.5. take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceeding.

10. Notwithstanding anything to the contrary in this Agreement, ELAN and COMPANY shall not be liable to the other by reason of any representation or warranty, condition or other term or any duty of common law, or under the express

terms of this Agreement, for any consequential or incidental loss or damage (whether for loss of profit or otherwise) and whether occasioned by the negligence of the respective parties, their employees or agents or otherwise.

11. ELAN represents and warrants that Elan Corporation plc will provide Elan Pharma Limited, Elan Pharma Inc. or any other subsidiaries with a licence and the rights to manufacture the PRODUCT in accordance with the terms of this Agreement.

ARTICLE VIII: CUSTOMER COMPLAINTS; PRODUCT RECALL

1. COMPANY shall notify ELAN promptly of any complaints from third parties reported to COMPANY involving any serious adverse reactions resulting from the use of the PRODUCT. COMPANY and ELAN shall establish a procedure for formal adverse event handling and reporting. It is envisaged that COMPANY shall be responsible for furnishing spontaneous post marketing reports to the FDA and other relevant regulatory agencies and ELAN will be responsible for furnishing COMPANY with periodic reports which are required by the FDA concerning manufacturing and GMP compliance. COMPANY and ELAN shall keep each other informed and shall copy the other party with all communications with the FDA and other relevant regulatory agencies with respect to the PRODUCT.

2. In the event of any recall of the PRODUCT, as suggested or requested by any governmental authority, COMPANY shall perform the recall of the PRODUCT in the TERRITORY. If the recall arises from ELAN's acts or omissions in the manufacturing or delivery of the PRODUCT, all reasonable trade notifications of the recall of PRODUCT, COMPANY's manufacturing cost of COMPOUND contained in the recalled PRODUCT, the price of the recalled PRODUCT charged to COMPANY by ELAN, and all freight charges associated with the recall of the PRODUCT (collectively referred to as "Recall Costs") shall be borne by **[*]** provided that **[*]**. In all other events the Recall Costs shall be borne by **[*]** in accordance with **[*]**. No royalty shall be payable by COMPANY on any recalled PRODUCT, whether due to the default of ELAN or COMPANY. Neither party shall be liable to the other or to any third party for consequential or incidental damages which may arise as a result of the recall of the PRODUCT.

ARTICLE IX: PROJECT TEAM

1. It is recognised by the parties hereto that a significant resource shall be required from each party to accomplish a successful NDA APPROVAL and launch of the PRODUCT, particularly in the co-ordination of logistics, finalisation of various specifications, methodologies transfer, supply and packaging configurations,

shipping and handling procedures etc., and for this purpose, the parties agree to the establishment of a PROJECT TEAM. The PROJECT TEAM shall meet from time to time as deemed necessary by the parties during the PROJECT, such meetings to continue until the time of launch or some such later time thereafter as may be agreed. The PROJECT TEAM shall review the clinical and regulatory strategy for the PRODUCT on an ongoing basis. Meetings shall be chaired by the chief representative of the COMPANY. At and between meetings of the PROJECT TEAM, each party shall keep the other fully and regularly informed as to its progress with its respective obligations.

2. The PROJECT TEAM shall also monitor the progress of the PROJECT against the time period set out in paragraphs 2.1.2. and 2.1.3. of Article V and shall report on delays in the conduct of the PROJECT which would materially affect ELAN's ability to achieve the tasks set out paragraphs 2.1.2. and 2.1.3. of Article V and recommend whether corrective action is required under the provisions of Article II, paragraph 7.

3. The PROJECT TEAM shall not be empowered to alter the terms of this Agreement.

4. Following the first launch of the PRODUCT, the parties shall meet on a semi-annual basis for the first, second and third year and on an annual basis thereafter. At such meetings, COMPANY shall report on the ongoing sales performance of the PRODUCT in the TERRITORY. ELAN shall report on matters such as manufacturing, quality and resource planning.

ARTICLE X: PAYMENTS, REPORTS AND AUDITS

1. COMPANY shall keep true and accurate records of gross sales of the PRODUCT by COMPANY, its AFFILIATES or permitted sub-licensees, the items deducted from the gross amount in calculating the NSP, the NSP and the royalties payable to ELAN under Article V hereof. COMPANY shall deliver to ELAN a written statement thereof within sixty (60) days following the end of each calendar quarter (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. The said written statements shall set forth on a country-by-country basis, the calculation of the NSP from gross revenues during that calendar quarter, the applicable percentage rate, and a computation of the sums due to ELAN ("the Statement"). The parties' financial officers shall agree upon the precise format of the Statement.

2. Payments due on NSP of the PRODUCT based on sales amounts in a currency other than United States Dollars shall first be calculated in the foreign currency and then converted to United States Dollars on the basis of the exchange rate in

effect for the purchase of United States Dollars with such foreign currency quoted in the Wall Street Journal (or comparable publication if not quoted in the Wall Street Journal) with respect to the sale of currency of the country of origin of such payment for the day prior to the date on which the payment by COMPANY is being made.

3. Any income or other taxes which COMPANY and ELAN, if applicable, is required by law to pay or withhold on behalf of the receiving party with respect to royalties and any other monies payable to such party under this Agreement shall be deducted from the amount of such NSP payments, royalties and other monies due. COMPANY and ELAN, if applicable, shall furnish the receiving party with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by the receiving party. COMPANY and ELAN, if applicable, shall promptly provide the receiving party with a certificate or other documentary evidence to enable the receiving party to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by the paying party. Both parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable the paying party to make such payments to the receiving party without any deduction or withholding.

4. All payments due hereunder shall be made to the designated bank account of ELAN in accordance with such timely written instructions as ELAN shall from time to time provide.

5. COMPANY shall pay interest to ELAN at the rate publicly announced by Morgan Guaranty Trust Company of New York at its principal office at its prime or best rate plus **[*]** on all late payments under this Agreement (applicable as of the date on which payment should have been made pursuant to the applicable provisions of this Agreement) from the date on which payment should have been made pursuant to the applicable provision until the date of payment.

6. COMPANY shall provide ELAN with quarterly sales reports outlining the status of the PRODUCT in the TERRITORY, **[*]**.

7. For the one hundred and eighty (180) day period following the close of each calendar year during the term of the Agreement, ELAN and COMPANY will provide each others independent certified accountants (reasonably acceptable to the other party) with access, during regular business hours and upon reasonable prior request and subject to the confidentiality provisions as contained in this Agreement, to such party's books and records relating to the PRODUCT, solely for the purpose of verifying the accuracy and reasonable composition of the calculations hereunder for the calendar year then ended.

8. In the event of a discovery of a discrepancy which exceeds **[*]** percent (**[*]**%) of the amount due or charged by a party for any period, the cost of such accountants shall be borne by the audited party; otherwise, such cost shall be borne by the auditing party.

9. ELAN shall make (and where relevant shall procure that ELAN's subcontractor shall make) that portion of its manufacturing facility where PRODUCT is manufactured, including all record and reference samples relating to the PRODUCT available for inspection by COMPANY's duly qualified person or by the relevant governmental or regulatory authority. The investigation shall be limited to determining whether there is compliance with cGMP and other requirements of applicable law.

ARTICLE XI PATENTS

1. ELAN shall make a good faith effort to secure the grant of all of the ELAN PATENT RIGHTS in the appropriate countries of the TERRITORY at its own expense and shall be the title holder thereof. ELAN shall keep COMPANY apprised of all significant activities in connection therewith in timely manner. ELAN agrees to defend and pay all governmental charges and maintenance fees thereon and extend the term of any resulting patent at COMPANY's request with COMPANY's assistance.

2. COMPANY and ELAN shall promptly inform the other in writing of any alleged infringement of which it shall become aware by a third party of any patents within the ELAN PATENT RIGHTS or COMPANY PATENT RIGHTS and provide such other with any available evidence of infringement.

3. Both ELAN and COMPANY recognise that it is most desirable that patent protection be secured for the PRODUCT. The parties will in good faith jointly decide how ELAN shall file and prosecute all patent applications regarding the PRODUCT and how to share the costs.

4. The following provisions shall apply to any proceedings ("Enforcement Proceedings") taken by the parties during the term of this Agreement in respect of infringements which relate to the enforcement of the ELAN PATENT RIGHTS, ELAN KNOW-HOW, COMPANY PATENT RIGHTS, AND COMPANY KNOW-HOW relating to the PRODUCT:

   4.1. The parties may agree to institute Enforcement Proceedings in their joint names and shall reach agreement as to the proportion in which they will share the proceeds of any such Enforcement Proceedings, and the expense

of any costs not recovered, or the costs or damages payable to the third party. The parties will share the proceeds of any Enforcement Proceedings in proportions equivalent to the proportions of each party's respective costs directly associated with the Enforcement Proceedings.

4.2. In the event that COMPANY does not wish to institute Enforcement Proceedings under paragraph 4.1, ELAN shall have the right to institute Enforcement Proceedings at its own expense and for its own benefit and COMPANY shall co-operate with any such Enforcement Proceedings. Any expenses borne by COMPANY shall be reimbursed by ELAN, provided that COMPANY shall bear the costs incurred by it if it elects to retain an independent firm of attorneys to advise it in relation to the Enforcement Proceedings.

4.3. In the event that ELAN does not wish to institute Enforcement Proceedings under paragraph 4.1., COMPANY shall have the right to institute Enforcement Proceedings at its own expense and for its own benefit and ELAN will co-operate with any such Enforcement Proceedings. Any expenses borne by ELAN shall be reimbursed by COMPANY provided that ELAN shall bear the costs incurred by it if it elects to retain an independent firm of attorneys to advise it in relation to the Enforcement Proceedings.

ARTICLE XII: SUNDRY CLAUSES

1. **Secrecy**

1.1. Any information, whether written or oral (oral information shall be reduced to writing within one month by the party giving the oral information and the written form shall be furnished to the other party) pertaining to the PRODUCT that has been or will be communicated or delivered by ELAN to COMPANY, and any information from time to time communicated or delivered by COMPANY to ELAN, including, without limitation, trade secrets, business methods, and cost, supplier, manufacturing and customer information, shall be treated by COMPANY and ELAN, respectively, as confidential information, and shall not be disclosed or revealed to any third party whatsoever or used in any manner except as expressly provided for herein; provided, however, that such confidential information shall not be subject to the restrictions and prohibitions set forth in this section to the extent that such confidential information:

1.1.1. is available to the public in public literature or otherwise, or after disclosure by one party to the other becomes public knowledge through no default of the party receiving such confidential information; or

1.1.2. was known to the party receiving such confidential information prior to the receipt of such confidential information by such party, whether received before or after the date of this Agreement; or

1.1.3. is obtained by the party receiving such confidential information from a third party not subject to a requirement of confidentiality with respect to such confidential information; or

1.1.4. is required to be disclosed pursuant to: (A) any order of a court having jurisdiction and power to order such information to be released or made public; or (B) any lawful action of a governmental or regulatory agency. In such event, the party receiving such confidential information shall notify the disclosing party of the required disclosure in advance to enable the disclosing party to have an opportunity to object to such governmental entity or court of law regarding the required disclosure. The receiving party shall use all reasonable efforts to obtain confidential treatment of such confidential information required to be disclosed; or

1.1.5. is independently discovered by the receiving party after the date of this Agreement without the aid, application or use of the confidential information of the disclosing party.

1.2. Each party shall take all such precautions as it normally takes with its own confidential information to prevent any improper disclosure of such confidential information to any third party; provided, however, that such confidential information may be disclosed within the limits required to obtain any authorisation from the FDA or any governmental or regulatory agency or, with the prior written consent of the other party, which shall not be unreasonably withheld, or as may otherwise be required in connection with the purposes of this Agreement.

1.3. COMPANY agrees that it will not use, directly or indirectly, any ELAN KNOW-HOW, or otherwise confidential information disclosed to COMPANY or obtained from ELAN pursuant to this Agreement, other than as expressly provided herein. ELAN agrees that it will not use, directly or indirectly, any COMPANY KNOW-HOW, or otherwise confidential information disclosed to ELAN or obtained from COMPANY pursuant to this Agreement, other than as expressly provided herein.

1.4. COMPANY and ELAN will not publicise the existence of this Agreement in any way without the prior written consent of the other subject to the disclosure requirements of applicable laws and regulations. In the event that either party wishes to make a public disclosure concerning this Agreement and such disclosure mentions the other party by name or description, such other party will

be provided with an advance copy of the disclosure and will have three (3) business days within which to approve or disapprove such use of its name or description. Approval shall not be unreasonably withheld by either party. Failure to respond within such three (3) business days shall be deemed to be approval. Absent approval, no public disclosure shall use the name or otherwise describe such party except to the extent required by law. Notwithstanding the foregoing, it is understood and agreed that no approval shall be required in the event that the information to be disclosed has previously been the subject of a prior disclosure.

2. **Assignments/ Sub-contracting**

This Agreement may not be assigned by COMPANY without the prior written consent of ELAN, such consent not being unreasonably withheld or delayed, save that COMPANY may assign this Agreement to its AFFILIATE or AFFILIATES without such consent provided that such assignment has no adverse tax implications for ELAN. ELAN may assign this Agreement to an AFFILIATE. ELAN shall also have the right to subcontract all or any portion of the PRODUCT to a third party with the prior written consent of COMPANY, such consent not being unreasonably withheld or delayed.

3. **Parties bound**

This Agreement shall be binding upon and enure for the benefit of parties hereto, their successors and permitted assigns.

4. **Severability**

If any provision in this Agreement is agreed by the parties to be, or is deemed to be, or becomes invalid, illegal, void or unenforceable under any law that is applicable hereto, (i) such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the parties, it will be deleted, with effect from the date of such agreement or such earlier date as the parties may agree, and (ii) the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

5. **Duration and Termination**

5.1. This Agreement is concluded for a period commencing as of the date of this Agreement and shall expire on a country by country basis after ten (10) years starting from the date of the launch of the PRODUCT, or for the life of the last to expire patent included in the ELAN PATENT RIGHTS whichever is longer ("the

Initial Period"). After the expiry of the Initial Period, the parties shall negotiate in good faith the terms of a new agreement, including an appropriate royalty, taking into account the then prevailing market conditions. Pending the execution of any new agreement, the terms of this Agreement shall continue.

If such a new agreement is not concluded, subject to giving two (2) years' written notice to commence after the expiry of the Initial Period, COMPANY may commence manufacturing the PRODUCT, or after any longer period in which ELAN continues to supply PRODUCT under a new agreement concluded between the parties, ELAN shall grant to COMPANY a production licence to the ELAN KNOW-HOW in terms similar to Article III paragraph 14 of the Agreement. In consideration of such a production licence to the ELAN KNOW-HOW, COMPANY shall pay an ongoing royalty of **[*]** percent (**[*]**%) on NSP of the PRODUCT to ELAN.

In the event that **[*]** (as the term is defined and accepted by the FDA or **[*]** by other regulatory authorities) generic competitor is approved and marketed for commercial sale in any country of the TERRITORY after the expiry of the Initial Period, **[*]**. However, the ongoing royalty of **[*]** percent (**[*]**%) on NSP of the PRODUCT shall be paid to ELAN in all other countries of the TERRITORY.

5.2. In addition to the rights of early or premature termination provided for elsewhere in this Agreement, it is hereby acknowledged that in the event that any of the terms or provisions hereof are incurably breached by either party, the non-breaching party may immediately terminate this Agreement by written notice. An incurable breach shall be committed:

5.2.1. when either party is dissolved, liquidated, discontinued, becomes insolvent, or when any proceeding is filed or commenced by or against either party under bankruptcy, insolvency or debtor relief laws and is not dismissed within ninety (90) days of filing, or

5.2.2. where there is a change in either party's ownership or control of more than forty (40%) per cent, or

5.2.3. where a technological competitor of ELAN or a company with a directly competing product acquires twenty (20%) percent or more of COMPANY's voting stock or where twenty (20%) percent or more of such company's voting stock is acquired by COMPANY, or

5.2.4. where a pharmaceutical company with a significant anti-depressant and obsessive compulsive disorder product portfolio acquires twenty (20%) percent or more of ELAN's voting stock or where twenty (20%) percent or more of such company's voting stock is acquired by ELAN; provided however that this paragraph shall only apply in the event that ELAN is exercising the licence under this Agreement to the COMPANY PATENT RIGHTS and KNOW-HOW.

Subject to the other provision of this Agreement, in the event of any other breach, the non-breaching party may terminate this Agreement by the giving of written notice to the breaching party that this Agreement will terminate on the sixtieth (60th) day from notice unless cure is sooner effected.

5.3. COMPANY may elect to terminate this Agreement in accordance with Article III, paragraph 4 and otherwise up to the date of filing of the NDA with the FDA in the United States of America. In addition to these and any other rights of termination specified in this Agreement, COMPANY may also terminate this Agreement for economic or strategic reasons at any time after COMPANY has filed the NDA with the FDA in the United States of America and said FDA has accepted such filing, by giving ninety (90) days notice to ELAN of such intention. In the event that COMPANY so elects to terminate this Agreement at any time after COMPANY has filed the NDA with the FDA in the United States of America up to the first anniversary of the launch of the PRODUCT in the United States of America, COMPANY shall pay to ELAN, in addition to any sums outstanding as referred to in paragraph 5.5. of this Article, an additional royalty payment as specified in Article V, paragraph 2.1.6. in recognition of the utilisation by COMPANY of the ELAN PATENT RIGHTS up to the date of such termination. In such an event and should ELAN commercialise the PRODUCT in accordance with Article II, paragraph 11 and Article V, paragraph 3.7., COMPANY shall be entitled to recover the $2,000,000 payable to ELAN in accordance with Article V, paragraph 2.1.6. as an additional royalty payable by ELAN to COMPANY in accordance with Article V, paragraph 3.7 following the first commercial sale of the PRODUCT in the TERRITORY by the ELAN. ELAN shall pay COMPANY such additional royalty by increasing the royalty calculated as payable on NSP to COMPANY by twenty-five percent (25%) in each quarter following first launch of PRODUCT until such time as total additional royalty payments reach $2,000,000, at which point this additional royalty shall cease.

5.4. Upon exercise of those rights of termination as specified in Article XII, paragraphs 5.1., 5.2 and 5.3., or elsewhere within the Agreement, this Agreement shall, subject to the other provisions of the Agreement and Article XII paragraph 5.5., automatically terminate forthwith and be of no further legal force or effect.

5.5. Upon termination of the Agreement by either party, or upon termination by ELAN of a licence for a particular country in accordance with Article II, paragraph 11 or any other the terms of the Agreement, the following shall be the consequences relating to the TERRITORY or the particular country, as applicable:

5.5.1. any sums that were due from COMPANY to ELAN prior to the exercise of the right to terminate this agreement as set forth herein shall be paid in full within sixty (60) days of termination of this Agreement and ELAN shall not be liable to repay to COMPANY any amount of money paid or payable by COMPANY to ELAN up to the date of termination of this Agreement;

5.5.2. all confidentiality provisions set out herein shall remain in full force and effect for a period of **[*]** from the date of termination of the Agreement;

5.5.3. all responsibilities and warranties shall insofar are appropriate remain in full force and effect;

5.5.4. the rights of inspection and audit shall continue in force for the period referred to in the relevant provisions of this Agreement;

5.5.5. depending on the scope of termination as provided for in this Agreement, ELAN shall be entitled to commercialise the PRODUCT for its own benefit in the TERRITORY or in the relevant country or countries of the TERRITORY;

5.5.6. Where a royalty is payable by ELAN to COMPANY in accordance with

Article V., paragraph 3.7 of the Agreement, COMPANY shall transfer to ELAN or ELAN's designee without charge, and/or permit ELAN or ELAN's designee without charge to conduct sufficient cross-referencing to, any and all pending or granted NDA APPROVALS for the PRODUCT for the relevant country or countries of the TERRITORY; and

5.5.7. COMPANY shall have an ongoing right for a period of six (6) months to sell or otherwise dispose of the stock of any PRODUCT on hand as of the date of termination of the AGREEMENT, which such sale shall be subject to Article V and the other applicable terms of this AGREEMENT.

5.6. In the event that this Agreement is terminated and should ELAN require a licence of the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in order to research, develop and commercialise the PRODUCT in accordance with Article II, paragraph 11:-

5.6.1. COMPANY shall grant ELAN a licence in respect of the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW subject to the payment of a royalty mutatis mutandis with Article V, paragraph 3.7 of this Agreement for a term of **[*]** starting from the date of the launch of the PRODUCT by ELAN or up to the expiration of the life of the last to expire patent included in the COMPANY PATENT RIGHTS, whichever is longer;

5.6.2. the parties shall enter into a further written licence and supply agreement which shall incorporate the foregoing provisions of this paragraph 5.6. and which shall include customary and reasonable terms relating to, inter alia, the supply of COMPOUND by COMPANY to ELAN, the timing of royalty payments to COMPANY, reporting obligations regarding net sales, audit rights of COMPANY with respect to books and records relating to net sales, and indemnity provisions, which obligations shall, unless otherwise agreed by the parties, be substantially similar to those in this Agreement with respect to commercialisation of the PRODUCT by COMPANY;

6. **Force Majeure**

Neither party to this Agreement shall be liable for delay in the performance of any of its obligations hereunder if such delay results from causes beyond its reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, or intervention of a government authority, non availability of raw materials, but any such delay or failure shall be remedied by such party as soon as practicable.

7. **Relationship of the Parties**

Nothing contained in this Agreement is intended or is to be construed to constitute ELAN and COMPANY as partners or joint venturers or either party as an employee of the other. Neither party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other party or to bind the other party to any contract, agreement or undertaking with any third party.

8. **Amendments**

No amendment, modification or addition hereto shall be effective or binding on either party unless set forth in writing and executed by a duly authorised representative of both parties.

9. **Waiver**

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.

10. **Headings**

The section headings contained in this Agreement are included for convenience only and form no part of the agreement between the parties. Save as otherwise provided herein, references to articles, paragraphs, clauses and appendices are to those contained in this Agreement.

11. **No effect on other agreements**

No provision of this Agreement shall be construed so as to negate, modify or affect in any way the provisions of any other agreement between the parties unless specifically referred to, and solely to the extent provided, in any such other agreement.

12. **Applicable Law**

12.1. This Agreement is construed under and ruled by the internal laws of the State of Georgia, without regard to conflicts of laws principles. For the purpose of this Agreement the parties submit to the exclusive jurisdiction of the courts of the State of Georgia.

12.2. Any controversy or claim arising out of or in relation to the Agreement, or the breach thereof, shall be settled by binding arbitration, which will be the parties exclusive remedy, and judgement on the award rendered by the arbitrators may be

entered in any court having jurisdiction thereof. Any such arbitration shall be conducted in the English language in Atlanta, Georgia and shall proceed pursuant to the then-existing Commercial Arbitration Rules of The American Arbitration Association ("Rules") but only to the extent the Rules do not conflict with the provisions of this Agreement.

12.3. Within fifteen (15) days after the demand for arbitration is sent to the other party, each party shall select one person to act as arbitrator and the two selected arbitrators shall select a third arbitrator within ten (10) days of their appointment. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator ,the third arbitrator shall be selected by The American Arbitration Association. A majority of the arbitrators shall be required to rule in favour of any final award.

12.4. The parties shall allow and participate in discovery in accordance with the Federal Rules of Civil Procedure for a period of ninety (90) days after the demand for arbitration is sent to the other party. Unresolved discovery disputes may be brought to the attention of the arbitrators and may be disposed of by the arbitrators.

12.5. All fees and expenses of the arbitration shall be borne by the parties equally. The prevailing party shall be entitled to an award of reasonable attorney fees, including disbursements.

13. **Notice**

13.1. Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or telecopied to:

- ELAN at

Elan Corporation plc.
Lincoln House,
Lincoln Place
Dublin 2
Ireland.

Attention: Vice-President & General Counsel,
Elan Pharmaceutical Technologies
Telephone: 353 1 7094301
Telefax : 353 1 6624960

- COMPANY at

Solvay Pharmaceuticals, Inc.
901 Sawyer Road,
Marietta, Georgia 30062,
United States of America.

Attention: Vice President, Law, Government & Public Affairs
Telephone: 770 578 5736
Telefax: 770 578 5749

or to such other address(es) and telecopier numbers as may from time to time be notified by either party to the other hereunder.

13.2. Any notice sent by mail shall be deemed to have been delivered within seven (7) working days after despatch and any notice sent by telex or telecopy shall be deemed to have been delivered within twenty four (24) hours of the time of the despatch. Notice of change of address shall be effective upon receipt.

IN WITNESS THEREOF the parties hereto have executed this Agreement in duplicate.

Executed by **COMPANY** on 22 December, 1997

By : /s/ David A. Dodd
Name: David A. Dodd
Title: President and CEO

Executed by **ELAN** 23 December, 1997

By: /s/ Seamus Mulligan
Name: Seamus Mulligan
Title: President – EPT

APPENDIX A

PART I

ELAN PATENT RIGHTS

United States of America Patent Numbers

[*]

PART II

COMPANY PATENT RIGHTS

Not filed with the executed document.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

APPENDIX B

THE PROJECT

For the consideration outlined in this Agreement, ELAN will undertake the PROJECT as described hereunder, consistent with the objectives of this Agreement and specifically with the provisions of Article III. The PROJECT will consist of four distinct stages of activities which are outlined below;

STAGE I	[*]
STAGE II	[*]
STAGE III	[*]
STAGE IV	[*]

[*]

APPENDIX C

PRODUCT SPECIFICATIONS

None.

APPENDIX D

MANUFACTURING COST

The following expenses are manufacturing expenses which are prepared in accordance with generally accepted accounting principles consistently applied.

The following expenses are included in manufacturing costs:

[*]

APPENDIX E

QUALITY PROCEDURES

QUALITY PROCEDURES APPENDIX

1. SPECIFICATIONS AND MASTER DOCUMENTATION

1.1. COMPANY will hold on file copies of all regulatory applications, submissions and approvals for the PRODUCT and shall allow ELAN access to the NDA for the United States of America and other registration applications as may be required, including all supplements, amendments, and related correspondence which provide the necessary documentation and information to ensure the PRODUCT is manufactured and tested in accordance with the relevant regulatory requirements.

1.2. ELAN will be responsible for preparing manufacturing and quality control documentation for the PRODUCT to reflect the formulation, method, manufacture and control parameters leading to bulk supply of finished PRODUCT (in capsule or tablet form) as detailed in the regulatory documents and in conformance with cGMP. COMPANY and ELAN shall designate primary contacts at each company for the dissemination of all necessary documentation to relevant internal personnel at each site.

1.3. COMPANY and ELAN shall agree and formalize a change control procedure to be in place on NDA APPROVAL which will allow for communication and authorization of proposed changes in the relevant manufacturing documentation of the COMPOUND and PRODUCT.

2. SUPPLY AND CONTROL OF MATERIAL

2.1. COMPANY will procure the COMPOUND. ELAN will procure all other materials for the PRODUCT.

2.2. ELAN will test and approve all raw materials in accordance with the requirements of the regulatory approval as set out in the relevant approved analytical protocols for the PRODUCT and in conformance with operating procedures.

2.3. ELAN will not change the source or grade of material used in the manufacture of the PRODUCT post NDA APPROVAL without prior change control communication. In the event such a change warrants it, COMPANY will be responsible for obtaining all required regulatory approvals.

2.4. COMPANY will ensure COMPOUND is manufactured and tested in accordance with the agreed specifications, relevant regulatory requirements, and in conformance with cGMP and operating procedures. This will be confirmed by certificates of analysis to accompany each lot of COMPOUND provided to ELAN.

2.5. COMPANY will ensure no revision in manufacturing and controls of COMPOUND without prior change control communication. In the event such a change warrants it, COMPANY will be responsible for obtaining all required regulatory approvals.

2.6. COMPANY will permit the appropriate ELAN personnel to periodically assess the COMPANY quality system in terms of its relevance to the manufacture and quality of the COMPOUND and will make available batch and related documentation for review at the COMPANY manufacturing site.

3. PROCESSING

3.1. ELAN will manufacture the PRODUCT in accordance with the NDA requirements and in conformance with cGMP and will supply the PRODUCT to COMPANY in the form of bulk capsules or tablets, as determined in the PROJECT. COMPANY will be responsible for the packaging of the PRODUCT into final market packaging in accordance with the NDA requirements and in conformance with cGMP.

3.2. ELAN will be responsible for validation of the current processes and equipment (and of any changes made to same) used by ELAN in the manufacture of the PRODUCT. Details of such validation work will be made available to COMPANY for review at ELAN's manufacturing site.

3.3. ELAN will permit the appropriate COMPANY personnel to periodically assess the ELAN quality system in terms of its relevance to the manufacture and quality control of the PRODUCT and will make available batch and related documentation for review at the ELAN manufacturing site.

4. PACKAGING, LABELLING AND TRANSPORTATION

4.1. COMPANY will pack, label and ship the COMPOUND to ELAN so as to permit safe storage and transport, to retain COMPOUND security, and to enable swift identification of package contents.

4.2. ELAN will pack, label and ship the PRODUCT in bulk capsules or tablets (as determined in the PROJECT) so as to permit safe storage and transport, to retain PRODUCT security and to enable swift identification of package contents.

4.3. Shipping containers will be appropriately labeled with PRODUCT labels detailing PRODUCT description, storage information, lot reference, manufacture date, quantity, and container number. An address label for the appropriate COMPANY destination will be attached to each shipping container. Any revisions to labeling requirements can be agreed in advance of NDA submission.

5. QUALITY CONTROL AND RELEASE FOR SHIPMENT

5.1. ELAN will test each batch of the PRODUCT as detailed in the approved analytical protocol and will review all relevant batch documentation prior to approval for shipment to COMPANY. ELAN will provide copies of confirmed out-of -specification investigations to COMPANY on commercial distributed PRODUCT.

5.2. On an exceptional basis and by prior arrangement with COMPANY, ELAN may authorize shipment of PRODUCT after testing but before final QA review. Such PRODUCT will not be released by COMPANY prior to receipt of certification from ELAN that the results of testing are satisfactory.

5.3. Final release of packaged PRODUCT to the market place is the responsibility of COMPANY's Quality Unit.

6. BATCH DOCUMENTATION

6.1. ELAN will retain batch records and related documents in accordance with regulatory and corporate retention requirements.

6.2. ELAN will, by issuing a certificate of analysis to the COMPANY, confirm that each batch of PRODUCT supplied to COMPANY complies with the relevant analytical specifications and that it has been manufactured in accordance with cGMP.

7. CUSTOMER COMPLAINTS

7.1. Clinical Complaints

7.1.1. For clinical complaints arising from the field (patient/practitioner), it will be the responsibility of COMPANY to log, investigate, follow up and respond to each complaint. In the event of COMPANY requiring ELAN to contribute to the investigation of such complaints, ELAN will respond to COMPANY within fourteen (14) working days or earlier, depending on the nature of the clinical complaint.

7.1.2. Field complaints received directly by ELAN, will be forwarded to COMPANY for processing.

7.1.3. Any field complaints which, upon review are adverse events by definition, will also be the responsibility of COMPANY.

7.2. Complaint Handling Non-Clinical

7.2.1. COMPANY will forward copies of complaints and related correspondence to ELAN for investigation if associated with any aspect of manufacture/handling carried out at ELAN.

7.2.2. On receipt of a complaint from COMPANY, ELAN will log and evaluate the incident. Within thirty (30) days, ELAN will provide a written response to COMPANY.

7.3 Complaint Reports

7.3.1 COMPANY will provide ELAN with a summary of all non-clinical complaints relating to the PRODUCT on a quarterly basis.

8. FIELD ALERT/RECALL

8.1. In the event of a field alert or recall of PRODUCT in the TERRITORY and subject to the provisions of Article VIII of this Agreement, as deemed appropriate or agreed with the relevant regulatory agency, COMPANY will be responsible for all communications with the regulatory authority and will perform the said recall.

8.2. ELAN will be provided with copies of all correspondence with the regulatory authority if related to manufacture/handling activities by ELAN.

9. RETAIN SAMPLES

9.1. ELAN will hold sufficient retains of the PRODUCT in bulk, to enable complete re-analysis to be performed twice. COMPANY will hold sufficient retains of the packaged PRODUCT to meet their own retest requirements. The results of any such analysis on retains of PRODUCT will be provided to COMPANY.

10. STABILITY

10.1. COMPANY will carry out all post marketing stability studies to meet NDA or other relevant regulatory commitments. COMPANY will provide ELAN with all stability reports, for informational purposes only. Any communication to the FDA or other relevant agencies will be made through COMPANY. In the event of a stability failure, COMPANY will notify ELAN immediately of the failure and will provide a written stability report within five (5) working days.

11. ADVERSE EVENTS

11.1. COMPANY will be responsible for meeting all regulatory obligations with regard to adverse event receipt, evaluation, and reporting.

12. ANNUAL PRODUCT REPORTS/REVIEWS

12.1. COMPANY is responsible for Annual Reports and similar regulatory obligations in support of regulatory applications (i.e., IND, NDA) for the PRODUCT. COMPANY will provide ELAN with their requirements and the defined review period in support of said applications.

12.2. ELAN will conduct an Annual Product Review in accordance with cGMP for the PRODUCT following NDA APPROVAL. COMPANY will provide the required documentation (e.g. complaint history, stability data, etc.) as requested by ELAN for completion of the report. Access to the Review will be made available to COMPANY for review at ELAN's manufacturing site.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

7 November 2006

ELAN CORPORATION, PLC.

AND

SOLVAY PHARMACEUTICALS INC.

AMENDMENT AGREEMENT NO. 3 TO THE LICENCE AGREEMENT OF 22 DECEMBER 1997

Luvox (fluvoxamine) CR
Worldwide

INDEX

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THIS AMENDMENT No 3 AGREEMENT is made the 7th day of November 2006

BETWEEN:

(1) **Elan Corporation, plc.**, a public limited company incorporated under the laws of Ireland, and having its registered office at Treasury Building, Grand Canal Street Lower, Dublin 2, Ireland; and

(2) **Solvay Pharmaceuticals Inc.**, a company organised under the laws of the State of Georgia and having its principal place of business at 901 Sawyer Road, Marietta, Georgia, 30062 United States of America ("**Solvay**")

RECITALS:

(A) Elan and Solvay entered into an agreement dated 22 December 1997 whereby, inter alia, Elan licensed to Solvay certain patents and know how to have manufactured oral controlled release dosage forms of fluvoxamine maleate (the "**First Agreement**").

(B) Elan and Solvay entered into (i) an Amendment Agreement dated 1 March 1999 whereby STAGE III of the PROJECT (as each of those terms was defined in the First Agreement) was amended (the "**Amendment Agreement No. 1**"); and (ii) a letter of amendment dated 13 April 2000 and countersigned 3 May 2000, whereby Article V, Section 2.1.3 was amended (the "**Amendment Agreement No. 2**").

(C) Solvay and Solvay Pharmaceuticals Marketing & Licensing AG of Binningerstrasse 94, 4123 Allschwil, Switzerland ("**SPML**") entered into an Assignment and Assumption Agreement dated 4 August 2000 (the "**Assignment Agreement**") whereby Solvay assigned to SPML its rights and obligations under the First Agreement as amended. Elan agreed to that assignment. Subsequently Solvay and SPML entered into a letter agreement for reassignment and re-assumption dated 13 December 2001, (the "**Re-assignment Agreement**") whereby SPML re-assigned to Solvay its rights and obligations under the First Agreement as amended. Elan also agreed to that assignment, as Elan hereby acknowledges and confirms.

(D) Elan and Solvay now wish to amend certain of the financial and other provisions of the **Original Agreement**, as hereinafter defined, with effect from the Amendment No. 3 Date.

(E) Elan and Solvay are desirous of entering into this Amendment No.3 Agreement to give effect to the arrangements described at Recital (D).

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. Preliminary

1.1. In this Amendment Agreement No. 3

"**Original Agreement**" shall mean the First Agreement as amended by the Amendment Agreement No. 1, Amendment Agreement No. 2, the Assignment Agreement and the Reassignment Agreement.

"**this Amendment**" shall mean this Amendment No 3 Agreement, including its recitals and schedules.

1.2. Except where expressly provided to the contrary in this Amendment Agreement No. 3:

1.2.1 all capitalised terms used in this Amendment Agreement No. 3 shall have the same meanings as are assigned thereto in the Original Agreement, as amended by this Amendment; and

1.2.2 this Amendment Agreement No. 3 shall be interpreted in the same manner as the Original Agreement.

2. Amendment of Definitions

2.1. ELAN and COMPANY hereby agree that the Original Agreement is hereby amended with effect from the Amendment No. 3 Date by the insertion of the following definitions:

"**Amendment Agreement No. 3**" shall mean the Amendment Agreement No. 3 between ELAN and COMPANY dated the 7th November 2006

"**Amendment No. 3 Date**" shall mean 7 November 2006.

3. Refund of Milestone and Re-Filing of Drug Master File "DMF"

3.1. ELAN and COMPANY acknowledge that COMPANY paid to ELAN the sum of $**[*]** pursuant to Article V Section 2.1.3 of the Original Agreement. The filing referred to in that Section subsequently having been withdrawn, ELAN and COMPANY agree that within five (5) business days of the signature of this Amendment Agreement No. 3 and upon receipt by ELAN of an appropriate invoice from the COMPANY, ELAN shall repay to COMPANY the sum of $**[*]**

3.2. The parties hereby agree that each party shall bear all costs and expenses incurred by it, pursuant to any development or other activities carried out by it in connection with the PRODUCT, from the date of the withdrawal referred to at Section 3.1 to the Amendment No. 3 Date. For the avoidance of doubt, insofar as either party has taken steps to discharge its responsibilities as listed in the attached Schedule A prior to the execution of this Amendment Agreement No. 3, that party shall be responsible for the reasonable costs and expenses associated with same except as expressly stated therein to be the responsibility of the other party.

3.3. Subject to Article III, Section 2 of the Original Agreement, the parties further agree that Schedule A hereto sets out the agreed allocation of responsibility including responsibility for costs and expenses for re-filing the DMF.

3.4. COMPANY acknowledges that the foregoing repayment and assumption of costs and expenses by ELAN is in complete substitution for any other remedy COMPANY may have or may have had against ELAN in respect of such withdrawal. COMPANY hereby waives and releases all such claims against ELAN.

3.5. COMPANY further acknowledges that such repayment and assumption of costs and expenses by ELAN is without prejudice to ELAN's right to the payment set out in Article V Section 2.1.3 as amended by this Amendment Agreement No. 3.

4. <u>Amendment of Financial Provisions</u>

ELAN and COMPANY hereby agree that Article V of the Original Agreement is hereby amended with effect from the Amendment No. 3 Date as follows:

4.1. by the deletion of the entirety of Section 2.1.3 and the substitution therefor of the following:

"2.1.3. $**[*]** due upon **[*]**.";

4.2. by the deletion of the amount "$**[*]**" in Section 2.1.4 and the substitution therefor of the amount "$**[*]**"; and by the addition at the end of that section of the word "and";

4.3. by the deletion of the amount "$**[*]**" in Section 2.1.5 and the substitution therefor of the amount "$**[*]**"; and by the deletion at the end of that section of the word "and";

4.4. by the deletion of Section 2.1.6 in its entirety;

4.5. by the deletion of paragraphs (i) and (ii) of Section 3.1 and the substitution therefor of the following paragraphs:

"(i) **[*]** percent (**[*]**%) on the first $**[*]** sales of PRODUCT, calculated as NSP value, in any one calendar year;

(ii) **[*]** percent (**[*]**%) on the next $**[*]** sales of PRODUCT, calculated as NSP value, in any one calendar year; and

(iii) **[*]** percent (**[*]**%) on sales of PRODUCT, calculated as NSP value, in excess of $**[*]** in any one calendar year.";

4.6. by the deletion in Section 3.1 of the hypothetical example (beginning with the words "EXAMPLE: If in any one year …" until the end of the Section) and the substitution therefor of the following:

"EXAMPLE: If in any one year period following the first launch of the PRODUCT, the annual NSP were $**[*]**, the royalty payable to ELAN shall be calculated as follows:

[*]

4.7. by the deletion of Section 3.7 in its entirety and the substitution therefor of the following;

"3.7 In consideration of the licence to the COMPANY PATENT RIGHTS and COMPANY KNOW-HOW in accordance with Article II, paragraph 11, ELAN shall pay to COMPANY:

(a) **[*]**% of net revenues achieved by ELAN in relation to the PRODUCT, "net revenues" meaning for this purpose **[*]**; and

(b) a royalty on NSP of the PRODUCT on sales by ELAN, its AFFILIATES or its permitted sub-licensees as follows:

(i) **[*]** percent (**[*]**%) on the first $**[*]** sales of PRODUCT, calculated as NSP value, in any one calendar year; and

(ii) **[*]** percent (**[*]**%) on sales of PRODUCT, calculated as NSP value, in excess of $**[*]** in any one calendar year.

Any such royalty payable by ELAN to COMPANY shall be calculated and paid mutatis mutandis as the terms of this Agreement."

4.8. by the deletion of Section 5 and the substitution therefor of the following paragraphs:

"5.1 The price of bulk capsules of the PRODUCT to be charged to COMPANY shall be as follows EX WORKS:

Dosage Strength	**Price per 1,000 capsules**
[*]	$**[*]**
[*]	$**[*]**

5.2 Payment for all such PRODUCT supplied to COMPANY shall be effected in U.S. Dollars ($) within thirty (30) days of the date of the relevant invoice.

5.3 COMPANY shall **[*]** manufactured by ELAN which **[*]** as laid out in its standard operating procedures then in force, at the following rates: **[*]**

5.4 ELAN shall provide COMPANY with a written statement of the amount of **[*]** following the end of each calendar quarter and a summary of the **[*]**, and COMPANY shall make a payment to ELAN in respect thereof not later than thirty (30) days of the end of the calendar quarter in question (or if later, fifteen (15) days from the date of such statement), subject to receipt of a proper invoice from ELAN in respect thereof.

5.5 The prices and **[*]** rates set forth in paragraphs 5.1 and 5.3 may each be increased not more than **[*]** by a percentage equal to **[*]** since the previous increase (or, as applicable, the Amendment No. 3 Date), by written notice from ELAN to COMPANY.

5.6 In the event that COMPANY places orders for delivery in any calendar year in excess of **[*]**mg equivalents (as referred to in Article IV Section 19), the price for all orders in excess of that number shall be reduced by **[*]**% (**[*]** per cent.)."

4.9. by the deletion of Article I Section 16 and Appendix D in their entirety.

5. <u>Amendments to Supply Terms</u>

ELAN and COMPANY hereby agree that Article IV of the Original Agreement is hereby amended with effect from the Amendment No. 3 Date as follows:

5.1. by the deletion from Article IV, Section 6 in its entirety and its replacement with the following:

"**6**. Within fifteen (15) days of NDA APPROVAL and at the beginning of each calendar month thereafter, COMPANY will provide a rolling month by month forecast for the **[*]** month period beginning on the first day of the calendar month following the calendar month in which the forecast is made and the **[*]** of such forecast shall be a binding purchase commitment of COMPANY. Additionally, prior to NDA APPROVAL and in August of each calendar year, COMPANY will provide a non-binding **[*]** forecast."

5.2 by the deletion of Article IV, Section 14 in its entirety and its replacement with the following:

"**14.** The Parties agree as follows:-

14.1 COMPANY shall be entitled to qualify an alternate facility as a second source of PRODUCT ("Second Source"). In the event COMPANY wishes to qualify a Second Source, it shall so notify

ELAN in writing at any time up to 30 (thirty) days after ELAN's notice to cease manufacturing under Section 18. If the operator of COMPANY's desired facility is not COMPANY or an affiliate of COMPANY, **[*]**. The operator of any such third party facility shall undertake to ELAN, in terms reasonably satisfactory to ELAN, to protect the confidentiality of ELAN's patents, manufacturing processes and/or any other industrial property rights (including the ELAN PATENT RIGHTS and ELAN KNOW-HOW). Thereafter, the parties shall negotiate in good faith a technology transfer program ("Program") consistent with this Agreement. Such program shall have due regard to the commercial interests of both parties in relation to the manufacture of PRODUCT and shall be such that the Program will be completed with due dispatch but without undue disruption to ELAN's other commercial activities, provided further that such program shall last not longer than **[*]** from its commencement.

14.2 At COMPANY's request, it shall be part of the Program that ELAN shall assist in qualifying the Second Source as an alternative site of manufacture of PRODUCT. Pursuant to this obligation ELAN shall:

14.2.1 Provide COMPANY with any technical data necessary to qualify the Second Source. To this end, ELAN shall impart to COMPANY the documentation constituting the required material support, more particularly practical performance advice, shop practice and specifications as to materials to be used and control methods;

14.2.2 Assist COMPANY with the working up and use of the technology and with the training of personnel which may reasonably be necessary in relation to the manufacture of PRODUCT by or on behalf of COMPANY.

14.3 In the event that personnel from COMPANY or from an approved third party manufacturer visit ELAN's premises, or personnel from ELAN, visit the premises of COMPANY or of an approved third part manufacturer, for the purpose of enabling COMPANY or such approved third party to manufacture PRODUCT, then:

(a) the party whose premises are visited shall take such steps to protect those personnel from physical injury in the course of the visit as it takes with its own personnel (but not less than the standard required by law); but;

(b) the visiting party shall ensure that those personnel are adequately trained in safety relating to pharmaceutical manufacturing generally, and that those personnel conduct themselves lawfully and in compliance with this Agreement.

14.4 COMPANY may acquire the following quantities of PRODUCT from the Second Source and accordingly, if so purchased, COMPANY shall have no obligation to purchase such quantities from ELAN and ELAN shall have no obligation to supply such quantities to COMPANY:

14.4.1 Such quantities of PRODUCT as are required to be produced in order to maintain any registration with the FDA or other relevant regulatory agency so as to permit PRODUCT to be manufactured at the Second Source;

14.4.2 Such further quantities of PRODUCT to make up any portion of a valid purchase order where, and for so long as the following conditions exist:

(i) ELAN fails to supply PRODUCT which has been ordered by COMPANY for a period exceeding **[*]** days from the receipt of a firm purchase order; or

(ii) There are delays in filling each of **[*]** successive orders which delays cumulatively exceed **[*]** when each delay is measured beginning on the **[*]** day from receipt of the corresponding firm purchase order; or

(iii) There is a shortfall in **[*]** successive orders delivered by ELAN which on a cumulative basis, exceeds **[*]** percent (**[*]**%) of the total amount of said **[*]** orders;

PROVIDED such failure, delay or shortfall is not caused by COMPANY or any other supplier of the Compound or other raw materials and PROVIDED FURTHER that ELAN, having received written notice from COMPANY, has not remedied the failure, delay or shortfall within a further period of **[*]** days from said notice.

14.5 In respect, of the establishment, qualification and operation of the Second Source, COMPANY shall be solely responsible for:

14.5.1 COMPANY's own costs and expenses;

14.5.2 All third party costs and expenses including reasonable out of pocket expenses incurred by ELAN; and

14.5.3 Work contracted by ELAN, its Affiliates and their employees and consultants under the Program in accordance with ELAN's **[*]**.

14.6 The provisions, of the Article IV, Section 14 **[*]**.

14.7 The parties acknowledge and confirm that to the extent that COMPANY is permitted hereunder to purchase PRODUCT from the Second Source, such right is by virtue of COMPANY's right under this Agreement to "have manufactured" PRODUCT. Nothing herein shall be deemed to permit COMPANY to sub-license the right to manufacture or have manufactured PRODUCT. "

5.3 By the deletion of Article IV Sections 18 and 19 and their replacement with the following:

"18. At any time during term of this Agreement, ELAN shall be entitled to notify COMPANY of its intention to cease manufacture of the PRODUCT, due to poor economic return on the PRODUCT. If it notifies COMPANY, ELAN's obligation to manufacture and supply PRODUCT shall terminate upon three (3) month's notice, provided that such termination shall not take effect until:

(i) the Second Source received the necessary governmental approvals to manufacture PRODUCT, and demonstrated its capability to manufacture the quantities of PRODUCT necessary to meet current forecasts in effect at that time, or

(ii) if earlier, three (3) years from the date of NDA APPROVAL in the United States, or

(iii) if earlier, five (5) years from the Amendment No. 3 Date.

In such an event, the parties confirm that the provisions of Article V, paragraph 3.6 shall apply to the sale of PRODUCT manufactured by COMPANY or a permitted third party manufacture.

"**19.** In the event that ELAN gives notice to terminate manufacture pursuant to Section 18, and such termination does not take effect before eighteen (18) months after the Amendment No. 3 Date, then:

19.1 As from eighteen (18) months after the Amendment No. 3 Date (or if later, three (3) months from the date of notice to terminate) until such termination becomes effective, COMPANY shall pay to ELAN a quarterly capacity fee ("CAPACITY FEE") equal to 60% of the applicable price of shortfall of PRODUCT ordered for delivery in that calendar quarter.

19.2 For this purpose, "shortfall" means the amount, if any, by which in the calendar quarter in question the quantities of PRODUCT properly ordered (with due lead time and in respect of which COMPOUND is duly delivered as required by this Agreement), expressed as 100mg equivalents is less than 4,973,898 (four million nine hundred and seventy three thousand eight hundred and ninety eight) ("MINIMUM CAPSULE EQUIVALENTS"); and one 100mg capsule is equal to one "100mg equivalent" and one 150mg capsule is equal to 1.5 (one and a half) "100mg equivalents".

19.3 The "applicable price" of such shortfall shall be the price of 100mg capsules as set out in Article V, Section 5.1, as adjusted.

19.4 In respect of the first and last calendar quarters in respect of which the CAPACITY FEE is payable, the MINIMUM CAPSULE EQUIVALENTS shall be reduced proportionately by reference to the period before or after the applicability of the CAPACITY FEE, as appropriate.

19.5 In respect of the final calendar quarter of each calendar year or the final calendar quarter in which the CAPACITY FEE is payable, the parties shall conduct a reconciliation such that the aggregate of CAPACITY FEES in that calendar year shall be the applicable price of the shortfall for the whole calendar year.

19.6 For the avoidance of doubt, ELAN shall not be obliged to give any credit or make any payment in respect of any excess of orders over the MINIMUM CAPSULE EQUIVALENTS, except as set out in paragraph 19.5, nor shall COMPANY be entitled to set any such excess in a given year against a shortfall in any subsequent year.

19.7 The CAPACITY FEE may be invoiced at the end of a calendar quarter and shall be payable within thirty (30) days."

5.4 By the deletion of Article IV, Section 20 in its entirety.

5.5 By replacing each occurrence in Article IV, Section 21 of the words "**[*]** days" with the words "**[*]** days", and the words "**[*]** days" with the words "**[*]** days".

6. Miscellaneous and Consequential Amendments

ELAN and COMPANY hereby agree that the Original Agreement is hereby further amended with effect from the Amendment No. 3 Date as follows:

6.1 By amending Article XII as follows:

6.1.1 by insertion in Article XII Section 5.2.1 after the word filing of a full stop and a new sentence: "Notwithstanding the bankruptcy of ELAN, or the impairment of performance by ELAN of its obligations under this Agreement as a result of bankruptcy or insolvency of ELAN, COMPANY shall be entitled to retain the licenses granted herein, subject to ELAN's rights to terminate this Agreement for reasons other than bankruptcy or insolvency as expressly provided for."

6.1.2 by deletion of Section 5.2.2; 5.2.3 and 5.2.4 of Article XII in their entirety.

6.1.3 by the insertion in Article XII Section 5.3 after the words "terminate this Agreement" of the words "in whole or with respect to one or more countries of the TERRITORY";

6.1.4 by the deletion from Article XII Section 5.3 of the third, fourth and fifth sentences, which is to say the passage beginning "In the event that COMPANY so elects to terminate …" through the end of that Section;

6.1.5 by the deletion in Article XII of Sections 5.5.5.; 5.5.6 and 5.5.7 and 5.6 in their entirety.

6.1.6 by the deletion of Article XII Section 13.1 and the substitution therefor of the following:

"13.1. Any notice to be given under this Agreement shall be sent in writing in English by registered airmail or fax to:

- ELAN at

Elan Corporation plc.
Treasury Building
Lower Grand Canal Street
Dublin 2
Ireland.

Attention: Vice President, Commercial Management
Fax: 353 1 709 4700

with a courtesy copy (receipt of which shall not constitute notice) to:

Elan Corporation plc.
Monksland
Athlone
County Westmeath
Ireland

Attention: Vice President & Legal Counsel, Elan Drug Technologies
Fax: +353 90 64 95350

COMPANY at

Solvay Pharmaceuticals, Inc.
901 Sawyer Road,
Marietta, Georgia 30062,
United States of America.

Attention: Senior Vice President, Law, Government & Public Affairs
Fax: +1 770 578 5749

or to such other address(es) and fax numbers as may from time to time be notified by either party to the other hereunder.

"13.2 Any notice sent by mail shall be deemed to have been delivered within seven (7) working days after despatch and any notice sent by fax shall be deemed to have been delivered within twenty four (24) hours of the time of the despatch. Notice of change of address shall be effective upon receipt."

6.2 Amending Article II:

6.2.1 By deleting from Article II Section 6.2.1 the words "once commercial sale of PRODUCT commences" and replacing them with the words "a reasonable time prior to the commencement of commercial sale in any given country of the TERRITORY"; and

6.2.2 By deleting from Article II, Section 12 the words “In consideration for the royalty which may be payable under Article V, paragraph 3.8.” and replacing them with the words “In consideration for the fees and royalty which may be payable under Article V, paragraph 3.7”.

6.3 By inserting the following new Article III, Sections 15 to 17:

“**15.** In the event that **[*]**, ELAN and COMPANY shall meet to discuss how to proceed, and any appropriate amendments to this Agreement, in good faith.

16. ELAN agrees to manufacture **[*]** commercial batches of each dosage strength of the PRODUCT for the purposes of process validation, and to conduct validation sampling and testing in respect thereof in accordance with the protocol to be agreed. In respect thereof, COMPANY shall pay to ELAN US$**[*]**, payable upon delivery. Subject to applicable law, COMPANY may use such process validation batches for commercial purposes, and for the avoidance of doubt if it does so, no further amount shall be payable under Article V, Section 5 (but without prejudice to any royalties). The parties shall additionally discuss in good faith stability requirements, and payment for work conducted by ELAN in respect thereof.

17. For the avoidance of doubt, **[*]** shall be **[*]** responsible for all costs associated with the proposed change in the manufacturer and manufacturing process for the COMPOUND in progress or to be progressed following the Amendment No. 3 Date, including any work conducted by ELAN on the basis set out in **[*]**.

18. As of the Amendment No. 3 Date, it is the parties’ expectation that the **[*]**mg dosage strength of the PRODUCT will not be developed or produced. In the event that FDA requests the development of the **[*]**mg dosage strength, the parties shall consult to agree an appropriate response to FDA in respect thereof. If, following such response, FDA still requires the development of the **[*]**mg dosage strength, the parties shall negotiate a development plan therefor in good faith. Such development shall be **[*]**.”

6.4 By deleting from Article IV, Section 25 the words “and keep such COMPOUND separate and apart from other raw materials”.

6.5 By deleting Article VI, Section 3 and replacing it with the following:

“**3.** Each party shall notify the other as soon as possible of any notification received by that party from the FDA, or any other regulatory authority to conduct an inspection of its manufacturing or other facilities used in the manufacturing, packaging, storage or handling of the COMPOUND or the PRODUCT.”

7. Other Provisions

Notwithstanding anything to the contrary in the Original Agreement and any Amendment thereof, subject to the allocation of responsibilities in Schedule A, COMPANY shall bear all cost and expenses of [*] required under the Original Agreement or any Amendment thereto.

8. No Other Amendment to Original Agreement

Except as modified herein, all of the covenants, terms and conditions of the Original Agreement remain in full force and effect and are hereby ratified and reaffirmed in all respects. In the event of any conflict, inconsistency or incongruity between the terms and conditions of this Amendment and the covenants, terms and conditions of the Original Agreement, the terms and conditions of this Amendment shall govern and control.

9. Counterparts

This Amendment may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Amendment.

10. Governing Law and Jurisdiction

This Amendment shall be governed by the laws of the State of Georgia. Any dispute arising in relation to it shall be resolved in the same manner as a dispute under the Original Agreement.

IN WITNESS WHEREOF the parties hereto have executed this Agreement

SIGNED

/s/ William F. Daniel

for and on behalf of
ELAN CORPORATION, PLC.

SIGNED

/s/ Laurence J. Downey, M.D.

for and on behalf of
SOLVAY PHARMACEUTICALS INC.

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Schedule A
Fluvoxamine CR Activities to NDA refiling /approval

I ELAN RESPONSIBILITIES

Preparation for Stability Batches including ordering, testing & release of raw materials, updating batch manufacturing records, relevant SOPs, protocols.

Manufacture, Test, Release batches of **[*]**mg & **[*]**mg with the proposed commercial manufacturing process. (Note: **[*]** batches of each strength to be manufactured. Solvay to bear costs of **[*]**)

Stability of bulk product: components and finished product for both **[*]**mg

Stability of Packaged Product in **[*]** of both **[*]**mg and **[*]**mg strengths. (Note: **[*]** to bear the costs of **[*]**)

[*] for Proposed Commercial manufacturing process, should the FDA insist on it

Update US DMF, including revisiting current NDA filing requirements, specifications justification, updating analytical protocols, stability reports, development report and MBRs

[*] prior to process validation

Process Validation for proposed commercial manufacture (at **[*]** expense as set out in Article III, Section 16 of the Agreement as amended)

Pre Approval Inspection preparation

Responses to FDA on CMC aspects of the filing

II SOLVAY RESPONSIBILITIES

Provide API for pre-validation / engineering, stability and validation batches

Carry out any **[*]** required under current NDA filing requirements e.g. **[*]**

[*]

Refiling the NDA

III EXCLUDED FROM ACTIVITIES TO REFILING / APPROVAL OF NDA

1. Qualification of an alternate source of API
2. Any additional activities requested by **[*]**

For the avoidance of doubt, **[*]** will bear all costs and expenses relating to activities at III, 1 to 2 above in the event they occur.

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EXHIBIT 10.50

XYREM®

Manufacturing Services and Supply Agreement

Between

Patheon Pharmaceuticals Inc.

and

Jazz Pharmaceuticals, Inc.

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MANUFACTURING SERVICES AND SUPPLY AGREEMENT

THIS MANUFACTURING SERVICES AND SUPPLY AGREEMENT (the "Agreement") made as of the 13th day of March, 2007, and with an Effective Date and a Manufacturing Commencement Date as set forth below.

B E T W E E N:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the
State of Delaware,

(hereinafter referred to as "**Patheon**"),

- and -

JAZZ PHARMACEUTICALS, INC.,
a corporation existing under the laws of the State of Delaware,

(hereinafter referred to as the "**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

INTERPRETATION

1.1 Definitions.

The following terms shall have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:

"**Act**" means the United States Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

"**Active Material**" means the active pharmaceutical ingredient listed on Schedule D hereto;

"**Active Material Reimbursement Value**" means the actual cost to Client of the Active Materials for the purposes of Section 10.2(b) of this Agreement as set forth in Schedule D hereto and as may be amended from time to time by the Client to reflect the actual cost of such Active Materials paid by the Client;

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement either directly or indirectly, by stock ownership or otherwise.

For the purposes of this definition, "control" means the ownership of shares carrying at least a majority of the votes in respect of the election of the directors of a corporation. Notwithstanding the foregoing, the owners of preferred stock (or common stock issued upon conversion thereof) of the Client such as financial institutions, venture capital funds and private equity investors will not be its “Affiliates” for purposes of this Agreement;

"**Annual Volume**" means the volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B hereto.

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

"**Batch**" means a specific quantity of Active Material and Components that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"**Bulk Product**" means unlabeled bottled and capped Product packaged in accordance with the applicable packaging configurations as set forth in the Specifications and Schedule M hereto which, prior to the Manufacturing Commencement Date, will be packaged in shippers by current supplier of Product and then delivered to Patheon for secondary packaging only;

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the State of Ohio which have been provided in writing to the Client by Patheon;

"**cGMPs**" means current good manufacturing practices, as applicable, as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) Division 2 of Part C of the Food and Drug Regulations (Canada);

(c) EC Directive 91/356/EEC; and

(d) the latest Health Canada, FDA and EMEA guidance documents pertaining to manufacturing and quality control practice, as updated, amended and revised from time to time and as applicable under the particular circumstances;

"**Components**" means, collectively, all packaging components, raw materials and ingredients, required to be used in order to produce the Product in accordance with the Specifications, other than the Active Material;

"**Deficiency Notice**" shall have the meaning ascribed thereto in Section 6.1(a);

"**DEA**" means the United States Drug Enforcement Administration or its international counterparts.

"Effective Date" means March 13, 2007 unless revised by mutual written agreement of the parties in accordance with this Agreement.

"**EMEA**" means the European Medicines Agency or any successor European governmental agency performing similar functions with respect to pharmaceutical products;

"**FDA**" means the United States government department known as the Food and Drug Administration or any successor United States governmental agency performing similar functions with respect to pharmaceutical products;

"**Firm Orders**" has the meaning specified in Section 5.1(b);

"**Fully Packaged Product**" means the Product packaged in accordance with the applicable packaging configurations as set forth in the Specifications and Schedule L hereto.

"**Health Canada**" means a section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and Health Products and Food Branch Inspectorate or any successor Canadian governmental agency performing similar functions with respect to pharmaceutical products;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, Inventions, copyright and industrial designs;

"**Invention**" means information relating to any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon in connection with the manufacture of the Product but, for greater certainty, does not include the Active Material;

"**Laws**" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority applicable to the activities hereunder;

"**Manufacturing Commencement Date"** means a date certain, specified in a written notice from Client to Patheon delivered at least sixty (60) days prior to such date, when Patheon will commence Manufacturing Services to manufacture and package Product hereunder.

"Manufacturing Services" means (i) during the period commencing on the Effective Date and ending on the day immediately preceding the Manufacturing Commencement Date, the Packaging Services only; and (ii) during the period commencing on the Manufacturing Commencement Date and throughout the term of this Agreement, all of the manufacturing, quality control, quality assurance and stability testing, packaging and related services, as contemplated in this Agreement, required to produce Product from the Active Material and Components;

"**Manufacturing Site**" means the US facility owned and operated by Patheon that is located at **[*]**;

"**Minimum Run Quantity**" means the minimum number and size of Batches of Product to be produced during the same cycle of manufacturing as set forth in Schedule B hereto;

"**NDA**" means a New Drug Application for the Product made in accordance with applicable regulations and requirements of the FDA as from time to time in effect;

"**Packaging Services**" means the packaging and related services performed or to be performed by Patheon hereunder to accept Bulk Product and package it into Fully Packaged Product after the Effective Date and prior to the Manufacturing Commencement Date.

"**Patheon Manufacturing Responsibilities**" means Patheon's responsibilities and obligations with respect to the provision of Manufacturing Services as set forth in Sections 2.1 and 2.2;

"**Product**" means the product listed on Schedule A hereto;

"**Quality Agreement**" means the agreement entered into between the parties hereto setting out the quality assurance standards to be applicable to the Manufacturing Services provided by Patheon, which agreement shall be in the form attached hereto as Schedule E;

"**Quota**" means the procurement quota quantity of Active Material allotted by the DEA to Patheon in order for Patheon to perform the Manufacturing Services.

“Regulatory Filings” means the NDA and any other filing under the United States Federal Food, Drug and Cosmetic Act and rules and regulations thereunder, and any corresponding filing required in other countries and jurisdictions (including, without limitation, the EMEA), in connection with the registration, manufacturing, sale and use of the Product, other than local or federal permits required to be obtained by Patheon in connection with performance of the Manufacturing Services.

"**Specifications**" means the file, for the Product, which is provided by the Client to Patheon in accordance with the procedures listed in Schedule A hereto and which contains documents relating to such Product, including, without limitation:

(a) specifications for the Active Material and Components;

(b) manufacturing specifications, vendors, directions and processes;

(c) storage requirements;

(d) environmental, health and safety information relating to the Product including material safety data sheets; and,

(e) the finished Product specifications, applicable packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by the Client in accordance with the terms of this Agreement;

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Territory**" means the entire world;

"**United States**" means the United States of America, its territories and possessions, including Puerto Rico and the U.S Virgin Islands; and

"**Year**" means in the first year of this Agreement, the period from the Commencement Date up to and including December 31 of the same calendar year, and thereafter shall mean a calendar year.

1.2 Currency.

Unless otherwise specifically provided herein, all monetary amounts are expressed in this Agreement in the lawful currency of the United States of America.

1.3 Sections and Headings.

The division of this Agreement into Articles, sections, subsections and Schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise specifically provided herein, any reference in this Agreement to a Section or Schedule refers to the specified Section or Schedule to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement and not to any particular part, Section, Schedule or the provision hereof.

1.4 Singular Terms.

Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa.

1.5 Schedules.

The following Schedules are attached to, incorporated in and form part of this Agreement:

Schedule A		Product Specifications
Schedule B	-	Minimum Run Quantity, Annual Volume, Fees & Price Adjustments
Schedule C	-	Stability Testing
Schedule D	-	Active Material & Active Material Reimbursement Value
Schedule E	-	Batch Numbering & Expiration Dates
Schedule F	-	Technical Dispute Resolution
Schedule G	-	Quality Agreement
Schedule H	-	Quarterly Active Materials Inventory Report
Schedule I	-	Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Schedule J	-	Form of Exclusive Components Purchasing Summary
Schedule K	-	Bill-Back Items
Schedule L	-	Packaging Configurations for Full Packaged Product
Schedule M		Packaging Configurations for Bulk Package Product

ARTICLE 2

MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon shall provide the Manufacturing Services for the fees specified in Schedules B and C. Patheon may change the Manufacturing Site for the Product only with the prior written consent of Client. None of the Manufacturing Services may be subcontracted by Patheon without the Client's prior written consent.

Client shall specify the Manufacturing Commencement Date by **[*]** days' written notice to Patheon. For clarity, the parties acknowledge that the Manufacturing Commencement Date is conditioned upon (i) the approval of Patheon as a manufacturer of the Product, including approval of Patheon's facility by the FDA and any other applicable regulatory Authority, (ii) receipt of appropriate Quota and (iii) **[*]** of Client's **[*]**,

During the period from the Effective Date through the day immediately preceding the Manufacturing Commencement Date, Patheon shall perform Packaging Services for Bulk Product on a non-exclusive basis in accordance with the description of services below as applicable to Packaging Services.

From and after the Manufacturing Commencement Date, Patheon shall perform the Manufacturing Services set forth below. The Client shall purchase (A) its entire requirements of **[*]** and **[*]** for distribution in **[*]**; provided, however, that the Client may establish other third party suppliers as additional manufacturers of the Product for **[*]**, and may purchase Product from such manufacturers, if **[*]** pursuant to the terms and conditions of this Agreement and (B) **[*]** for distribution in **[*]**, in each case, from Patheon pursuant to the terms of this Agreement. In providing the Manufacturing Services, Patheon shall perform the following services:

(a) Conversion of Active Materials and Components. Patheon shall convert Active Material and Components into Product.

(b) Quality Control and Quality Assurance of Product manufactured by Patheon. Patheon shall perform the quality control and quality assurance testing specified in the Quality Agreement. Each time Patheon ships Product to the Client, it shall provide the Client with a certificate of analysis that sets out the test results for each Batch of Product, and that certifies that such Batch has been evaluated by Patheon's Quality Control/Quality Assurance department and that the Product complies with the Specifications and was manufactured in accordance with cGMPs. Patheon shall test or cause to be tested each Batch of Product to be supplied pursuant to this Agreement, in accordance with the testing

methods for the Product set forth in the Specifications, before delivery of such Batch to the Client. Notwithstanding the foregoing, the Client reserves the right to test or have tested all Product supplied by Patheon and pursuant to Section 6.1 hereof to reject any Product that fails to comply with the Specifications or Product that is not made in accordance with cGMPs.

(c) Testing of Components and Active Material.

(i) Components. Patheon shall purchase and test all Components at Patheon's expense and as specified by the Specifications. The Client will have the right to specify the suppliers for the Components. Patheon shall not change any Specifications or supplier of such Components without the prior written consent of the Client.

(ii) Active Material. Promptly following receipt of the Active Material to be supplied by Client, Patheon will test (pursuant to test methods and drug specifications to be provided by the Client) and approve such Active Material as acceptable for performing Manufacturing Services under this Agreement. Patheon will notify the Client in writing within **[*]** days of receipt of any failure of Active Material unless earlier notice is required by Law; absent any such notice Active Material will be deemed to be accepted and approved by Patheon.

(d) Stability Testing. Patheon shall conduct stability testing on the Product in accordance with agreed upon protocols and Specifications in Schedule C. Patheon shall not make any changes to these Specifications or testing protocols without prior written approval from the Client. Patheon will promptly provide any and all data and results relating to the stability testing upon request by the Client. In the event that any Batch of the Product fails, or is suspected to fail, stability testing, Patheon will notify the Client within one Business Day and Patheon and the Client shall jointly determine the proceedings and methods to be undertaken to investigate the causes of such failure.

(e) Packaging. During the period between the Effective Date and the Manufacturing Commencement Date, Patheon shall convert Bulk Product into Fully Packaged Product for the Client in accordance with the applicable Specifications from time to time as requested by Client. From and after the Manufacturing Commencement Date, Patheon shall package Bulk Product and Fully Packaged Product, as specified by Client in its purchase orders, each in accordance with the applicable Specifications. In addition, Patheon shall assign Batch numbers and expiration dates for all Product shipped, if applicable. Such Batch numbers and expiration dates shall be affixed on the Product and on the shipping cartons, as applicable, of each Product as outlined in the Specifications and as required by cGMPs. The system used by Patheon for Batch numbering and expiration dates of Product manufactured by Patheon is detailed in the Quality Agreement attached hereto as Schedule G. The Client may, in its sole discretion, make changes to labels, product inserts and other

packaging for the Product. Patheon's name shall not appear on the label or anywhere else on the Product unless: (i) required by any Laws; or (ii) **[*]** expressly consents to such use of its name in writing.

(f) Active Materials and Client Supplied Components Importing. The Client will deliver all Active Materials and Components which Client is responsible for supplying (if any) to Patheon [*] (INCOTERMS 2000).

(g) Bill-Back Items. The expenses in respect of all third party supplier fees for the purchase of columns, standards, tooling, and other project specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components, shall be set forth on Schedule K hereto, as may be amended from time to time by the written consent of both parties, and charged to the Client at **[*]**.

2.2 Standard of Performance.

Patheon shall provide the Manufacturing Services in accordance with the Specifications, all applicable Laws and cGMPs.

2.3 Active Material Reports and Quota.

(a) Reporting. Patheon shall provide the Client with a quarterly inventory report of the Active Materials held by Patheon in accordance with the inventory report form annexed hereto as Schedule H, which shall contain the following information for such quarter:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications and is held at the beginning of the applicable period, less the inventory of Active Materials that complies with the Specifications and is held at the end of such period. The Quantity Dispensed shall only include Active Materials received and dispensed in connection with commercial manufacturing of Product and, for certainty, shall not include any Active Materials received or dispensed in connection with technical transfer activities or development activities during the applicable period, including, without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

Quantity Converted: The total amount of Active Materials contained in the Product produced with the **[*]** (including any **[*]** in accordance with **[*]**), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 as a result of a failure by Patheon to provide Manufacturing Services in accordance with Specifications, cGMPs and all applicable Laws.

(b) Quota. The parties acknowledge that the Active Material is scheduled under the Federal Controlled Substances Act. Patheon is required to obtain a Quota from the DEA before producing Product. In that regard, throughout the term hereof, Patheon will submit to DEA in a timely manner all necessary documents to obtain a Quota sufficient to meet Client's forecasts made pursuant to Section 5.1(a). Additional request(s) will be submitted by Patheon to DEA in a timely manner as necessary to reflect changes in Client's forecast requirements of Active Material and Product. Patheon further agrees to **[*]** obtain a Quota from the DEA that allows Patheon to manufacture all of Client's forecasted requirements for Product including cooperating with the Client in connection with any discussions with the DEA regarding a Quota. PATHEON ACKNOWLEDGES THAT TIME IS OF THE ESSENCE IN PERFORMING ITS OBLIGATIONS UNDER THIS PROVISION.

(c) Unused Active Material; Reports. Patheon will use **[*]** to avoid any loss of Active Material. If and to the extent that Active Material is spilled, lost, scrapped or otherwise unusable hereunder, Patheon will dispose of such Active Material in accordance with applicable regulations and will prepare all necessary disposal reporting documents and furnish such to DEA in accordance with applicable regulations and take such steps as are necessary to reclaim such lost amounts of Active Material for the Quota in the same Quota year any such loss occurs. In the event of any diversion of Active Material, Patheon will prepare all required diversion reports and will, contemporaneously with the filing thereof with DEA in accordance with applicable regulations, provide a copy to Client.

(d) Registrations. Patheon will acquire and maintain current DEA registrations required to manufacture, hold, import and export Product

(e) Volumes Constrained by Quota. Notwithstanding any other provision of this Agreement, in the event of any inconsistency or conflict between this Agreement and any terms or provisions hereof relating to quantity of Product to be ordered, manufactured, purchased or sold under this Agreement, applicable law and regulations relating to Quota shall control.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Pursuant to the terms of this Agreement, the Client shall pay Patheon for the provision of the Manufacturing Services according to the fees specified in Schedules B and C hereto (such fees being subject to adjustment in accordance with the terms hereof).

3.2 Active Materials.

The Client shall **[*]**, deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) in sufficient quantities and at such times to facilitate the provision of the Manufacturing Services by Patheon. The Active Materials shall be **[*]** by Patheon **[*]** on the terms and subject to the conditions herein contained. **[*]** shall pay **[*]** $**[*]** per **[*]** (each **[*]** to hold **[*]**), per **[*]** for **[*]** Active Materials in **[*]** plus a **[*]**. The parties acknowledge and agree that title to the Active Materials shall **[*]** the property of **[*]**. Any Active Materials received by it shall only be used by Patheon to provide the Manufacturing Services. Patheon's liability with respect to any lost or damaged Active Materials shall be as set forth in Section 10.2(b).

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 Pricing.

The fees for the Manufacturing Services (which fees include **[*]**) shall be as set forth in Schedules B and C and are subject to the adjustments set forth therein and in Section 4.2 hereof. Subsequent Year’s pricing, and adjustments to pricing, are set forth in Schedule B hereof.

4.2 Adjustments Due to Technical Changes.

For changes to the Specifications or manufacturing processes that are required by applicable Laws ("**Required Manufacturing Changes**"), Patheon and the Client shall cooperate in making such changes and use commercially reasonable efforts to implement such changes promptly in a manner that minimizes any effect on the supply hereunder to the Client of Product meeting Specifications. All costs associated with Required Manufacturing Changes directly related to the **[*]** shall be borne by **[*]**. All other costs associated with Required Manufacturing Changes under this Agreement, including, without limitation, obsolete Components, Regulatory Filings, work in process, equipment and Product shall be borne by **[*]**. Amendments to the Specifications or the Quality Agreement requested by the Client that are not Required Manufacturing Changes ("**Client Requested Changes**") will only be implemented following **[*]** necessitated by any such amendment. Amendments to the Specifications, the Quality Agreement or the Manufacturing Site requested by Patheon that are not Required Manufacturing Changes ("**Patheon Requested Changes**") will only be implemented following the approval of Client, **[*]**, and the costs of the Patheon Requested Changes will be borne by **[*]**. If the Client accepts a proposed fee change, the proposed change in the Specifications shall be implemented, and the fee change shall become effective only with respect to those orders of the Product that are manufactured in accordance with the revised Specifications. In addition, with respect to the **[*]** Requested Changes, the **[*]** agrees to purchase, at **[*]** (including all costs incurred by **[*]** in connection with the purchase and handling of such **[*]**), all **[*]** utilized under the **[*]** Specifications and purchased or maintained by Patheon in order to fill Firm Orders or in accordance with Section 5.2, to the extent that such **[*]** can **[*]** under the revised Specifications. Open purchase orders for

Components no longer required under any revised Specifications that were placed by Patheon in accordance with this Agreement with suppliers in order to fill Firm Orders or in accordance with Section 5.2 shall be cancelled where possible, and where such orders are not subject to cancellation without penalty, shall be **[*]**.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling Forecasts. The Client shall provide Patheon with a written non-binding **[*]** forecast of the volume of each Product that the Client then anticipates will be required to be produced and delivered to the Client during each **[*]** of that **[*]** period. Such forecast will be updated by the Client **[*]** on or before the **[*]** day of each **[*]** on a rolling **[*]** basis. The most recent **[*]** forecast shall prevail.

(b) Firm Orders. On or before the **[*]** day of each **[*]** the Client shall issue firm written orders ("**Firm Orders**") for the Product from time to time at Client's discretion to be produced and delivered to the Client on a date not less than **[*]** from the **[*]** the date that the Firm Order is submitted. Such Firm Orders submitted to Patheon shall specify the Client's purchase order number, quantities by Product, type of packaging, delivery schedule and any other elements necessary to ensure the timely production and shipment of the Product. The quantities of Product ordered in such written orders shall be firm and binding on the Client. Notwithstanding the foregoing, and subject to the availability of required Components, Patheon will permit amendments and substitutions to Firm Orders issued by the Client upon prior written notice to Patheon in respect of Product packaging; provided, however no amendments or substitutions will be accepted by Patheon once **[*]**, as the case may be, has commenced.

(c) Acceptance. Firm Orders placed with Patheon by the Client pursuant to the provisions of Section 5.1(b) shall be acknowledged by Patheon in writing within **[*]** days of receipt thereof. Patheon will **[*]** ensure that all Product ordered by the Client in accordance with this Agreement will be shipped in accordance with the delivery dates specified in the Client's purchase order but in no event shall the **[*]** delivery date be **[*]** from the **[*]**, and Patheon will notify the Client promptly of any significant anticipated delay no later than **[*]** prior to such delivery date.

5.2 Reliance by Patheon.

The Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted pursuant to Sections 5.1(a) and (b) in ordering the Components required to meet such Firm Orders. In addition, the Client understands that to ensure an orderly supply of such Components, it may be desirable for Patheon to purchase such Components in sufficient volumes to meet the production requirements for Product during **[*]** of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed in writing to by Patheon and the

Client. Accordingly, the Client authorizes Patheon to purchase Components in order to satisfy the production requirements for Product for the first [*] contemplated in the most recent forecast provided by the Client pursuant to Section 5.1(a) and agrees that Patheon may make such other purchases of Components to meet production requirements during such longer periods as may be agreed to in writing from time to time by the Client at the request of Patheon or the Client. If Components ordered by Patheon pursuant to Firm Orders under this Section 5.2 are not included in finished Product purchased by the Client within [*] after the date of the Firm Order in respect of which such purchases have been made (or such longer period as the parties may agree) or if such Components have expired during such period, then [*]; provided, however, that in the event such Components are incorporated into Product subsequently purchased by the Client or into third party products manufactured by Patheon and subsequently purchased by a third party, the [*] of such Components [*].

Patheon shall provide Client, initially upon execution of this Agreement and thereafter on an annual basis, with a listing of all Components which Patheon anticipates purchasing pursuant to the terms of this Agreement in the form set out in Schedule J (the "**Components Purchasing Summary**"). Patheon will advise the Client in writing which Components have a limited shelf-life and which are subject to minimum order quantities specified by the supplier. **[*]** for the **[*]** Components **[*]** purchased by Patheon in accordance with the terms of this Agreement but not used to perform the Manufacturing Services prior to the expiry of the Component's shelf life, so long as such Components have expiration dating of at least **[*]** from the date of purchase by Patheon. If Patheon is able to use such Components in activities other than the Manufacturing Services, Patheon will **[*]** the Client any **[*]** for such Components.

5.3 Minimum Orders.

The Client may only order Product in multiples of the Minimum Run Quantities set out in Schedule B.

5.4 Shipments.

Shipments of Product shall be made **[*]** (as such term is defined in INCOTERMS 2000) Patheon's shipping point unless otherwise mutually agreed to in writing by the parties. Risk of loss or of damage to Product shall remain with Patheon until **[*]** at which time risk of loss or damage shall transfer to the Client. Patheon shall, in accordance with the Client's instructions and as agent for the Client, (i) arrange for shipping to be paid by the Client and (ii) at the Client's risk and expense, obtain any export licence or other official authorization necessary to export the Product from the US. The Client shall arrange for insurance and shall select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Product shall be transported in accordance with the Specifications and other applicable Laws.

5.5 Invoices and Payment.

Invoices shall be sent by fax or e-mail to such fax number or e-mail address as may be provided by the Client in writing from time to time but no earlier than **[*]**; provided, however, that if Client requests Patheon to hold or store Bulk Product or Fully Packaged Product for more than **[*]** after completion of the applicable Manufacturing Services, Patheon may invoice Client for any such Product **[*]**. Patheon shall also submit to the Client, with each shipment of Product, a duplicate copy of the invoice covering such shipment. Patheon shall also provide the Client with an invoice covering **[*]** pursuant to the terms and conditions of this Agreement and, in accordance with Section **[*]**. Each such invoice shall, to the extent applicable, identify the Client purchase order number, Product numbers, names and quantities, unit price, freight charges and the total amount to be remitted by the Client. The Client shall pay all such invoices within thirty (30) days of the date thereof. Notwithstanding the foregoing, the Client may withhold any amounts invoiced by Patheon that it disputes. If the Client disputes any invoice, the Client shall within **[*]** after such invoice is furnished to it notify Patheon that it disputes the accuracy or appropriateness of such invoice and specify the particular respects in which such invoice is inaccurate or inappropriate. The Client and Patheon will make good faith efforts to resolve any disputes within **[*]** thereafter. Any amounts that are disputed by the Client shall not be due until **[*]** following the resolution of such dispute.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. The Client has the right to reject any portion of any shipment of Product that deviates from the Specifications or cGMPs, without invalidating any remainder of such shipment. The Client or its designee shall inspect the Product manufactured by Patheon upon receipt thereof and shall use its commercially reasonable efforts to give Patheon written notice (a "**Deficiency Notice**") of all claims for Product that deviate from the Specifications or cGMPs within **[*]** after the Client's or its designee's receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within **[*]** after discovery thereof by the Client, but in no event after the expiration date of the Product). Should the Client fail to provide Patheon with the Deficiency Notice within the applicable period described above, then the delivery shall be deemed to have been accepted by the Client on the day after the end of the period described above.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon shall have **[*]** to advise the Client by notice in writing that it disagrees with the contents of such Deficiency Notice. If the Client and Patheon fail to agree within **[*]** after Patheon's notice to the Client as to whether any Product identified in the Deficiency Notice deviates from the Specifications or cGMPs, then the parties shall mutually select a laboratory to evaluate if the Product deviates from the Specifications or cGMPs. Such evaluation shall be binding on the parties, and if such evaluation certifies that any Product deviates

from the Specifications or cGMPs, the Client may reject such Product in the manner contemplated in this Section 6.1. If such evaluation does not so certify in respect of any such Product, then the Client shall be deemed to have accepted delivery of such Product on the **[*]** day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the **[*]** day after discovery thereof by the Client, but in no event after the expiration date of the Product).

(c) Patheon Responsibility. In the event the Client rejects Product in accordance with this Section 6.1, and the deviation is determined to arise from Patheon's failure to provide the Manufacturing Services in accordance with Specifications or cGMPs, Patheon will credit the Client's account for Patheon's invoice price to the Client for such defective Product. If the Client shall have previously paid for such defective Product, Patheon shall promptly, at the Client's election, either: (i) refund the invoice price for such defective Product; (ii) offset such amount against other amounts due to Patheon hereunder; or (iii) replace such Product with conforming Product without the Client being liable for payment therefor under Section 3.1, contingent upon the receipt from the Client of all Active Material required for the manufacture of such replacement Product. Subject to the conditions and limitations set out in Section 10.2, Patheon shall be responsible for paying for any Active Material used for the rejected Product under this Section 6.1(c).

(d) Shortages. In the event of a shortage of Product in any shipment by Patheon, at the Client's election, Patheon shall **[*]** to make up the shortage **[*]**; provided, however, that if the shortage is more than **[*]**% of the quantity ordered **[*]**, Patheon will **[*]** to make up the shortage **[*]** after the shortage is reported to Patheon, but no later than **[*]** thereafter, if so requested by the Client, on the following terms: (i) Patheon will manufacture Product in increments of any Minimum Run Quantity listed on Schedule B as determined by the Client and (ii) the **[*]** such Product will equal the **[*]** set forth on **[*]** without regard to **[*]**.

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and the Client shall each maintain such records as may be necessary to permit a Recall of any Product delivered to the Client or customers of the Client. Each party shall promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Product and/or which might result in the Recall or seizure of the Product. Upon receiving any such notice or upon any such discovery, each party shall cease and desist from further shipments of such Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, shall be made and implemented by the Client. For purposes of this Agreement, "**Recall**" shall mean any action (i) by the Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); or (ii) by any regulatory authorities to detain or destroy any of the Product. Recall shall also include any action by either party to refrain from selling or shipping quantities of the Product to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. In the event (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert with respect to a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders such a Recall, or (iii) the Client determines that any Product should be Recalled or that a "dear doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by the Client, having regard to all applicable Laws.

(c) Product Returns. The Client shall have the responsibility for coordinating customer returns of the Product. Patheon shall provide the Client with such assistance as the Client may reasonably require to coordinate Product returns.

(d) Patheon's Responsibility. To the extent that a Recall or return results from, or arises out of, a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications and cGMPs, Patheon shall be responsible for the documented out-of-pocket expenses of such Recall or return and shall **[*]** to replace the Recalled or returned Product with new Product, contingent upon the receipt of all Active Materials required for the manufacture of such replacement Product. In the event that Patheon is unable to replace the Recalled or returned Product (except where such inability results from a failure to receive the required Active Materials due to the fault of Client), then at Client's request, Patheon will reimburse the Client for the price that the Client paid to Patheon for manufacturing the affected Product. In either case, subject to the conditions and limitations set out in Section 10.2, Patheon shall pay all costs related to the Active Materials required for the manufacture of replacement Product. In all other circumstances, Recalls, returns or other corrective actions shall be made at the Client's cost and expense.

(e) Patheon will be responsible for investigating all Recalls and returns (other than as a result of the expiration of such Product) resulting from Patheon's failure to manufacture the Product in accordance with the Specifications and cGMPs, at its own expense, and Patheon will promptly report to the Client in writing the results of any such investigation.

6.3 Disposition of Defective or Recalled Product.

The Client shall not dispose of any damaged, defective, returned or Recalled Product in relation to which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so. Alternatively, Patheon may instruct the Client to return such Product to Patheon at Patheon's expense, provided that Client will reimburse Patheon for the cost of such shipping if it is determined that Patheon does not bear any liability for such damaged, defective, returned or Recalled Product. Patheon shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Product in relation to which it bears responsibility under Section 6.1 or 6.2 hereof. In all other circumstances, the Client shall bear the cost of disposition with respect to any damaged, defective, returned or Recalled Product.

6.4 Customer Questions and Complaints.

The Client shall have the sole responsibility for responding to questions and complaints from the Client's customers. Questions or complaints received by Patheon from the Client's customers shall be promptly referred to the Client. Patheon shall co-operate as reasonably required to allow the Client to determine the cause of and resolve any customer questions and complaints. Such assistance shall include follow-up investigations, including testing. In addition, within ten (10) days from the date of request, Patheon shall provide the Client with all necessary information in Patheon's possession or control that will enable the Client to respond properly to questions or complaints relating to the Product. If it is determined that the cause of any customer complaint resulted from a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications and cGMPs and any additional procedures agreed upon in writing by Patheon and the Client, or a breach of this Agreement by Patheon, all costs incurred in respect of this Section 6.4 shall be borne by Patheon. In all other circumstances, the Client shall bear the cost incurred with respect to this Section 6.4.

6.5 Sole Remedy.

Except for the indemnity provided in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 shall be the Client's sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, Applicable Laws or any additional procedures agreed upon in writing by the Client and Patheon.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each party shall forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers shall meet not less than quarterly to review the current status of the business relationship, including, but not limited to, equipment and facilities updates, current and anticipated manufacturing capacity, planned work or changes to the Manufacturing Site where the Product is being produced and anticipated shut downs of such site, and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to Section 7.7 and the Confidentiality Agreement (as defined in Section 11.1), Patheon may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Product, regarding the manufacture by Patheon of the Product if in the opinion of Patheon's counsel, such communication is necessary to

comply with the terms of this Agreement or the requirements of any law, governmental order or regulation; provided, however, that unless in the reasonable opinion of Patheon's counsel there is a legal prohibition against doing so, Patheon shall permit the Client to accompany and take part in Patheon's communications with the agency, and to receive copies of all such communications from such agency to Patheon.

7.3 Records and Accounting by Patheon.

Patheon shall keep records of the manufacture, testing and shipping of the Product, and retain samples of such Product as are necessary to comply with the Specifications and all manufacturing regulatory requirements and Laws applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of such records and samples shall be retained for a period of **[*]** following the date of Product expiry, or longer if required by Law, after which Patheon may destroy such records or samples; provided, however, Patheon shall notify the Client in writing at least thirty (30) days prior to such destruction and shall retain or deliver such records or samples to the Client, at the Client's option and expense, if the Client so requests.

7.4 Inspection; Audit.

The Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, provided a Patheon representative is present during any such inspection. Furthermore, the Client shall have the right, if Client reasonably deems it necessary, to request additional documentation from Patheon to verify Patheon's calculation of **[*]** and Patheon will use its reasonable commercial efforts to provide such documentation.

7.5 Access.

Patheon shall provide the Client with reasonable access at mutually agreeable times to its Manufacturing Site in which the Product is manufactured, stored, handled or shipped in order to permit the Client's verification of Patheon's compliance with the Patheon Manufacturing Responsibilities and with all applicable Laws. Patheon agrees to permit the Client to review Patheon's standard operating procedures for the manufacture of the Product and those associated with the general facilities, equipment, or procedures required for compliance with cGMPs or DEA requirements. For greater certainty, the right of access provided in this Section 7.5 shall not include a right to access or inspect Patheon's financial records. Patheon shall **[*]** obtain the right for the Client to have similar inspection rights with respect to all third party suppliers used by Patheon to provide the Components. If deficiencies are found by the Client during the course of such inspections, the parties will promptly meet to discuss and resolve them, and the Client will be entitled to make reasonable follow up inspections to monitor correction of the deficiencies. Patheon shall notify the Client of any inspections by, or communications with, any governmental agency involving the Product. Patheon shall furnish to the Client all material information supplied to, or supplied by, such regulatory Authority or third party supplier to the extent that such report relates to Product, or the ability of Patheon to supply such Product, within three (3) Business Days of their receipt of such information or delivery of such information, as the case may be. Patheon will promptly correct any deficiencies noted by governmental agencies in any such inspections.

7.6 Reports.

Patheon will supply on **[*]** basis all Product data, including release test results, complaint test results, all investigations (in manufacturing, testing and storage), and the like, that the Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any annual product report that the Client is required to file with the FDA. Patheon will supply the Client, no later than five (5) days following the last day of the preceding month, with a written summary report of the Active Material inventory for such prior month, in such detail requested and satisfactory to the Client, in order that the Client may properly account for the Active Material held by Patheon pursuant to this Agreement. At the Client's request and subject to an additional fee to be agreed by the parties, Patheon will prepare on behalf of the Client additional specialized **[*]** product reports in accordance with the Client's instructions. At the Client's request and expense, Patheon will provide the data described in this Section 7.6 on a **[*]** basis.

7.7 Regulatory Filings.

(a) Regulatory Filings. The Client shall have the sole responsibility for filing all documents with the FDA and other regulatory Authorities and taking any other actions that may be required of Client to obtain Regulatory Approval for the commercial manufacture of the Product (except as provided in the last sentence of this clause 7.7(a)). Patheon shall use commercially reasonable efforts to assist the Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain FDA and other regulatory approval for the commercial manufacture of the Product by Patheon as quickly as reasonably possible. Copies of all relevant Chemistry and Manufacturing Controls ("**CMC**") submissions and any related FDA correspondence are to be provided to Patheon by the Client. Patheon shall have the sole responsibility to obtain and maintain any required local, federal or other permits or approvals (other than the NDA or foreign equivalents) to allow Patheon to perform Manufacturing Services hereunder.

(b) [*] Data. **[*]** filing any CMC-related documents with the FDA or other regulatory Authority that incorporate data generated by Patheon, **[*]** incorporating such data so as to **[*]** of such documents **[*]** data.

(c) [*] CMC. At least **[*]** filing with the FDA the CMC section of a NDA covering manufacture of the Product by Patheon, the Client **[*]** supporting documents which have been relied upon to prepare the CMC portion so as to **[*]** the CMC portion accurately describes the work **[*]** pursuant to this Agreement.

(d) Pre-Approval Inspection. Subject to subsection (e) below, if **[*]** under paragraph (c) above within the time stipulated in these paragraphs and if **[*]** reasonably believes that **[*]** with the FDA may be jeopardized, **[*]** may, in its reasonable, good faith discretion, **[*]** provided that such **[*]** within **[*]** of **[*]**.

(e) Deficiencies. If in **[*]** good faith discretion, acting reasonably, **[*]** determines that any of the information **[*]** in accordance with **[*]** is **[*]** in any material manner (the "**[*]**"), **[*]** within **[*]** of receipt of such information from **[*]**. Failure to notify the Client within the applicable period set forth above will constitute **[*]** acceptance of the **[*]** in accordance with **[*]**. Until such **[*]** or agreement has been reached with the **[*]**, **[*]** reserves the right **[*]**. In such event, **[*]** shall not be construed as a breach of any of its obligations under this Agreement. Any such **[*]** that is delayed shall be rescheduled as soon as reasonably practicable.

(f) Client Responsibility. For clarity, the parties agree that in **[*]** the documents referred to in **[*]** above, Patheon's role will be limited to **[*]** of the description of the **[*]**. As such, Patheon shall not assume any responsibility for the accuracy of a Regulatory Filing except as to **[*]**. Subject to Patheon's obligation to cooperate with the Client pursuant to the terms and conditions of this Agreement, the responsibility of the preparation and filing of a Regulatory Filing shall be borne by the Client.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement shall become effective as of the date hereof and shall continue until five (5) years following the Manufacturing Commencement Date (the "**Initial Term**"), unless terminated earlier by one of the parties in accordance with Article 8 of this Agreement; provided further that the Client shall have the option, in its sole discretion, to extend the Initial Term of this Agreement for successive terms of two years each by providing Patheon with written notice of such election not less than twelve (12) months prior to the expiration of the then current term.

8.2 Termination for Cause.

(a) Either party at its sole option may terminate this Agreement upon written notice in circumstances where the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under this Agreement within sixty (60) days following receipt of a written notice (the "**Remediation Period**") of said breach that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved party's right to terminate this Agreement pursuant to this Section 8.2(a) may only be exercised for a period of sixty (60) days following the expiry of the Remediation Period (in circumstances where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party shall be deemed to have waived the breach of the representation, warranty or obligation described in the Breach Notice.

(b) Either party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other party in the event that: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party; or (iii) this Agreement is assigned by such other party for the benefit of creditors.

(c) The Client may terminate this Agreement upon thirty (30) days' prior written notice in the event that any governmental agency takes any action, or raises any objection, that prevents the Client from importing, exporting, purchasing or selling the Product.

(d) Patheon may terminate this Agreement at any time on or after January 31, 2009 on sixty (60) days' prior written notice if the Client has not delivered written notice specifying a Manufacturing Commencement Date as of the date of such notice.

(e) Patheon may terminate this Agreement on 12 months prior written notice if the Client assigns pursuant to Section 13.6 any of its rights under this Agreement to an assignee that, in the opinion of Patheon acting reasonably and in good faith, is: (i) not able to pay for Product it orders under this Agreement; or (ii) a competitor of Patheon provided, however, no competitor of Patheon shall be permitted to have access to the Manufacturing Site. For purposes of this Agreement, a competitor of Patheon is a legal entity, 50% of whose revenues are derived from pharmaceutical contract manufacturing services.

8.3 Termination by the Client.

(a) The Client may terminate this Agreement at any time upon twelve (12) months' prior written notice to Patheon.

(b) The Client may terminate this Agreement at any time on or after December 31, 2007 upon thirty (30) days notice if Patheon has not (i) obtained approval as a manufacturer of the Product, including approval of Patheon's facility by the FDA and any other applicable regulatory Authority or (ii) obtained a Quota for the Product for calendar year 2008.

8.4 Termination due to Product Discontinuation.

Except as provided in Section 8.2(c), the Client may terminate this Agreement upon ninety (90) days' prior notice if it intends to no longer order the Product due to the Product's discontinuance in the market.

8.5 Obligations on Termination.

If this Agreement expires or is terminated in whole or in part for any reason, then (in addition to any other remedies either party may have in the event of default by the other party):

(a) subject to Sections 6.1 and 6.2, the Client shall take delivery of and pay for all undelivered Product (i) that is manufactured and/or packaged pursuant to a Firm Order and (ii) that meets the Specifications and (iii) was manufactured in accordance with cGMPs and any additional procedures agreed upon in writing by the parties, at the price in effect at the time the Firm Order was placed;

(b) the Client shall purchase, **[*]**, the Inventory applicable to the Product which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2 prior to notice of termination being given;

(c) the Client shall **[*]** pursuant to Patheon's orders with suppliers of Components, provided such orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2; and

(d) Patheon shall return to the Client all unused Active Materials (with shipping and related expenses, if any, to be borne by **[*]**).

Any termination or expiration of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this Agreement.

8.6 Survival.

The provisions of Articles 1, 6, 9, 10, 11 and 12 and Sections 2.2, 5.5, 7.3, 7.6, 8.5, 8.6, 13.1, 13.2, 13.3, 13.5, 13.6, 13.8, 13.9, 13.12, 13.13, 13.14, and 13.15, shall survive the termination of this Agreement for any reason.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents and warrants that it has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties.

The Client represents and warrants that:

(a) The Client has the right to disclose the Specifications to Patheon; and

(b) Except with respect to the Patheon Intellectual Property as to which the Client makes no representations or warranties, the Client is not aware of any Intellectual Property of any third party that is necessary for the Client to make, have made, use or sell the Product as contemplated hereby;

(c) The Client is not aware of any action or other legal proceedings alleging that third party Intellectual Property rights would be infringed by the manufacture of the Product as contemplated hereby.

9.3 Patheon Warranties.

Patheon covenants, represents and warrants that (a) it shall perform the Manufacturing Services in accordance with the Specifications, cGMPs and all applicable Laws and that any Product supplied by it hereunder at the time of shipment, shall comply with the Specifications, (b) Patheon is not aware of any Intellectual Property of any third party that is necessary for Patheon to manufacture the Product as contemplated hereby and (c) the Active Material will not be used for any purpose beyond or different from the scope of the Manufacturing Services or otherwise in violation of the terms and conditions of this Agreement. Patheon acknowledges that the Product is controlled under Schedule III of the Controlled Substances Act and, as such, is subject to regulations and restrictions concerning its sale and distribution. Patheon agrees to comply with all such regulations and restrictions, as well as any reasonable instructions from the Client with respect to the use and storage of the Product. Without limiting the foregoing, (a) Patheon will obtain and/or maintain in force during the term of the Agreement all licenses and authorizations from the Drug Enforcement Administration or any other regulatory or governmental agency which are necessary for it to manufacture and possess the Product; and (b) Patheon will keep the Product in a secure location with access limited to authorized employees.

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Act.

9.5 Regulatory Approvals.

The Client shall be solely responsible for obtaining or maintaining, on a timely basis, any regulatory approvals in respect of the marketing of the Product by the Client or the regulatory approval of the Specifications, including, without limitation, all marketing and post-marketing approvals. Patheon shall be solely responsible for obtaining and maintaining all permits, approvals and quotas necessary in order for Patheon to manufacture the Product in its facilities as contemplated hereby, and for those facilities themselves.

9.6 Compliance with Laws.

Each party, in connection with its performance under this Agreement, shall comply with all applicable Laws.

9.7 No Warranty.

NEITHER PATHEON NOR THE CLIENT MAKES ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCT.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Neither party shall be liable to the other in contract, tort, negligence, breach of statutory duty or otherwise for any (direct or indirect) loss of profits, of production, of anticipated savings, of business or goodwill or for any liability, damage, costs or expense of any kind incurred by the other party of an indirect or consequential nature.

10.2 Limitation of Liability.

(a) **[*]**. Except as to the extent caused by the negligence or willful misconduct of Patheon, its employees or agents, under no circumstances whatsoever shall Patheon be responsible for any loss or damage to the **[*]**. Patheon's maximum liability for loss or damage to the **[*]** shall not exceed the **[*]**.

(b) Product. Except as expressly provided by applicable law or regulation or to the extent that Patheon has failed to provide the Manufacturing Services in accordance with the Specifications, cGMPs or all applicable Laws, Patheon shall not be liable nor have any responsibility for any deficiencies in, or other liabilities associated with, any Product manufactured by it, including, without limitation, the costs and expenses of any Recall (collectively, "**Product Claims**"). For greater certainty, Patheon shall have no obligation for any Product Claims to the extent such Product Claim (i) is caused by **[*]** provided by the Client, the **[*]** or any distribution thereof, (ii) results from a defect in a Component supplied by the Client or the Active Material that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) is caused by actions of third parties occurring after such Product is shipped by Patheon pursuant to Section 5.5, (iv) is due to packaging or labelling defects or omissions for which Patheon has no responsibility, or (v) is due to any other breach by the Client of its obligations under this Agreement.

(c) Maximum Liability. Except as set forth in this subsection (c), Patheon's maximum liability under this Agreement for any reason whatsoever, including, without limitation, any **[*]** hereof or resulting from a breach of its representations, warranties or other obligations under this Agreement shall **[*]**. For purposes of determining **[*]** hereunder, the **[*]** will be based upon the **[*]** Notwithstanding the foregoing, Patheon's maximum liability

under this Agreement, for any liability under Section 10.3 hereof for personal injury, sickness, disease or death that results from the failure by Patheon to provide the Manufacturing Services in accordance with the Specifications and cGMPs shall not **[*]**.

10.3 Patheon.

Subject to Sections 10.1 and 10.2, Patheon agrees to defend, indemnify and hold the Client, its officers, employees and agents harmless against any and all losses, damages, costs, claims, demands, judgments and liability to, from and in favor of third parties other than Affiliates, (together, "Losses") resulting from, or relating to any claim of personal injury or property damage to the extent that such injury or damage is the result of (i) a failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs or all applicable Laws, or (ii) the gross negligence or willful misconduct of Patheon or (iii) the breach of this Agreement by Patheon, including without limitation, any representation or warranty of Patheon contained herein, and in each case, except to the extent that any such losses, damages, costs, claims, demands, judgments and liability are due to the gross negligence or wrongful act(s) of the Client, its officers, employees or agents or Affiliates.

In the event of a claim, the Client shall: (a) promptly notify Patheon of any such claim; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with Patheon in the defence of such claim; (d) permit Patheon to control the defence and settlement of such claim, all at Patheon's cost and expense.

10.4 Client.

Subject to Sections 10.1 and 10.2, the Client agrees to defend, indemnify and hold Patheon, its officers, employees and agents (together "Patheon Indemnitees") harmless against any and all Losses resulting from, or relating to (a) any claim of personal injury or property damage to the extent that such injury or damage is the result of a breach of this Agreement by the Client, including, without limitation, any representation or warranty of Client contained herein, (b) any claim that the Specifications for the Product do not conform to all applicable cGMPs, laws and regulations and (c) any claim that the Product, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs (i) may not be lawfully sold and distributed in every jurisdiction in which the Client markets such Product, or (ii) is not safe for human consumption, except to the extent that any such Losses are due to the gross negligence or wrongful act(s) of Patheon, its officers, employees or agents or Affiliates.

Subject to Sections 10.1 and 10.2, Client agrees to defend, indemnify and hold the Patheon Indemnitees harmless against any and all Losses resulting from or relating to any claim that the manufacture, use or sale of the Product infringes any Third Party Rights, except to the extent such infringement or alleged infringement results from Patheon's manufacturing processes. In the event of any claim described in this Section 10.4, Patheon shall: (a) promptly notify the Client of any such claims; (b) use commercially reasonable efforts to mitigate the effects of such claim; (c) reasonably cooperate with the Client in the defence of such claim; (d) permit the Client to control the defence and settlement of such claim, all at the Client's cost and expense.

10.5 Reasonable Allocation of Risk.

The parties acknowledge and agree that the provisions of this Agreement (including, without limitation, this Article 10) are reasonable and create a reasonable allocation of risk having regard to the relative profits the parties respectively expect to derive from the Product, and that Patheon, in its fees for the provision of the Manufacturing Services, has not accepted a greater degree of the risks arising from the manufacture, distribution and use of the Product, based on the fact that the Client has developed and holds the marketing approval for the Product and requires Patheon to manufacture and label the Product strictly in accordance with the Specifications, and that the Client and not Patheon is in a position to inform and advise potential users of the Product as to the circumstances and manner of use of the Product.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality.

The Confidentiality Agreement effective March 13, 2007 between the parties (the "Confidentiality Agreement") will govern the confidentiality obligations of the parties hereunder; provided, however, that:

(a) Confidential Information disclosed orally need not be summarized in writing as provided in Paragraph 4 of the Confidentiality Agreement and;

(b) The Confidentiality Agreement will continue in effect until termination of this Agreement; and

(c) The obligations of confidentiality and non-use under the Confidentiality Agreement will continue until [*] years after termination of this Agreement for any reason, including the end of its term.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

In the event of any dispute arising out of or in connection with this Agreement (other than a dispute determined in accordance with Section 6.1(b) or a Technical Dispute), the parties shall first try to solve it amicably. In this regard, any party may send a notice of dispute to the other, and each party

shall appoint, within **[*]** Business Days from receipt of such notice of dispute, a single representative having full power and authority to solve the dispute. The representatives so designated shall meet as necessary in order to solve such dispute. If these representatives fail to solve the matter within **[*]** from their appointment, or if a party fails to appoint a representative within the **[*]** Business Day period set forth above, such dispute shall immediately be referred to the Chief Operating Officer, Executive Vice President, Operations or Chief Business Officer (or such other officer as they may designate) of each party who will meet and discuss as necessary in order to try to solve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, their dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

12.2 Technical Dispute Resolution.

In the event of a dispute (other than disputes in relation to the matters set out in Sections 6.1(b) and 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, quality control testing, handling, storage or other activities under this Agreement (a "**Technical Dispute**"), the parties shall make all reasonable efforts to resolve the dispute by amicable negotiations. In this regard, senior representatives of each party shall, as soon as practicable and in any event no later than **[*]** Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. In the event that the parties cannot agree whether a dispute is a Technical Dispute or are unable to resolve a Technical Dispute, Section 12.1 shall prevail. For greater certainty, the parties agree that the release of the Product for sale or distribution pursuant to the applicable marketing approval for such Product shall not by itself indicate compliance by Patheon with its obligations in respect of the Manufacturing Services and further that nothing in this Agreement (including Schedule F) shall remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Product is to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property which Patheon must use in order to perform the Manufacturing Services solely for the manufacture of the Product for the Client.

(b) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services, to the extent it is specific to the development, manufacture, use and sale of the Product that is the subject of the Manufacturing Services, shall be the exclusive property of Client.

(c) All Intellectual Property generated or derived by Patheon in the course of performing the Manufacturing Services which are not related to or derived from the Client's Intellectual Property or specific to, or dependent upon, the Product and which have general application to manufacturing

processes or formulation development of drug product or drug delivery systems shall be the exclusive property of Patheon (the "Patheon Intellectual Property Rights"). Patheon hereby grants to Client, a non-exclusive, paid-up, royalty-free, transferable license of the Patheon Intellectual Property Rights which Client may use for the manufacture of the Product.

(d) Patheon shall give the Client written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute improvements or other modifications of the Product or processes or technology owned or otherwise controlled by Client.

(e) Each party shall be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on its own Inventions.

(f) Each party agrees and acknowledges that it will not acquire by virtue of this Agreement any interest in or to any trademarks or trade names of the other party; provided, however, that the Client shall have the right to identify Patheon as the manufacturer of the Product.

13.2 Intellectual Property.

Subject to Section 13.1, all Intellectual Property of the Client shall be owned by the Client and all Intellectual Property of Patheon shall be owned by Patheon. The Client and Patheon hereby acknowledge that neither party has, nor shall it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing. Each party agrees not to use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement. Each party agrees to execute all applications, assignments or other instruments reasonably requested by the other party, in order for such party to establish its ownership of such Intellectual Property and to obtain whatever protection for such Intellectual Property, including patent and copyright rights, in any and all countries on such Intellectual Property as the requesting party will determine. Each party further agrees to cooperate fully with the other party in the process of securing and enforcing the other party's rights to such Intellectual Property, applicable.

13.3 Insurance.

Each party shall maintain commercial general liability insurance, through the term of this Agreement, which insurance shall afford limits of not less than $**[*]** for each occurrence for personal injury or property damage liability. Furthermore, each party shall maintain products liability insurance, through the term of this Agreement and for a period of **[*]** years thereafter, which insurance shall afford limits of not less than $**[*]** in the aggregate per annum with respect to product and completed operations liability. This insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement. If requested each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits of liability. The insurance certificate shall further provide for a minimum of thirty (30) days' written notice to the insured of a cancellation of, or material

change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault on the part of such party, then such party shall forthwith notify the other party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The parties are independent contractors and this Agreement shall not be construed to create between Patheon and the Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners or any similar relationship, the existence of which is expressly denied by the parties hereto.

13.5 No Waiver.

Either party's failure to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any of its rights or obligations hereunder except with the written consent of the Client, such consent not to be unreasonably withheld, provided that any assignee shall covenant in writing to be bound by the terms of this Agreement.

(b) Subject to Section 8.2(d), the Client may assign this Agreement or any of its rights or obligations hereunder without approval from Patheon; provided, however, that (i) the Client shall give prompt written notice of any assignment to Patheon after the assignment, and (ii) any assignee shall covenant in writing to be bound by the terms of this Agreement.

(c) Notwithstanding the foregoing provisions of this Section 13.6, either party may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, provided that such assignee executes an agreement with the non-assigning party hereto whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a cause or contingency beyond such party's reasonable control, including, but not limited to, strikes or other labour disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power or components (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 shall immediately notify the other party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control

that prevents such performance and shall use its commercially reasonable efforts to eliminate, cure and overcome any of such causes and resume the performance of its obligations. Neither party shall be entitled to rely on a Force Majeure Event **[*]** which would otherwise **[*]** under this Agreement.

13.8 Notices.

Any notice, approval, instruction or other written communication required or permitted hereunder shall be sufficient if made or given to the other party by personal delivery, by facsimile communication or by sending the same by first class mail, postage prepaid to the mailing address, or facsimile number set forth below:

If to the Client:

Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304
U.S.A.

Attention: Vice President, Product Development

Facsimile No.: (650) 496-3781

with a copy to:

Jazz Pharmaceuticals Inc
3180 Porter Drive
Palo Alto, CA 04304

Attention: General Counsel

Facsimile No.: (650) 496-3781

If to Patheon:

Patheon Pharmaceuticals Inc.
c/o Patheon Inc.,
7070 Mississauga Road, Suite 350
Mississauga, Ontario L5N 7J8
Canada

Attention: President

Facsimile No.: (905) 812-6705

with a copy to:

Patheon Pharmaceuticals Inc
2110 East Galbraith Road
Cincinnati, Ohio 45237-1625
Attention: Director of Legal Services

Facsimile No.: (513)948-6927

or to such other addresses or facsimile number provided to the other party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery or by facsimile shall be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five (5) days after being deposited in the United States or Canadian mail, postage prepaid or upon receipt, whichever is sooner.

13.9 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such determination shall not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct.

13.10 Entire Agreement.

This Agreement, together with the Quality Agreement, Confidentiality Agreement, that certain Capital Expenditure and Equipment Agreement dated as of the date hereof, and that certain Pharmaceutical Development Services Agreement dated as of January 2, 2007, in each case by and between Patheon and the Client, to the extent expressly incorporated herein, constitutes the full, complete, final and integrated agreement between the parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions or understandings with respect to the subject matter hereof. Any modification, amendment or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, this Agreement will prevail.

13.11 Other Terms.

The parties agree that no terms, provisions or conditions of any purchase order or other business form or written authorization used by the Client or Patheon will have any effect on the rights, duties or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of the Client or Patheon to object to such terms, provisions, or conditions unless such document specifically refers to this Agreement and is signed by both parties.

13.12 Third Party Beneficiary.

Nothing in this Agreement shall confer or be construed as conferring on any other third party any benefit or the right to enforce any express or implied term of this Agreement.

13.13 Exclusivity.

During the term of this Agreement and for **[*]** thereafter, Patheon will not develop, make, have made, use, sell, have sold, offer for sale, import or commercialize, or assist any other third party, in any of the foregoing with respect to the Product, other than the Client pursuant to this Agreement.

13.14 Publicity.

Each party agrees not to issue any press release or other public statement disclosing the existence of, or relating to this Agreement, without the prior written consent of the other party; provided, however, that neither party shall be prevented from complying with any duty of disclosure it may have pursuant to applicable Laws or governmental orders.

13.15 Execution in Counterparts.

This Agreement may be executed in two counterparts, by original or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.16 Governing Law.

This Agreement shall be construed and enforced in accordance with the laws of the State of New York.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the date first written above.

PATHEON PHARMACEUTICALS INC.

By /s/ Riccardo Trecroce
Name: Riccardo Trecroce
Title: Secretary

JAZZ PHARMACEUTICALS, INC.

By /s/ Janne Wissel
Name: Janne Wissel
Title: Sr VP, Development

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SCHEDULE A

PRODUCT SPECIFICATIONS

If the Specifications provided are subsequently amended, then the Client shall provide Patheon with copies of such revised Specifications. Upon receipt of the revised Specifications, Patheon shall provide the Client with a signed and dated receipt evidencing such acceptance of the revised Specifications by Patheon.

[*]

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SCHEDULE B

MINIMUM RUN QUANTITY, ANNUAL VOLUME, FEES & PRICE ADJUSTMENTS

1. Xyrem Oral Solution – [*] mL Bottle

Batch Size (L)			**[*]**	
Market	US		EU/Canada	
Minimum Annual Qty (bottle)	**[*]**		**[*]**	
Run Quantity (bottles)	**[*]**	**[*]**	**[*]**	**[*]**
Pkg Run Quantity (batch)	**[*]**	**[*]**	**[*]**	**[*]**
Materials	**[*]**	**[*]**	**[*]**	**[*]**
Conversion Cost	**[*]**	**[*]**	**[*]**	**[*]**
Price per Bottle*	**[*]**	**[*]**	**[*]**	**[*]**

Split Lot Charge - **[*]**
This charge is for splitting off a portion of a US lot for “EU” type bottles for the Canadian market.

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Price for Double Batch Size

Xyrem oral solution: [*] ml/bottle

Batch size	**[*]**	**[*]**
Market	US	EU
Annual Qty (bottles)	**[*]**	**[*]**
Run Quantity (bottles)	**[*]**	**[*]**
Materials	**[*]**	**[*]**
Conversion	**[*]**	**[*]**
Price per bottle*	**[*]**	**[*]**

Split lot charge **[*]**

This charge is for splitting off a portion of a US lot for “EU” type bottles for the Canadian market.

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* Pricing is based on the fact that Patheon will do the following:

Procurement of raw materials and packaging components as defined in schedule J. Jazz Pharmaceuticals will furnish the API, Sodium Oxybate. Price does include the performance of all QC testing requirements for raw materials, packaging components and finished product.

Manufacturing Assumptions [*]

Packaging Assumptions[*]

Product Release Testing for Non-Patheon Product [*]

2. Subsequent Years' Pricing.

The fees for the Manufacturing Services provided pursuant to the terms of this Agreement during any Year following December 31, 2008 shall be determined in accordance with the following:

(a) Manufacturing and Component Costs. On the first day of the applicable Year during the term of this Agreement, Patheon shall **[*]** (i) for **[*]** in respect of the Product **[*]** to reflect **[*]**, unless the parties otherwise agree in writing; and (ii) for **[*]** in such costs. **[*]**.

(b) Pricing Basis. The Client acknowledges that the fee for Manufacturing Services in respect of a Product in any Year is **[*]** and is subject to change if **[*]** unless Client agrees **[*]** provided that such Product **[*]**. In addition, if Patheon and the Client agree that the **[*]** in respect of a Product shall be reduced whether as a result of a **[*]** or otherwise and, as a result of such reduction, **[*]**, then Patheon shall be entitled to **[*]**.

In connection with a **[*]** pursuant to clause 2 of this Schedule B, Patheon shall **[*]** a revised Schedule B in draft form and a statement outlining (i) **[*]** upon which such **[*]** is based and (ii) the **[*]** to Patheon **[*]** upon which any **[*]** is based, if applicable. In connection with all **[*]** pursuant to clauses 2(b) of this Schedule B, Patheon shall deliver to the Client by not later than **[*]** a revised Schedule B in draft form and such **[*]**. Upon delivery of such a request, each of the Client and Patheon shall forthwith **[*]** in respect of the Product and **[*]**. Such **[*]** shall be effective with respect to any **[*]** after the end of the **[*]**.

3. Adjustments to Pricing.

During any Year of this Agreement, the fees set out in Schedule B shall be subject to adjustment in accordance with the following:

(a) **[*] Pricing**. The Manufacturing Fees describe the fees that are payable by Client for Product based on the **[*]**. The parties shall estimate the Manufacturing Fees payable by Client in any Year based on the **[*]**. Within **[*]** of the end of the each Year, the parties shall reconcile the difference which may be payable by either party based on the **[*]**.

(b) **[*]**.

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In connection with a **[*]** pursuant to this clause 3 of Schedule B, Patheon shall deliver to the Client a revised Schedule B and such **[*]**. Upon delivery of such a request, each of the Client and Patheon shall forthwith **[*]**.

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SCHEDULE C

STABILITY TESTING

[*]

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SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
Sodium Oxybate, Powder	Lonza, Inc.

[*]

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SCHEDULE E

BATCH NUMBERING & EXPIRATION DATES

Each batch of the Product manufactured by Patheon will bear a unique batch number using the Patheon batch numbering system. This number will appear on all documents relating to the particular batch of Product.

Patheon will calculate the expiration date for the Product for each batch by adding the expiration period of the Product supplied by the Client to the date of Manufacture of each batch.

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SCHEDULE F

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 shall be resolved in the following manner: **[*]**

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SCHEDULE G

QUALITY AGREEMENT

{This Schedule G has been filed separately as an exhibit to the Jazz Pharmaceuticals, Inc. Registration Statement on Form S-1 in executed form.}

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SCHEDULE H

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: JAZZ PHARMACEUTICALS, INC.
FROM: PATHEON PHARMACEUTICALS INC.
RE: Active Materials quarterly inventory report pursuant to Section 2.3(a) of the Manufacturing Services Agreement dated • (the "Agreement")

[*]
Capitalized terms used in this report have the meanings given to such terms in the Agreement.

DATE: _____

PATHEON PHARMACEUTICALS INC.

Per: _____
Name:
Title:

[*]

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SCHEDULE I

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD.
Intentionally Left Blank

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SCHEDULE J

COMPONENTS PURCHASING SUMMARY

Dated: October 19, 2006
[*]

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SCHEDULE K

POTENTIAL BILL-BACK ITEMS

[*]

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SCHEDULE L
PACKAGING CONFIGURATIONS
Referenced in the definition section
[*]

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated March 6, 2007 (except for the seventh paragraph of Note 2, as to which the date is May 15, 2007), with respect to the consolidated financial statements and schedule of Jazz Pharmaceuticals, Inc. included in Amendment No. 5 to the Registration Statement (Form S-1 No. 333-141164) and related Prospectus of Jazz Pharmaceuticals, Inc. for the registration of shares of its common stock.

/s/ Ernst & Young LLP

Palo Alto, California
May 30, 2007

Exhibit 23.2

Consent of Independent Auditors

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated March 6, 2007, with respect to the financial statements of Orphan Medical, Inc. included in Amendment No. 5 to the Registration Statement (Form S-1 No. 333-141164) and related Prospectus of Jazz Pharmaceuticals, Inc. for the registration of shares of its common stock.

/s/ Ernst & Young LLP

Palo Alto, California
May 30, 2007

Chadwick L. Mills
(650) 843-5654
cmills@cooley.com

May 31, 2007

Via EDGAR and Courier

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F Street NE
Washington, DC 20549
Attn: Mary K. Fraser
Jeffrey P. Riedler

RE: Jazz Pharmaceuticals, Inc.
Amendment No. 5 to the Registration Statement on Form S-1
Registration No. 333-141164

Ladies and Gentlemen:

On behalf of Jazz Pharmaceuticals, Inc. (the "***Registrant***"), we are transmitting for filing Amendment No. 5 (the "***Amendment***") to the Registration Statement on Form S-1, File No. 333-141164 (the "***Registration Statement***"). We are also transmitting for filing a free writing prospectus relating to the Registrant's preliminary prospectus dated May 17, 2007 (the "***FWP***"). We are sending copies of this letter, the FWP and the Amendment, as well as one copy of the Amendment marked to show changes to Amendment No. 4 to the Registration Statement filed with the U.S. Securities and Exchange Commission (the "***Commission***") on May 24, 2007, to the staff of the Commission (the "***Staff***") in the care of Ms. Fraser.

In addition, please note that we are sending to the Staff in the care of Ms. Fraser one copy of our letter responding to comments received from the Staff by letter dated May 30, 2007 with respect to the Registrant's Application for Confidential Treatment filed March 28, 2007. Attached thereto is one copy of each agreement bracketed and highlighted to indicate those selected provisions for which the Registrant continues to request an order granting confidential treatment.

Finally, please note that the Registrant has filed its request for a declaration of effectiveness at 4:00 p.m. Eastern time today, May 31, 2007.

Please direct any questions or comments regarding this filing to me at (650) 843-5654, Suzanne Sawochka Hooper at (650) 843-5180 or John M. Geschke at (650) 843-5757 if the Staff requires any additional information prior to acceleration of effectiveness of if there is anything that we or the Registrant can do to further facilitate your review.

Sincerely,

/s/ CHADWICK L. MILLS

Chadwick L. Mills

cc: Matthew K. Fust, Jazz Pharmaceuticals, Inc.
Carol A. Gamble, Esq., Jazz Pharmaceuticals, Inc.
P.J. Honerkamp, Esq., Jazz Pharmaceuticals, Inc.
Bruce Dallas, Esq., Davis Polk & Wardwell
John M. Geschke, Esq., Cooley Godward Kronish LLP