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

FORM 10-Q

(Mark One)

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2016

or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to

Commission File Number: 001-33500

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**98-1032470**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

Fourth Floor, Connaught House,
One Burlington Road, Dublin 4, Ireland
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒		Accelerated filer	☐
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 3, 2016, 60,421,794 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2016

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We own or have rights to various copyrights, trademarks and trade names used in our business in the United States and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Erwinase®, Defitelio® (defibrotide sodium), Defitelio® (defibrotide) and Prialt® (ziconotide) intrathecal infusion. This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 979,780	$ 988,785
Investments	764	—
Accounts receivable, net of allowances	223,802	209,685
Inventories	25,369	19,451
Prepaid expenses	18,472	20,699
Other current assets	22,431	19,047
Total current assets	1,270,618	1,257,667
Property and equipment, net	86,788	85,572
Intangible assets, net	1,348,160	1,185,606
Goodwill	670,991	657,139
Deferred tax assets, net, non-current	122,036	122,863
Deferred financing costs	6,843	7,209
Other non-current assets	29,543	27,548
Total assets	$ 3,534,979	$ 3,343,604
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 32,622	$ 21,807
Accrued liabilities	307,504	164,070
Current portion of long-term debt	37,592	37,587
Income taxes payable	19,735	1,808
Deferred revenue	1,378	1,370
Total current liabilities	398,831	226,642
Deferred revenue, non-current	3,441	3,721
Long-term debt, less current portion	1,146,433	1,150,857
Deferred tax liability, net, non-current	299,627	294,485
Other non-current liabilities	79,207	69,253
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	472	471
Additional paid-in capital	1,586,750	1,562,900
Accumulated other comprehensive loss	(222,284)	(267,472)
Retained earnings	242,441	302,686
Total shareholders' equity	1,607,440	1,598,646
Total liabilities and shareholders' equity	$ 3,534,979	$ 3,343,604

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues:		
Product sales, net	$ 333,916	$ 307,035
Royalties and contract revenues	2,094	2,268
Total revenues	336,010	309,303
Operating expenses:		
Cost of product sales (excluding amortization of intangible assets)	23,439	28,298
Selling, general and administrative	128,765	112,388
Research and development	31,252	27,181
Acquired in-process research and development	8,750	—
Intangible asset amortization	22,642	24,677
Total operating expenses	214,848	192,544
Income from operations	121,162	116,759
Interest expense, net	(12,192)	(16,245)
Foreign currency gain (loss)	(819)	2,245
Income before income tax provision	108,151	102,759
Income tax provision	34,030	32,059
Net income	$ 74,121	$ 70,700
Net income per ordinary share:		
Basic	$ 1.21	$ 1.16
Diluted	$ 1.19	$ 1.12
Weighted-average ordinary shares used in per share calculations - basic	61,142	60,803
Weighted-average ordinary shares used in per share calculations - diluted	62,474	62,964

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Net income	$ 74,121	$ 70,700
Other comprehensive income (loss):		
Foreign currency translation adjustments	45,188	(156,497)
Other comprehensive income (loss)	45,188	(156,497)
Total comprehensive income (loss)	119,309	(85,797)
Comprehensive loss attributable to noncontrolling interests, net of tax	—	(10)
Comprehensive income (loss) attributable to Jazz Pharmaceuticals plc	$ 119,309	$ (85,787)

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Operating activities		
Net income	$ 74,121	$ 70,700
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	22,642	24,677
Share-based compensation	24,183	20,819
Depreciation	2,527	2,232
Acquired in-process research and development	8,750	—
Loss on disposal of property and equipment	37	8
Excess tax benefit from share-based compensation	(7,938)	(10,635)
Deferred income taxes	(1,962)	(9,261)
Provision for losses on accounts receivable and inventory	898	426
Amortization of debt discount and deferred financing costs	5,362	6,016
Other non-cash transactions	1,579	(5,384)
Changes in assets and liabilities:		
Accounts receivable	(13,802)	(4,769)
Inventories	(6,307)	(1,842)
Prepaid expenses and other current assets	(1,231)	(15,670)
Other long-term assets	(1,985)	(3,278)
Accounts payable	10,664	3,303
Accrued liabilities	(6,706)	(17,485)
Income taxes payable	25,758	30,163
Deferred revenue	(266)	(285)
Other non-current liabilities	7,392	6,820
Net cash provided by operating activities	143,716	96,555
Investing activities		
Purchases of property and equipment	(2,472)	(14,410)
Acquisition of in-process research and development	(8,750)	—
Acquisition of investments	(773)	—
Net proceeds from sale of business	—	32,703
Net cash provided by (used in) investing activities	(11,995)	18,293
Financing activities		
Proceeds from employee equity incentive plans	3,780	13,504
Repayments of long-term debt	(9,397)	(2,284)
Payment of employee withholding taxes related to share-based awards	(12,476)	(14,778)
Share repurchases	(134,365)	(10,338)
Excess tax benefit from share-based compensation	7,938	10,635
Net cash used in financing activities	(144,520)	(3,261)
Effect of exchange rates on cash and cash equivalents	3,794	(13,026)
Net increase (decrease) in cash and cash equivalents	(9,005)	98,561
Cash and cash equivalents, at beginning of period	988,785	684,042
Cash and cash equivalents, at end of period	$ 979,780	$ 782,603

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. The Company and Summary of Significant Accounting Policies

Jazz Pharmaceuticals plc is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs.

We have a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in patients with narcolepsy;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Defitelio® (defibrotide sodium)**, a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, or SOS, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications;
- Acquiring clinically meaningful and differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing targeted development of post-discovery differentiated product candidates.

We apply a disciplined approach to allocating our resources between investments in our current commercial and development portfolio and acquisitions or in-licensing of new assets.

Throughout this report, unless otherwise indicated or the context otherwise requires, all references to "Jazz Pharmaceuticals," "the registrant," "we," "us," and "our" refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries. Throughout this report, all references to "ordinary shares" refer to Jazz Pharmaceuticals plc's ordinary shares.

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or U.S. GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our annual consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2015.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three months ended March 31, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, for any other interim period or for any future period.

These condensed consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our subsidiaries, and intercompany transactions and balances have been eliminated.

Adoption of New Accounting Standard

Effective January 1, 2016, we adopted Accounting Standards Update, or ASU, No. 2015-03 "Interest - Imputation of Interest", or ASU No. 2015-03. ASU No. 2015-03 requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt liability instead of as an asset. The standard requires retrospective application. The adoption of ASU No. 2015-03 resulted in a $16.1 million reduction of both deferred financing costs and long-term debt, less current portion in our condensed consolidated balance sheets as of December 31, 2015.

Significant Risks and Uncertainties

Our financial results remain significantly influenced by sales of Xyrem. In the three months ended March 31, 2016, net product sales of Xyrem were $249.5 million, which represented 75% of total net product sales. Our ability to maintain or increase sales of Xyrem in its approved indications is subject to a number of risks and uncertainties, including the potential introduction of generic competition or an alternative sodium oxybate product that competes with Xyrem; changed or increased regulatory restrictions or regulatory actions by the FDA; our suppliers' ability to obtain sufficient quotas from the U.S. Drug Enforcement Administration, or DEA; any supply, manufacturing or distribution problems arising with any of our suppliers or distributors, all of whom are sole source providers for us; any increase in pricing pressure from or restrictions on reimbursement imposed by third party payors; changes in healthcare laws and policy; continued acceptance of Xyrem by physicians and patients; changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem; and operational disruptions at the central pharmacy or any failure to comply with our risk evaluation and mitigation strategy, or REMS, obligations to the satisfaction of the FDA.

Seven companies have sent us notices that they have filed abbreviated new drug applications, or ANDAs, with the FDA seeking approval to market a generic version of Xyrem. We have filed lawsuits against each of these companies seeking to prevent the introduction of a generic version of Xyrem that would infringe our patents, and in the second quarter of 2016, we settled two of these lawsuits. We cannot predict the timing or outcome of the ongoing litigation proceedings. Although no trial date has been set in any of the current ANDA suits, we anticipate that trial on some of the patents in the case against the first ANDA filer, Roxane Laboratories, Inc., or Roxane, could occur as early as the third quarter of 2016. Certain ANDA filers have also filed petitions for inter partes review, or IPR, by the Patent Trial and Appeal Board, or the PTAB, of the U.S. Patent and Trademark Office, or USPTO, with respect to the validity of certain distribution, method of use and formulation patents covering Xyrem. The PTAB has issued decisions instituting IPR trials with respect to patents and patent claims that are the subject of certain of these petitions, and we expect the PTAB to issue final decisions in the first of these trials in July 2016. For a description of these matters, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate products that compete with Xyrem, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Approval of an ANDA with respect to a generic version of Xyrem will require a REMS, which may be either a single shared REMS with Xyrem or a separate REMS with differing but comparable aspects of elements to assure safe use, or ETASU, in the approved Xyrem REMS. We and the ANDA applicants had interactions with respect to developing a single shared REMS for several years. The ANDA applicants are not currently engaging in single shared REMS discussions with us, but we are seeking to continue the interactions with the goal of developing a single shared REMS. However, we cannot predict whether, or to what extent, our interactions with the ANDA applicants will continue or whether we will develop a single shared REMS. We are aware that, separate from the discussions with us, the FDA and ANDA applicants have exchanged communications regarding a REMS for sodium oxybate. If we and the ANDA applicants do not develop a single shared REMS, or we do not license or share intellectual property pertinent to our Xyrem REMS with generic competitors within a time frame or on terms that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to approve the ANDA of one or more generic competitors with a separate REMS that differs in some aspects from our approved Xyrem REMS. We also may face pressure to develop a single shared REMS with potential generic competitors for Xyrem that is different from the approved Xyrem REMS or to license or share intellectual property pertinent to the Xyrem REMS, or elements of the Xyrem REMS, including proprietary data required for safe distribution of sodium oxybate, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared REMS for sodium oxybate, licensing or sharing intellectual property pertinent to our Xyrem REMS or elements of the Xyrem REMS, or the FDA's response to a request by one or more ANDA applicants for a waiver of the requirement for a single shared REMS, including in connection with a certification that the applicant had been unable to obtain a license. The FDA's response to any such request could include approval of one or more ANDAs. In addition, the Federal Trade Commission, or FTC, other governmental authorities or others could claim or determine that we are using the Xyrem REMS in an anticompetitive manner (including in light of the FDA's statement in the Xyrem REMS approval letter that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the Federal Food, Drug and Cosmetic Act, or FDCA) or have engaged in other anticompetitive practices.

In late August 2015, we implemented the final Xyrem REMS, which was approved by the FDA in February 2015, and we have submitted and expect to continue to submit ongoing assessments as set forth in the FDA's Xyrem REMS approval letter. The process under which enrolled patients receive Xyrem is complex, and we are continuing to transition prescribers and patients to the final Xyrem REMS process and documentation requirements. We cannot guarantee that we will be able to

complete the transition of prescribers and patients to the final Xyrem REMS in a timely manner, that our ongoing assessments will be satisfactory to the FDA or that the Xyrem REMS will satisfy the FDA's expectations in its evaluation of the Xyrem REMS on an ongoing basis. Any failure to comply with the REMS obligations could result in enforcement action by the FDA; lead to changes in our Xyrem REMS obligations; negatively affect sales of Xyrem; result in additional costs and expenses for us; and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Obtaining and maintaining appropriate reimbursement for Xyrem in the U.S. is increasingly challenging due to, among other things, the attention being paid to healthcare cost containment and prescription drug pricing, pricing pressure from third party payors and increasingly restrictive reimbursement conditions being imposed by third party payors. In this regard, we have experienced and expect to continue to experience increasing pressure from third party payors to agree to discounts, rebates or other pricing terms for Xyrem. Any such restrictive pricing terms or additional reimbursement conditions could have a material adverse effect on our Xyrem revenues. In addition, drug pricing by pharmaceutical companies has recently come under close scrutiny, particularly with respect to companies that have increased the price of products after acquiring those products from other companies. We expect that healthcare policies and reforms intended to curb healthcare costs will continue to be proposed, which could limit the prices that we charge for our products, including Xyrem, limit our commercial opportunity and/or negatively impact revenues from sales of our products. Also, price increases on Xyrem and our other products, and negative publicity regarding pricing and price increases generally, whether with respect to our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of Xyrem and our other products.

In the three months ended March 31, 2016, sales of our second largest product, Erwinaze/Erwinase (which we refer to in this report as Erwinaze unless otherwise indicated or the context otherwise requires), were $51.2 million which represented 15% of total net product sales. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing sales and marketing and research and development activities. However, a significant challenge to our ability to maintain current sales levels and to increase sales is our extremely limited inventory of Erwinaze and our need to avoid supply disruptions due to capacity constraints, production delays, quality or regulatory challenges or other manufacturing difficulties. Erwinaze is licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL. The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product. We are working with PBL to evaluate potential expansion of its production capacity to increase the supply of Erwinaze over the longer term. As a consequence of constrained manufacturing capacity, we have had an extremely limited or no ability to build product inventory levels that can be used to absorb disruptions to supply resulting from quality, regulatory or other issues, and we have experienced product quality, manufacturing and inventory challenges that have resulted in disruptions in our ability to supply certain markets and caused us to implement batch-specific, modified product use instructions. We expect that we will continue to experience inventory challenges. If capacity constraints or supply disruptions continue, whether as a result of continued quality or other manufacturing issues, regulatory issues or otherwise, we may be unable to build a desired excess level of product inventory, our ability to supply the market may continue to be compromised and physicians' decisions to use Erwinaze in the future may be negatively impacted. If we fail to obtain a sufficient supply of Erwinaze, our sales of and revenues from Erwinaze, our potential future maintenance and growth of the market for this product, and/or our business, financial condition, results of operations and growth prospects could be materially adversely affected. Our ability to successfully and sustainably maintain or grow sales of Erwinaze is also subject to a number of other risks and uncertainties, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to E. coli-derived asparaginase within that population, our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries, as well as those other risks and uncertainties discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

In the three months ended March 31, 2016, sales of Defitelio/defibrotide represented 5% of our net product sales. We acquired this product in January 2014 in connection with our acquisition of Gentium S.r.l., or Gentium, which we refer to as the Gentium Acquisition, and secured worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. We launched Defitelio in certain European countries in 2014 and continue to launch in additional European countries on a rolling basis. On March 30, 2016, the FDA approved our new drug application, or NDA, for Defitelio for the treatment of adult and pediatric patients with VOD, also known as SOS, with renal or pulmonary dysfunction following HSCT. We launched Defitelio in the U.S. shortly after FDA approval.

Our ability to realize the anticipated benefits from our investment in this product is subject to risks and uncertainties, including:

- the acceptance of Defitelio in the U.S. by hospital pharmacy and therapeutics committees and the availability of adequate coverage and reimbursement by government programs and third party payors;

- U.S. market acceptance of Defitelio at its commercial price now that it is no longer available to new patients under an expanded access treatment protocol;
- the lack of experience of U.S. physicians in diagnosing and treating VOD, particularly in adults, and the possibility that physicians may delay initiation of treatment or terminate treatment before the end of the recommended dosing schedule;
- our ability to successfully maintain or grow sales of Defitelio in Europe;
- delays or problems in the supply or manufacture of the product;
- the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in HSCT treatment protocols reduce the incidence of VOD);
- our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA for Defitelio; and
- our ability to obtain marketing approval in other countries and to develop the product for additional indications.

If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product will be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. For more information, see the risk factor under the heading *"While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects"* in Part II, Item 1A of this Quarterly Report on Form 10-Q.

In addition to risks specifically related to Xyrem, Erwinaze and Defitelio/defibrotide, we are subject to other challenges and risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations. These risks and uncertainties include:

- the challenges of protecting and enhancing our intellectual property rights;
- the challenges of achieving and maintaining commercial success of our products;
- delays or problems in the supply or manufacture of our products, particularly with respect to certain products as to which we maintain limited inventories, and our dependence on single source suppliers to continue to meet our ongoing commercial demand or our requirements for clinical trial supplies;
- the need to obtain and maintain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the U.S. in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by third party payors;
- our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business;
- the challenges of compliance with the requirements of the FDA, the DEA, and non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, adverse event reporting and product recalls or withdrawals;
- the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, and the uncertainty of clinical success, such as the risk that results from preclinical studies and/or early clinical trials may not be predictive of results obtained in later and larger clinical trials planned or anticipated to be conducted for our product candidates;
- the inherent uncertainty associated with the regulatory approval process, especially as we continue to undertake increased activities and make growing investment in our product pipeline development projects;
- the risks associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historic business, the increase in geographic dispersion among our centers of operation and the risks that we may acquire unanticipated liabilities along with acquired businesses or otherwise fail to realize the anticipated benefits (commercial or otherwise) from such transactions; and

- possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

Any of these risks and uncertainties could have a material adverse effect on our business, financial condition, results of operations and growth prospects. All of these risks and uncertainties are discussed in greater detail, along with other risks and uncertainties, in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, cash equivalents, investments and marketable securities. Our investment policy permits investments in U.S. federal government and federal agency securities, corporate bonds or commercial paper issued by U.S. corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, and tax-exempt obligations of U.S. states, agencies and municipalities and places restrictions on credit ratings, maturities, and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and marketable securities and issuers of investments to the extent recorded on the balance sheet.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the United States, and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We monitor deteriorating economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of March 31, 2016, five customers accounted for 91% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliates, or Express Scripts, which accounted for 70% of gross accounts receivable and McKesson Corporation and its affiliates, or McKesson, which accounted for 10% of gross accounts receivable. As of December 31, 2015, five customers accounted for 90% of gross accounts receivable, including Express Scripts, which accounted for 69% of gross accounts receivable, and IDIS Limited, or IDIS, which accounted for 11% of gross accounts receivable.

We depend on single source suppliers for each of our products, product candidates and their active pharmaceutical ingredients.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed 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.

Net Income per Ordinary Share

Basic net income per ordinary share is based on the weighted-average number of ordinary shares outstanding. Diluted net income per ordinary share is based on the weighted-average number of ordinary shares outstanding and potentially dilutive ordinary shares outstanding.

Basic and diluted net income per ordinary share were computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2016	2015
Numerator:		
Net income	$ 74,121	$ 70,700
Denominator:		
Weighted-average ordinary shares used in per share calculation - basic	61,142	60,803
Dilutive effect of employee equity incentive and purchase plans	1,332	2,161
Weighted-average ordinary shares used in per share calculation - diluted	62,474	62,964
Net income per ordinary share:		
Basic	$ 1.21	$ 1.16
Diluted	$ 1.19	$ 1.12

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans and our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, are determined by applying the treasury stock method to the assumed exercise of share options, the assumed vesting of outstanding restricted stock units, or RSUs, the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP, and the assumed issuance of ordinary shares upon exchange of the 2021 Notes. The potential issue of approximately 2.9 million ordinary shares issuable upon exchange of the 2021 Notes had no effect on diluted net income per ordinary share because the average price of our ordinary shares for the three months ended March 31, 2016 and 2015 did not exceed the effective exchange price of $199.77 per ordinary share.

The following table represents the weighted-average ordinary shares that were excluded from the calculation of diluted net income per ordinary share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended March 31,	
	2016	2015
1.875% exchangeable senior notes due 2021	2,878	2,878
Options to purchase ordinary shares and RSUs	2,305	1,322
Ordinary shares under ESPP	104	—

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2016-09, “Improvements to Employee Share-Based Payment Accounting”. The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, statutory tax withholding requirements, accounting for forfeitures and classification on the statement of cash flows. ASU No. 2016-09 is effective for us beginning January 1, 2017. We are currently assessing our approach to the adoption of this standard and the impact on our results of operations and financial position.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)”. Under the new guidance, lessees will be required to recognize a right-of-use asset, which represents the lessee’s right to use, or control the use of, a specified asset for the lease term, and a corresponding lease liability, which represents the lessee’s obligation to make lease payments under a lease, measured on a discounted basis. ASU No. 2016-02 is effective beginning January 1, 2019 and early application is permitted. ASU No. 2016-02 must be adopted on a modified retrospective transition basis for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements. We are currently assessing our approach to the adoption of this standard and the potential impact on our results of operations and financial position.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers”, or ASU No. 2014-09, which states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this, an entity will need to identify the contract with a customer; identify the separate performance obligations in the contract; determine the transaction price; allocate the transaction price to the separate performance obligations in the contract;

and recognize revenue when (or as) the entity satisfies each performance obligation. In August 2015, the FASB issued ASU No. 2015-14, "Revenue from Contracts with Customers: Deferral of the Effective Date", which deferred the effective date of ASU No. 2014-09. ASU No.2014-09 will now be effective for us beginning January 1, 2018 and can be adopted on a full retrospective basis or on a modified retrospective basis. We are currently assessing our approach to the adoption of this standard and the potential impact on our results of operations and financial position.

2. Asset Acquisition

In March 2016, we acquired all of the outstanding shares of Alizé Pharma II S.A.S., a privately held biotechnology company, for an upfront payment of $8.8 million. In connection with the acquisition, we obtained intellectual property and know-how related to recombinant crisantaspase. The transaction includes contingent regulatory milestone payments of up to €10.0 million. The transaction was accounted for as an asset acquisition and the upfront payment was charged to acquired in-process research and development, or IPR&D, expense upon closing of the transaction.

3. Fair Value Measurement

Cash, cash equivalents and investments consisted of the following (in thousands):

	March 31, 2016					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 263,502	$ —	$ —	$ 263,502	$ 263,502	$ —
Time deposits	717,042	—	—	717,042	716,278	764
Totals	$ 980,544	$ —	$ —	$ 980,544	$ 979,780	$ 764

	December 31, 2015					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 274,945	$ —	$ —	$ 274,945	$ 274,945	$ —
Time deposits	713,840	—	—	713,840	713,840	—
Totals	$ 988,785	$ —	$ —	$ 988,785	$ 988,785	$ —

Cash equivalents and investments are considered available-for-sale securities. We use the specific-identification method for calculating realized gains and losses on securities sold and include them in interest expense, net in the condensed consolidated statements of income. Our investment balance represents time deposits with original maturities of greater than 90 days.

The following table summarizes, by major security type, our available-for-sale securities as of March 31, 2016 and December 31, 2015 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	March 31, 2016		December 31, 2015	
	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Time deposits	$ 717,042	$ 717,042	$ 713,840	$ 713,840

As of March 31, 2016, our available-for-sale securities included time deposits which were measured at fair value using Level 2 inputs and their carrying values were approximately equal to their fair values. Level 2 inputs, obtained from various third party data providers, represent quoted prices for similar assets in active markets, or these inputs were derived from observable market data, or if not directly observable, were derived from or corroborated by other observable market data.

There were no transfers between the different levels of the fair value hierarchy in 2016 or in 2015.

As of March 31, 2016, the estimated fair value of our 2021 Notes was approximately $591 million. The fair value of the 2021 Notes was estimated using quoted market prices obtained from brokers (Level 2). The estimated fair value of our borrowings under our term loan and other borrowings were approximately equal to their respective book values based on the borrowing rates currently available for variable rate loans (Level 2).

4. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Raw materials	$ 2,145	$ 2,608
Work in process	14,875	11,836
Finished goods	8,349	5,007
Total inventories	$ 25,369	$ 19,451

5. Goodwill and Intangible Assets

The gross carrying amount of goodwill was as follows (in thousands):

Balance at December 31, 2015	$ 657,139
Foreign exchange	13,852
Balance at March 31, 2016	$ 670,991

The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	March 31, 2016				December 31, 2015		
	Remaining Weighted-Average Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies	12.1	$ 1,552,761	$ (350,397)	$ 1,202,364	$ 1,321,324	$ (324,044)	$ 997,280
Manufacturing contracts	1.8	12,111	(6,633)	5,478	11,697	(5,676)	6,021
Trademarks	—	2,892	(2,892)	—	2,882	(2,882)	—
Total finite-lived intangible assets		1,567,764	(359,922)	1,207,842	1,335,903	(332,602)	1,003,301
Acquired IPR&D assets		140,318	—	140,318	182,305	—	182,305
Total intangible assets		$ 1,708,082	$ (359,922)	$ 1,348,160	$ 1,518,208	$ (332,602)	$ 1,185,606

The increase in the gross carrying amount of intangible assets as of March 31, 2016 compared to December 31, 2015 is primarily due to the capitalization of a $150.0 million milestone payable to Sigma-Tau Pharmaceuticals Inc., or Sigma-Tau, that was triggered by the FDA approval of Defitelio on March 30, 2016. Additionally, after receiving FDA approval of Defitelio, we reclassified $48.4 million of acquired IPR&D from an indefinite-lived intangible asset to an acquired developed technology finite-lived intangible asset. The Defitelio acquired developed technology asset will be amortized over its estimated useful life of 14 years. The increase in the gross carrying amount was also due to the positive impact of foreign currency translation adjustments due to the strengthening of the euro against the U.S. dollar.

The assumptions and estimates used to determine future cash flows and remaining useful lives of our intangible and other long-lived assets are complex and subjective. They can be affected by various factors, including external factors, such as industry and economic trends, and internal factors such as changes in our business strategy and our forecasts for specific product lines.

Based on finite-lived intangible assets recorded as of March 31, 2016, and assuming the underlying assets will not be impaired and that we will not change the expected lives of the assets, future amortization expenses were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2016 (remaining)	$ 80,539
2017	107,385
2018	104,480
2019	104,255
2020	103,044
Thereafter	708,139
Total	$ 1,207,842

6. Certain Balance Sheet Items

Property and equipment consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Construction-in-progress	$ 66,185	$ 63,008
Computer software	15,273	15,797
Computer equipment	10,798	10,963
Leasehold improvements	9,262	9,301
Machinery and equipment	6,032	5,828
Furniture and fixtures	2,605	2,580
Land and buildings	1,838	1,775
Subtotal	111,993	109,252
Less accumulated depreciation and amortization	(25,205)	(23,680)
Property and equipment, net	$ 86,788	$ 85,572

Accrued liabilities consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Accrued milestone payment	$ 150,000	$ —
Rebates and other sales deductions	71,153	67,454
Employee compensation and benefits	28,634	35,595
Sales returns reserve	5,736	6,110
Royalties	5,679	4,211
Professional fees	3,446	3,038
Accrued interest	1,348	4,043
Accrued construction-in-progress	1,157	1,637
Contract claim settlement	—	18,000
Other	40,351	23,982
Total accrued liabilities	$ 307,504	$ 164,070

7. Debt

The following table summarizes the carrying amount of our indebtedness (in thousands):

	March 31, 2016	December 31, 2015
1.875% exchangeable senior notes due 2021	$ 575,000	$ 575,000
Unamortized discount on 1.875% exchangeable senior notes due 2021	(115,014)	(119,467)
1.875% exchangeable senior notes due 2021, net	459,986	455,533
Term loans	723,529	732,398
Other borrowings	510	513
Total debt	1,184,025	1,188,444
Less current portion	37,592	37,587
Total long-term debt	$ 1,146,433	$ 1,150,857

Exchangeable Senior Notes

The 2021 Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of Jazz Pharmaceuticals plc. The Issuer's obligations under the 2021 Notes are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. No subsidiary of Jazz Pharmaceuticals plc guaranteed the 2021 Notes. Subject to certain local law restrictions on payment of dividends, among other things, and potential negative tax consequences, we are not aware of any significant restrictions on the ability of Jazz Pharmaceuticals plc to obtain funds from the Issuer or Jazz Pharmaceuticals plc's other subsidiaries by dividend or loan, or any legal or economic restrictions on the ability of the Issuer or Jazz Pharmaceuticals plc's other subsidiaries to transfer funds to Jazz Pharmaceuticals plc in the form of cash dividends, loans or advances. There is no assurance that in the future such restrictions will not be adopted.

As of March 31, 2016, the carrying value of the equity component of the 2021 Notes, net of equity issuance costs, was $126.9 million.

Maturities

Scheduled maturities with respect to our long-term debt are as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2016 (remainder)	$ 28,193
2017	42,283
2018	61,038
2019	79,793
2020	520,452
Thereafter	575,000
Total	$ 1,306,759

8. Commitments and Contingencies

Indemnification

In the normal course of business, we enter into 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. Our exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against us. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations.

We have agreed to indemnify our executive officers, directors and certain other employees 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 we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage and the willingness of the insurer to assume coverage, and subject

to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we did not recognize any liabilities relating to these obligations as of March 31, 2016 and December 31, 2015. 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 we may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

We have noncancelable operating leases for our office buildings and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force. Future minimum lease payments under our noncancelable operating and facility leases as of March 31, 2016 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2016 (remainder)	$ 9,175
2017	13,014
2018	8,552
2019	7,277
2020	6,715
Thereafter	66,588
Total	$ 111,321

In January 2015, we entered into an agreement to lease office space located in Palo Alto, California in a building to be constructed by the landlord. We expect to occupy this office space by the end of 2017. In connection with this lease, the landlord is providing a tenant improvement allowance for the costs associated with the design, development and construction of tenant improvements for the leased facility. We are obligated to fund all costs incurred in excess of the tenant improvement allowance. The scope of the planned tenant improvements do not qualify as “normal tenant improvements” under the lease accounting guidance. Accordingly, for accounting purposes, we have concluded we are the deemed owner of the building during the construction period. As of March 31, 2016, we recorded project construction costs of $5.1 million incurred by the landlord as construction-in-progress in property and equipment, net and a corresponding financing obligation in other non-current liabilities in our condensed consolidated balance sheets. We will increase the asset and financing obligation as additional building costs are incurred by the landlord during the construction period. In the three months ended March 31, 2016, we recorded rent expense associated with the ground lease of $0.5 million in our condensed consolidated statements of income.

As of March 31, 2016, we had $53.4 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

We are involved in legal proceedings, including the following matters:

Xyrem ANDA Matters. On October 18, 2010, we received a notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Roxane’s initial notice alleged that all five patents then listed for Xyrem in the FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” or Orange Book, on the date of the notice are invalid, unenforceable or not infringed by Roxane’s proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane’s initial notice in the U.S. District Court for the District of New Jersey, or the District Court, seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane’s ANDA was stayed for 30 months, or until April 2013. That stay has expired. Additional patents covering Xyrem have been issued since December 2010, and after receiving Paragraph IV Certification notices from Roxane with respect to those patents, we have filed additional lawsuits against Roxane to include these additional patents in the litigation. All of the lawsuits filed against Roxane between 2010 and 2012 have been consolidated by the District Court into a single case, which we refer to as the first Roxane consolidated case. In the first Roxane consolidated case, we allege that 10 of our patents covering Xyrem are or will be infringed by Roxane’s ANDA and seek a permanent injunction to prevent Roxane from launching a generic version of Xyrem that would infringe these patents.

After receiving additional Paragraph IV Certification notices from Roxane, we filed three actions against Roxane in the District Court on February 20, 2015, June 1, 2015 and January 27, 2016 that have since been consolidated, which we refer to as the second Roxane consolidated case. In the second Roxane consolidated case, we allege that five of our patents covering

Xyrem are or will be infringed by Roxane's ANDA and seek a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe those patents.

In December 2013, the District Court permitted Roxane to amend its answer in the first Roxane consolidated case to allege certain equitable defenses, and the parties were given additional time for discovery on those new defenses. In addition, in March 2014, the District Court granted our motion to bifurcate and stay the portion of the first Roxane consolidated case regarding patents related to the distribution system for Xyrem. Although no trial date has been scheduled, we anticipate that trial on the patents in the first Roxane consolidated case that are not subject to the stay could occur as early as the third quarter of 2016. We do not have any estimate of a possible trial date on the patents in the first Roxane consolidated case that are currently subject to the stay or for the second Roxane consolidated case.

In April 2015, Roxane moved in the second Roxane consolidated case to dismiss claims involving our patent covering a part of the Xyrem label that instructs prescribers on adjusting the dose of Xyrem when it is being co-administered with divalproex sodium (also known as valproate or valproic acid) on the grounds that this patent does not cover patentable subject matter. In October 2015, the District Court administratively terminated this motion to dismiss (without prejudice) pending the outcome of IPR proceedings before the PTAB, relating to the patent that was the subject of Roxane's motion. Such IPR proceedings were filed by Par, Ranbaxy and Amneal and are discussed below.

The actual timing of events in our litigation with Roxane may be significantly earlier or later than we currently anticipate. We cannot predict the specific timing or outcome of events in these matters or the impact of these matters on other ongoing proceedings with any ANDA filer.

On December 10, 2012, we received notice of Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On January 18, 2013, we filed a lawsuit against Amneal in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. On November 21, 2013, we received notice of Paragraph IV Certification from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 27, 2013, we filed a lawsuit against Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents.

In April 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request in May 2014. The order consolidating the cases provides that Amneal's 30-month stay period will be extended to coincide with the date of Par's 30-month stay period. As a result, the FDA's approval of both Amneal's and Par's ANDAs is stayed until the earlier of (i) May 20, 2016, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

Additional patents covering Xyrem have issued since April 2014 and have been listed in the Orange Book for Xyrem. Amneal and Par have given us additional notices of Paragraph IV Certifications regarding such patents, and we have filed additional lawsuits against Amneal and Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's and Par's ANDAs and seeking a permanent injunction to prevent Amneal and Par from introducing a generic version of Xyrem that will infringe these patents.

On June 4, 2014, we received a notice of Paragraph IV Certification from Ranbaxy Laboratories Limited, or Ranbaxy, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On July 15, 2014, we filed a lawsuit against Ranbaxy in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that will infringe these patents. Since June 2014, we have received additional notices of Paragraph IV Certification from Ranbaxy regarding newly issued patents for Xyrem listed in the Orange Book, and we have filed additional lawsuits against Ranbaxy in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that will infringe these patents.

On October 30, 2014, we received a notice of Paragraph IV Certification from Watson Laboratories, Inc., or Watson, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Watson in the District Court alleging that our patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents. In March 2015, Watson moved to dismiss the portion of the case based on our Orange Book-listed patents covering the distribution system for Xyrem on the grounds that these patents do not cover patentable subject matter. In November 2015, the District Court administratively terminated this motion to dismiss (without prejudice) pending the outcome of IPR proceedings before the PTAB relating to the patents that were the subject of Watson's motion. Since March 2015, we have received an additional notice of Paragraph IV Certification from Watson regarding newly issued patents for Xyrem listed in the Orange Book, and we have filed an additional lawsuit against Watson in the District Court alleging that our

patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents.

In April 2015, the District Court issued an order that consolidated all then-pending lawsuits against Amneal, Par, Ranbaxy and Watson into one case.

On June 8, 2015, we received a Paragraph IV Certification from Wockhardt Bio AG, or Wockhardt, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On July 17, 2015, we filed a lawsuit in the District Court alleging that our patents covering Xyrem were or would be infringed by Wockhardt's ANDA and seeking a permanent injunction to prevent Wockhardt from introducing a generic version of Xyrem that would infringe our patents. On November 26, 2015, we received an additional notice of Paragraph IV Certification from Wockhardt regarding newly issued patents listed in the Orange Book, and we filed an additional lawsuit against Wockhardt in the District Court alleging that our patents covering Xyrem were or would be infringed by Wockhardt's ANDA and seeking a permanent injunction to prevent Wockhardt from introducing a generic version of Xyrem that would infringe these patents.

On July 23, 2015, we received a Paragraph IV Certification from Lupin Inc., or Lupin, that it has submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On September 2, 2015, we filed a lawsuit in the District Court alleging that our patents covering Xyrem are or will be infringed by Lupin's ANDA and seeking a permanent injunction to prevent Lupin from introducing a generic version of Xyrem that would infringe our patents.

In January 2016, the District Court issued an order consolidating all of the cases then pending against Amneal, Par, Ranbaxy, Watson, Wockhardt and Lupin into a single case for all purposes. In April 2016, the District Court issued orders consolidating two cases against Amneal and Ranbaxy relating to later-issued patents with the previously consolidated case against Amneal, Par, Ranbaxy, Watson and Lupin.

We entered into settlement agreements with Wockhardt and Ranbaxy on April 18, 2016 and May 9, 2016, respectively, that resolved our patent litigation against Wockhardt and Ranbaxy. Under the settlement agreements, we granted each of Wockhardt and Ranbaxy a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events. The specific terms of the settlement agreements are confidential.

The settlements with Wockhardt and Ranbaxy do not resolve the litigation against Amneal, Par, Watson and Lupin, which is ongoing. We cannot predict the specific timing or outcome of events in this matter with respect to the remaining defendants or the impact of developments involving any specific parties or patents on other ongoing proceedings with any ANDA filer.

Xyrem Post-Grant Patent Review Matters. In January 2015, certain of the ANDA filers filed petitions for IPR with respect to the validity of six patents covering the distribution system for Xyrem. In July 2015, the PTAB issued decisions instituting IPR trials with respect to these petitions, and we expect the PTAB to issue final decisions on the validity of the patents in July 2016. In September 2015, certain of the ANDA filers filed a petition for IPR with respect to the validity of an additional patent covering the distribution system for Xyrem. In March 2016, the PTAB issued a decision instituting an IPR trial with respect to three claims of the patent subject to this petition, and we expect the PTAB to issue final decisions on the validity of these claims in March 2017. The PTAB denied the petition with respect to the other 25 claims of the patent.

In October 2015, Ranbaxy and Par filed petitions for IPR with respect to the validity of one of our patents covering a method for prescribing Xyrem when it is being co-administered with divalproex sodium, and Amneal filed an IPR petition on the same patent in February 2016. In April 2016, the PTAB denied Par's petition in its entirety and issued a decision on Ranbaxy's petition, instituting an IPR trial with respect to 16 of the claims under the patent subject to this petition and denying the petition with respect to the other 18 claims. We expect a decision on the Amneal petition in August 2016. In March 2016, Ranbaxy filed a petition for IPR with respect to the validity of the second of our patents covering a method for prescribing Xyrem when it is being co-administered with divalproex sodium. In connection with settlement of our litigation with Ranbaxy in May 2016, we expect to file a joint motion with Ranbaxy to terminate both of the IPR petitions filed by Ranbaxy.

In December 2015, Wockhardt filed a petition for IPR with respect to the validity of one of our patents covering the formulation of Xyrem. In April 2016, following settlement of our patent litigation against Wockhardt, we and Wockhardt filed a joint motion to terminate the IPR petitions filed or joined by Wockhardt.

We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, whether the PTAB will terminate the IPRs as requested by the parties, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

Other Contingencies

We have not previously submitted pricing data for two radiopharmaceutical products, Quadramet® (samarium sm 153 lexidronam injection) and ProstaScint® (capromab pendetide), for Medicaid and the Public Health Service's 340B drug pricing discount program, or 340B program. We engaged in interactions with the Centers for Medicare and Medicaid Services, or CMS, and a trade group, the Council on Radionuclides and Radiopharmaceuticals, or CORAR, regarding the reporting of Medicaid pricing data and paying Medicaid rebates for radiopharmaceutical products. In addition to the discussions with CMS as part of CORAR, we have had separate discussions with CMS directly regarding Quadramet. We sold Quadramet to a third party in December 2013, but we retained any liabilities related to sales of the product during prior periods. Similarly, we sold ProstaScint to a third party in May 2015, but we retained any liabilities related to sales of the product during prior periods. We are currently unable to predict whether price reporting and rebates will be required for Quadramet and ProstaScint and, if so, for what period they will be required. The initiation of any reporting of Medicaid pricing data for Quadramet or ProstaScint could result in retroactive 340B ceiling price liability for these two products. We are currently unable to reasonably estimate an amount or range of a potential contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results.

In May 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, and, for Xyrem, documents concerning our provision of financial assistance to Medicare patients. Other companies have disclosed similar inquiries. We intend to cooperate with this subpoena. We are unable to predict how long this investigation will continue or its outcome, but it is possible that we will incur significant costs in connection with the investigation, regardless of the outcome.

9. Shareholders' Equity

The following tables present a reconciliation of our beginning and ending balances in shareholders' equity for the three months ended March 31, 2016 and 2015, respectively (in thousands):

	Total Shareholders' Equity
Shareholders' equity at January 1, 2016	$ 1,598,646
Issuance of ordinary shares in conjunction with employee equity incentive plans	3,780
Employee withholding taxes related to share-based awards	(12,476)
Share-based compensation	24,608
Tax benefit from employee share options	7,938
Shares repurchased	(134,365)
Other comprehensive income	45,188
Net income	74,121
Shareholders' equity at March 31, 2016	$ 1,607,440

	Attributable to:		
	Jazz Pharmaceuticals plc	Noncontrolling interests	Total Shareholders' Equity
Shareholders' equity at January 1, 2015	$ 1,371,144	$ 64	$ 1,371,208
Issuance of ordinary shares in conjunction with employee equity incentive plans	13,504	—	13,504
Employee withholding taxes related to share-based awards	(14,778)	—	(14,778)
Share-based compensation	20,896	—	20,896
Tax benefit from employee share options	10,635	—	10,635
Shares repurchased	(10,338)		(10,338)
Other comprehensive loss	(156,487)	(10)	(156,497)
Net income	70,700	—	70,700
Shareholders' equity at March 31, 2015	$ 1,305,276	$ 54	$ 1,305,330

Share Repurchase Program

In November 2015, our board of directors authorized a share repurchase program pursuant to which we are authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300 million, exclusive of any brokerage commissions. Under this share repurchase program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. In the three months ended March 31, 2016, we spent a total of $134.4 million to purchase 1.1 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $123.77 per share. All ordinary shares repurchased by us were canceled.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of March 31, 2016 and December 31, 2015 were as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2015	$ (267,472)	$ (267,472)
Other comprehensive income	45,188	45,188
Balance at March 31, 2016	$ (222,284)	$ (222,284)

During the three months ended March 31, 2016, other comprehensive income reflects foreign currency translation adjustments, primarily due to the strengthening of the euro against the U.S. dollar.

10. Segment and Other Information

Our operating segment is reported in a manner consistent with the internal reporting provided to the chief operating decision maker, or CODM. Our CODM has been identified as our chief executive officer. We have determined that we operate in one business segment, which is the identification, development and commercialization of meaningful pharmaceutical products that address unmet medical needs. The following table presents a summary of total revenues (in thousands):

	Three Months Ended March 31,	
	2016	2015
Xyrem® (sodium oxybate) oral solution	$ 249,537	$ 212,690
Erwinaze®/Erwinase® (asparaginase *Erwinia chrysanthemi*)	51,173	50,353
Defitelio® (defibrotide sodium)/defibrotide	17,897	17,363
Prialt® (ziconotide) intrathecal infusion	6,209	6,764
Psychiatry	7,002	9,093
Other	2,098	10,772
Product sales, net	333,916	307,035
Royalties and contract revenues	2,094	2,268
Total revenues	$ 336,010	$ 309,303

The following table presents a summary of total revenues attributed to geographic sources (in thousands):

	Three Months Ended March 31,	
	2016	2015
United States	$ 305,879	$ 269,247
Europe	25,020	32,635
All other	5,111	7,421
Total revenues	$ 336,010	$ 309,303

The following table presents a summary of the percentage of total revenues from customers that represented more than 10% of our total revenues:

	Three Months Ended March 31,	
	2016	2015
Express Scripts	74%	69%
McKesson	13%	1%
Accredo Health Group, Inc.	—%	13%

At the end of the second quarter of 2015, we transitioned the U.S. distribution of Erwinaze from Accredo Health Group, Inc. to McKesson.

The following table presents total long-lived assets, consisting of property and equipment, by location (in thousands):

	March 31, 2016	December 31, 2015
Ireland	$ 64,070	$ 62,795
United States	12,757	12,794
Italy	7,941	7,928
Other	2,020	2,055
Total long-lived assets	$ 86,788	$ 85,572

11. Share-Based Compensation

Share-based compensation expense related to share options, RSUs and grants under our ESPP was as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Selling, general and administrative	$ 20,204	$ 16,639
Research and development	3,290	3,485
Cost of product sales	689	695
Total share-based compensation expense, pre-tax	24,183	20,819
Tax benefit from share-based compensation expense	(6,963)	(6,154)
Total share-based compensation expense, net of tax	$ 17,220	$ 14,665

Share Options

The table below shows the number of shares underlying options granted to purchase our ordinary shares, the weighted-average assumptions used in the Black-Scholes option pricing model and the resulting weighted-average grant date fair value of share options granted:

	Three Months Ended March 31,	
	2016	2015
Shares underlying options granted (in thousands)	1,009	880
Grant date fair value	$ 40.17	$ 57.49
Black-Scholes option pricing model assumption information:		
Volatility	39%	39%
Expected term (years)	4.2	4.2
Range of risk-free rates	1.0-1.5%	1.1-1.3%
Expected dividend yield	—%	—%

Restricted Stock Units

The table below shows the number of RSUs granted covering an equal number of our ordinary shares and the weighted-average grant date fair value of RSUs granted:

	Three Months Ended March 31,	
	2016	2015
RSUs granted (in thousands)	400	338
Grant date fair value	$ 123.46	$ 174.56

The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares on that date. The fair value of RSUs is expensed ratably over the vesting period of four years.

As of March 31, 2016, compensation cost not yet recognized related to unvested share options and RSUs was $95.5 million and $109.7 million, respectively, which is expected to be recognized over a weighted-average period of 2.8 years and 2.7 years, respectively.

12. Restructuring

In the three months ended March 31, 2016, we recorded severance costs of $1.4 million for terminated employees in connection with the reorganization of our operations primarily in France and Italy. These one-time termination benefits were recorded over the remaining service period where employees were required to stay through their termination date to receive the benefits and included within cost of product sales and selling, general and administrative expenses in our consolidated statements of income. As of March 31, 2016, we had incurred total termination benefit costs of $2.5 million in connection with this reorganization. We do not expect to incur any additional material one-time termination benefit costs relating to these restructuring activities in 2016.

The following table summarizes the amounts related to restructuring through March 31, 2016 (in thousands):

	Termination Benefits
Balance at December 31, 2015	$ 1,105
Expense	1,410
Payments	(879)
Balance at March 31, 2016	$ 1,636

The balances as of March 31, 2016 and December 31, 2015 were included within accrued liabilities in our condensed consolidated balance sheets.

13. Income Taxes

Our income tax provision was $34.0 million and $32.1 million in the three months ended March 31, 2016 and 2015, respectively. The effective tax rates were 31.5% and 31.2% in the three months ended March 31, 2016 and 2015, respectively. The increase in the effective tax rate for the three months ended March 31, 2016 compared to the same period in 2015 was primarily due to the impact of changes in tax rates in certain jurisdictions in which we operate and a decrease in originating tax credits, partially offset by changes in income mix among the various jurisdictions in which we operate. The effective tax rate for the three months ended March 31, 2016 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, uncertain tax positions, and various expenses not deductible for tax purposes, partially offset by originating tax credits and deductions available in relation to subsidiary equity. We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

Our deferred tax assets are comprised primarily of U.S. federal and state net operating loss carryforwards and tax credit carryforwards, foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain U.S. state and foreign deferred tax assets. Each reporting period, we evaluate the need for a valuation allowance on our deferred tax assets by jurisdiction and adjust our estimates as more information becomes available.

We are required to 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. As a result, we have established a liability for certain tax benefits which we judge may not be sustained upon examination. Our most significant tax jurisdictions are Ireland, the United

States (both at the federal level and in various state jurisdictions), Italy and France. Because of our net operating loss carryforwards and tax credit carryforwards, substantially all of our tax years remain open to federal, state, and foreign tax examination. Certain of our subsidiaries are currently under examination by the French tax authorities for fiscal years 2012 and 2013 and by Italian tax authorities for fiscal year 2012. These examinations may lead to ordinary course adjustments or proposed adjustments to our taxes. In December 2015, we received proposed tax assessment notices from the French tax authorities for 2012 and 2013 relating to certain transfer pricing adjustments. The notices propose additional French tax of approximately $43.3 million, including interest and penalties through the date of the assessment, translated at the foreign exchange rate at March 31, 2016. We disagree with the proposed assessment and intend to contest it vigorously.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that could impact our business. In particular, we encourage you to review the risks and uncertainties described in Part II, Item 1A "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations. See the "Cautionary Note Regarding Forward-Looking Statements" that appears at the end of this discussion. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Overview

Jazz Pharmaceuticals plc is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs.

We have a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in patients with narcolepsy;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Defitelio® (defibrotide sodium)**, a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, or SOS, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications;
- Acquiring clinically meaningful and differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing targeted development of post-discovery differentiated product candidates.

We apply a disciplined approach to allocating our resources between investments in our current commercial and development portfolio and acquisitions or in-licensing of new assets.

In the three months ended March 31, 2016, our total net product sales increased by 9% compared to the same period in 2015, primarily due to an increase in Xyrem product sales. We expect total net product sales to increase in 2016 over 2015, primarily due to anticipated growth in sales of Xyrem and Defitelio. For additional information regarding our net product sales, see "—Results of Operations."

On March 30, 2016, the FDA granted marketing approval for Defitelio for the treatment of adult and pediatric patients with VOD, also known as SOS, with renal or pulmonary dysfunction following HSCT. We launched Defitelio in the U.S. shortly after FDA approval.

In the three months ended March 31, 2016, we continued our focus on research and development activities, which currently include clinical development of new product candidates, activities related to line extensions and new indications for existing products and the generation of additional clinical data for existing products, all in our sleep and hematology/oncology therapeutic areas.

A summary of our ongoing development activities is provided below:

Project	Disease Area	Status
Sleep		
JZP-110	EDS in narcolepsy	Phase 3 clinical trial initiated in second quarter of 2015; targeting preliminary data by the end of the fourth quarter of 2016
	EDS in obstructive sleep apnea, or OSA	Two Phase 3 clinical trials initiated in second quarter of 2015; targeting preliminary data by the end of the fourth quarter of 2016
JZP-386	EDS in narcolepsy	Phase 1 clinical trials completed; further evaluation ongoing
Xyrem	Cataplexy with narcolepsy in children and adolescents	Phase 3 clinical trial ongoing; enrollment completion expected in second half of 2016
Hematology/Oncology		
Defibrotide	Prevention of VOD in high-risk patients	Preparing to initiate Phase 3 clinical trial; initiation of patient enrollment expected by the fourth quarter of 2016

In the sleep area, we have ongoing and planned development programs for Xyrem and certain other product candidates.

- *JZP-110.*

  Phase 3 Clinical Trials. JZP-110 is a late-stage investigational compound being developed for potential treatment of EDS in patients with narcolepsy and EDS in patients with OSA. We acquired worldwide development, manufacturing and commercial rights to JZP-110 from Aerial BioPharma LLC, or Aerial, in January 2014, other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights. We initiated patient enrollment in our Phase 3 clinical program in the second quarter of 2015. We are conducting one Phase 3 clinical trial in patients with EDS associated with narcolepsy and two Phase 3 clinical trials in patients with EDS associated with OSA. Approximately 800 patients are expected to be enrolled in these three trials in the aggregate. We are targeting preliminary data from these trials by the end of the fourth quarter of 2016. However, our ability to meet this goal for each trial depends on an acceleration of enrollment rates. Subject to the results of these trials, we anticipate submitting an NDA in the second half of 2017. In addition, we expect to enroll up to 600 patients from certain of our Phase 2 and Phase 3 clinical trials in an open label extension trial evaluating the long-term safety and maintenance of efficacy of JZP-110.

  Other Activities. We are also exploring additional potential indications for JZP-110.

- *Xyrem.*

  Phase 3 Clinical Trial of Xyrem in Children and Adolescents. While in many patients narcolepsy can begin during childhood and adolescence, there is limited information on the treatment of pediatric narcolepsy patients with Xyrem. We have worked with the FDA and several leading specialists to design a clinical trial to generate additional data on the treatment of pediatric narcolepsy patients with Xyrem. In the fourth quarter of 2014, we initiated a Phase 3 clinical trial to assess the safety and efficacy of Xyrem in children and adolescents aged seven to 17 who have narcolepsy with cataplexy. We expect to complete enrollment in this trial in the second half of 2016.

  Other Activities. We are also pursuing other activities related to the potential development of options for narcolepsy patients that would provide clinically meaningful improvements compared to Xyrem, including once-nightly dosing. Although results from our Phase 1 trial of JZP-386, a deuterium-modified analog of sodium oxybate, which we licensed from Concert Pharmaceuticals, Inc., or Concert, in February 2013, did not support advancing JZP-386 into a later-stage clinical trial, the clinical data demonstrated that JZP-386 provided favorable deuterium-related effects, including higher serum concentrations and correspondingly increased pharmacodynamics effects at clinically relevant time points compared to Xyrem, and a safety profile similar to that observed with Xyrem. We are exploring formulation options designed to leverage the positive effects observed in the studies.

In the hematology and oncology area, we also have ongoing and planned development activities.

- *Defibrotide.*

  Planned Phase 3 Clinical Trial. We are preparing to commence a Phase 3 clinical trial to evaluate the safety and efficacy of defibrotide for the prevention of VOD in high-risk patients. We expect to initiate patient enrollment by the fourth quarter of 2016.

  Other Activities. We are also exploring additional potential indications for defibrotide and assessing the potential to pursue regulatory approval of defibrotide in additional countries.

- *Erwinaze.* We are pursuing activities related to the potential development of an effective and well-tolerated long-acting recombinant crisantaspase that would offer benefits compared to Erwinaze. We are also assessing the potential to pursue regulatory approval of Erwinaze in additional countries.

For 2016 and beyond, we expect that our research and development expenses will increase from historical levels, particularly as we initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates. We anticipate that we will continue to face a number of challenges and risks to our business and our ability to execute our strategy for the remainder of 2016 and beyond. Some of these challenges and risks are specific to our business, and others are common to companies in the pharmaceutical industry with development and commercial operations.

Xyrem. Our financial results remain significantly influenced by sales of Xyrem, which accounted for 75% of our net product sales in the three months ended March 31, 2016 and 73% of our net product sales in the year ended December 31, 2015. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product. We are also focusing on the lifecycle management of Xyrem, including seeking to enhance and enforce our intellectual property rights and to develop product, service and safety improvements for patients.

Our ability to maintain or increase Xyrem product sales is subject to risks and uncertainties, including those discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. In particular, seven companies have sent us notices that they have filed abbreviated new drug applications, or ANDAs, with the FDA seeking approval to market a generic version of Xyrem. We have filed lawsuits against each of these companies seeking to prevent the introduction of a generic version of Xyrem that would infringe our patents, and in the second quarter of 2016, we settled two of these lawsuits. We cannot predict the timing or outcome of the ongoing litigation proceedings. Although no trial date has been set in any of the current ANDA suits, we anticipate that trial on some of the patents in the case against the first ANDA filer, Roxane Laboratories, Inc., or Roxane, could occur as early as the third quarter of 2016. Certain ANDA filers have also filed petitions for *inter partes* review, or IPR, by the Patent Trial and Appeal Board, or the PTAB, of the U.S. Patent and Trademark Office, or USPTO, with respect to the validity of certain distribution, method of use and formulation patents covering Xyrem. The PTAB has issued decisions instituting IPR trials with respect to patents and patent claims that are the subject of certain of these petitions, and we expect the PTAB to issue final decisions in the first of these trials in July 2016. For a description of these matters, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate products that compete with Xyrem, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Approval of an ANDA with respect to a generic version of Xyrem will require a risk evaluation and mitigation strategy, or REMS, which may be either a single shared REMS with Xyrem or a separate REMS with differing but comparable aspects of elements to assure safe use, or ETASU, in the approved Xyrem REMS. We and the ANDA applicants had interactions with respect to developing a single shared REMS for several years. The ANDA applicants are not currently engaging in single shared REMS discussions with us, but we are seeking to continue the interactions with the goal of developing a single shared REMS. However, we cannot predict whether, or to what extent, our interactions with the ANDA applicants will continue or whether we will develop a single shared REMS. We are aware that, separate from the discussions with us, the FDA and ANDA applicants have exchanged communications regarding a REMS for sodium oxybate. If we and the ANDA applicants do not develop a single shared REMS, or we do not license or share intellectual property pertinent to our Xyrem REMS with generic competitors within a time frame or on terms that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to approve the ANDA of one or more generic competitors with a separate REMS that differs in some aspects from our approved Xyrem REMS. We also may face pressure to develop a single shared REMS with potential generic competitors for Xyrem that is different from the approved Xyrem REMS or to license or share intellectual property pertinent to the Xyrem REMS, or elements of the Xyrem REMS, including proprietary data required for safe distribution of sodium oxybate, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared REMS for sodium oxybate, licensing or sharing intellectual property pertinent to our Xyrem REMS or elements of the Xyrem REMS, or the FDA's response to a request by one or more ANDA applicants for a waiver of the requirement for a single shared REMS, including in connection with a certification that the applicant had been unable to obtain a license. The FDA's response to any such request could include approval of one or more ANDAs. In addition, the Federal Trade Commission, or FTC, other governmental authorities or others could claim or determine that we are using the Xyrem REMS in an anticompetitive manner (including in light of the FDA's statement in the Xyrem REMS approval letter that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the Federal Food, Drug and Cosmetic Act, or FDCA) or have engaged in other anticompetitive practices.

In late August 2015, we implemented the final Xyrem REMS, which was approved by the FDA in February 2015, and we have submitted and expect to continue to submit ongoing assessments as set forth in the FDA's Xyrem REMS approval letter. The process under which enrolled patients receive Xyrem is complex, and we are continuing to transition prescribers and patients to the final Xyrem REMS process and documentation requirements. We cannot guarantee that we will be able to

complete the transition of prescribers and patients to the final Xyrem REMS in a timely manner, that our ongoing assessments will be satisfactory to the FDA or that the Xyrem REMS will satisfy the FDA's expectations in its evaluation of the Xyrem REMS on an ongoing basis. Any failure to comply with the REMS obligations could result in enforcement action by the FDA; lead to changes in our Xyrem REMS obligations; negatively affect sales of Xyrem; result in additional costs and expenses for us; and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. Further, we cannot predict whether the FDA will seek to require or ultimately require modifications to the Xyrem REMS, including with respect to the distribution system, or seek to otherwise impose or ultimately impose additional requirements to the Xyrem REMS, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could potentially make it easier for ANDA applicants to obtain FDA approval of their ANDAs, make it more difficult or expensive for us to distribute Xyrem, make distribution easier for future generic competitors, impair the safety profile of Xyrem and/or negatively affect sales of Xyrem.

Obtaining and maintaining appropriate reimbursement for Xyrem in the U.S. is increasingly challenging due to, among other things, the attention being paid to healthcare cost containment and prescription drug pricing, pricing pressure from third party payors and increasingly restrictive reimbursement conditions being imposed by third party payors. In this regard, we have experienced and expect to continue to experience increasing pressure from third party payors to agree to discounts, rebates or other pricing terms for Xyrem. Any such restrictive pricing terms or additional reimbursement conditions could have a material adverse effect on our Xyrem revenues. In addition, drug pricing by pharmaceutical companies has recently come under close scrutiny, particularly with respect to companies that have increased the price of products after acquiring those products from other companies. We expect that healthcare policies and reforms intended to curb healthcare costs will continue to be proposed, which could limit the prices that we charge for our products, including Xyrem, limit our commercial opportunity and/or negatively impact revenues from sales of our products. Also, price increases on Xyrem and our other products, and negative publicity regarding pricing and price increases generally, whether with respect to our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of Xyrem and our other products.

Erwinaze/Erwinase. Sales of our second largest product, Erwinaze/Erwinase (which we refer to in this report as Erwinaze unless otherwise indicated or the context otherwise requires), accounted for 15% of our net product sales in the three months ended March 31, 2016 and in the year ended December 31, 2015. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing sales and marketing and research and development activities. However, a significant challenge to our ability to maintain current sales levels and to increase sales is our extremely limited inventory of Erwinaze and our need to avoid supply interruptions of Erwinaze due to capacity constraints, production delays, quality or regulatory challenges or other manufacturing difficulties. Erwinaze is licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL. The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product. We are working with PBL to evaluate potential expansion of its production capacity to increase the supply of Erwinaze over the longer term. As a consequence of constrained manufacturing capacity, we have had an extremely limited or no ability to build product inventory levels that can be used to absorb disruptions to supply resulting from quality, regulatory or other issues, and we have experienced product quality, manufacturing and inventory challenges that have resulted in disruptions in our ability to supply certain markets and caused us to implement batch-specific, modified product use instructions. We expect that we will continue to experience inventory challenges. If capacity constraints or supply disruptions continue, whether as a result of continued quality or other manufacturing issues, regulatory issues or otherwise, we may be unable to build a desired excess level of product inventory, our ability to supply the market may continue to be compromised and physicians' decisions to use Erwinaze in the future may be negatively impacted. If we fail to obtain a sufficient supply of Erwinaze, our sales of and revenues from Erwinaze, our potential future maintenance and growth of the market for this product, and/or our business, financial condition, results of operations and growth prospects could be materially adversely affected. Our ability to successfully and sustainably maintain or grow sales of Erwinaze is also subject to a number of other risks and uncertainties, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population, our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries, as well as those other risks and uncertainties discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Defitelio. Sales of Defitelio accounted for 5% of our net product sales in the three months ended March 31, 2016 and in the year ended December 31, 2015. We acquired this product in January 2014 in connection with our acquisition of Gentium S.r.l., or Gentium, which we refer to as the Gentium Acquisition, and secured worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. We launched Defitelio in certain European countries in 2014 and continue to launch in additional European countries on a rolling basis. On March 30, 2016, the FDA approved our new drug application, or NDA, for Defitelio for the treatment of adult and pediatric patients with VOD, also known as SOS, with renal or pulmonary dysfunction following HSCT. We launched Defitelio in the U.S. shortly after FDA approval.

Our ability to realize the anticipated benefits from our investment in this product is subject to risks and uncertainties, including:

- the acceptance of Defitelio in the U.S. by hospital pharmacy and therapeutics committees and the availability of adequate coverage and reimbursement by government programs and third party payors;
- U.S. market acceptance of Defitelio at its commercial price now that it is no longer available to new patients under an expanded access treatment protocol;
- the lack of experience of U.S. physicians in diagnosing and treating VOD, particularly in adults, and the possibility that physicians may delay initiation of treatment or terminate treatment before the end of the recommended dosing schedule;
- our ability to successfully maintain or grow sales of Defitelio in Europe;
- delays or problems in the supply or manufacture of the product;
- the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in HSCT treatment protocols reduce the incidence of VOD);
- our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA for Defitelio; and
- our ability to obtain marketing approval in other countries and to develop the product for additional indications.

If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product will be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. For more information, see the risk factor under the heading "*While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

In addition to risks specifically related to Xyrem, Erwinaze and Defitelio, other key challenges and risks that we face include risks and uncertainties related to:

- the challenges of protecting and enhancing our intellectual property rights;
- the challenges of achieving and maintaining commercial success of our products;
- delays or problems in the supply or manufacture of our products, particularly with respect to certain products as to which we maintain limited inventories, and our dependence on single source suppliers to continue to meet our ongoing commercial demand or our requirements for clinical trial supplies;
- the need to obtain and maintain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the U.S. in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by third party payors;
- our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business;
- the challenges of compliance with the requirements of the FDA, the U.S. Drug Enforcement Administration, or DEA, and non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, adverse event reporting and product recalls or withdrawals;
- the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, and the uncertainty of clinical success, such as the risk that results from preclinical studies and/or early clinical trials may not be predictive of results obtained in later and larger clinical trials planned or anticipated to be conducted for our product candidates;
- the inherent uncertainty associated with the regulatory approval process, especially as we continue to undertake increased activities and make growing investment in our product pipeline development projects;
- the risks associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historic business, the increase in geographic dispersion among our centers of operation and the risks that we may acquire unanticipated liabilities along with acquired businesses or otherwise fail to realize the anticipated benefits (commercial or otherwise) from such transactions; and

- possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

Any of these risks and uncertainties could have a material adverse effect on our business, financial condition, results of operations and growth prospects. All of these risks and uncertainties are discussed in greater detail, along with other risks and uncertainties, in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Results of Operations

The following table presents revenues and expenses for the three months ended March 31, 2016 and 2015, respectively (in thousands, except percentages):

	Three Months Ended March 31,		Increase/
	2016	2015	(Decrease)
Product sales, net	$ 333,916	$ 307,035	9%
Royalties and contract revenues	2,094	2,268	(8)%
Cost of product sales (excluding amortization of intangible assets)	23,439	28,298	(17)%
Selling, general and administrative	128,765	112,388	15%
Research and development	31,252	27,181	15%
Acquired in-process research and development	8,750	—	N/A(1)
Intangible asset amortization	22,642	24,677	(8)%
Interest expense, net	12,192	16,245	(25)%
Foreign currency (gain) loss	819	(2,245)	(136)%
Income tax provision	34,030	32,059	6%

(1) Comparison to prior period not meaningful.

Revenues

The following table presents product sales, royalties and contract revenues, and total revenues for the three months ended March 31, 2016 and 2015, respectively (in thousands, except percentages):

	Three Months Ended March 31,		Increase/
	2016	2015	(Decrease)
Xyrem® (sodium oxybate) oral solution	$ 249,537	$ 212,690	17%
Erwinaze®/Erwinase® (asparaginase *Erwinia chrysanthemi*)	51,173	50,353	2%
Defitelio® (defibrotide sodium)/defibrotide	17,897	17,363	3%
Prialt® (ziconotide) intrathecal infusion	6,209	6,764	(8)%
Psychiatry	7,002	9,093	(23)%
Other	2,098	10,772	(81)%
Product sales, net	333,916	307,035	9%
Royalties and contract revenues	2,094	2,268	(8)%
Total revenues	$ 336,010	$ 309,303	9%

Product Sales, Net

Xyrem product sales increased in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to a higher average net selling price and, to a lesser extent, an increase in sales volume. A price increase was instituted in February 2016. Xyrem product sales volume increased by 4% in the three months ended March 31, 2016 compared to the same period in 2015. The sales volume increase was driven by an increase in the average number of patients on Xyrem, which includes new patients, patients who have restarted Xyrem therapy and active patients who remained on Xyrem therapy. Erwinaze product sales increased in the three months ended March 31, 2016 compared to the same period in 2015, due to price

increases instituted in January 2016 and July 2015 and, to a lesser extent, an increase in sales volume, partially offset by higher chargebacks and rebates resulting from increased utilization under the 340B drug pricing discount and Medicaid programs. The Erwinaze sales volume increase was primarily driven by existing treatment sites identifying additional ALL patients with hypersensitivity to *E. coli*-derived asparaginase and, to a lesser extent, growth in new treatment sites prescribing Erwinaze. In the three months ended March 31, 2016, Erwinaze sales volume was impacted by continuing supply challenges that disrupted our ability to supply certain markets. Defitelio/defibrotide product sales increased by 3% in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to higher average net selling prices and, to a lesser extent, an increase in sales volume, partially offset by the impact of foreign exchange on sales made in euro. Prialt product sales decreased in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to a decrease in sales volumes. Psychiatry product sales decreased in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to generic competition. Other sales decreased in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to our sale of certain products and the related business that we acquired as part of our acquisition of EUSA Pharma Inc., or EUSA Pharma, which we refer to as the EUSA Acquisition. We expect total product sales will increase in 2016 over 2015, primarily due to anticipated growth in sales of our lead marketed products, partially offset by decreases in sales of certain other products.

Royalties and Contract Revenues

Royalties and contract revenues decreased slightly in the three months ended March 31, 2016 compared to the same period in 2015. We expect royalties and contract revenues in 2016 to increase slightly compared to 2015, primarily due to higher royalties on our out-licensed products.

Cost of Product Sales

Cost of product sales decreased in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to a change in product mix, partially offset by an increase in net product sales. Gross margin as a percentage of net product sales in the three months ended March 31, 2016 was 93.0% compared to 90.8% for the same period in 2015. The increase in our gross margin percentage in the three months ended March 31, 2016 was primarily due to a change in product mix. We expect that our cost of product sales in 2016 will be higher compared to 2015, primarily due to increased net product sales.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to an increase in compensation-related expenses of $8.1 million driven by higher headcount, an increase in legal fees and expenses and an increase in other expenses related to the expansion and support of our business. We expect selling, general and administrative expenses in 2016 to increase compared to 2015, primarily due to an increase in compensation-related expenses driven by higher headcount, expenses related to the launch of Defitelio in the U.S. and an increase in expenses related to REMS and pharmacy services.

Research and Development Expenses

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, milestone payments and other research and development costs. Clinical study and outside services costs relate primarily to services performed by clinical research organizations, materials and supplies, and other third party fees. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. We do not track fully-burdened research and development expenses on a project-by-project basis. We manage our research and development expenses by identifying the research and development activities that we anticipate will be performed during a given period and then prioritizing efforts based on our assessment of which development activities are important to our business and have a reasonable probability of success, and by dynamically allocating resources accordingly. We also continually review our development pipeline projects and the status of their development and, as necessary, reallocate resources among our development pipeline projects that we believe will best support the future growth of our business.

The following table provides a breakout of our research and development expenses by major categories of expense (in thousands):

	Three Months Ended March 31,	
	2016	2015
Clinical studies and outside services	$ 18,556	$ 15,303
Personnel expenses	10,228	10,108
Other	2,468	1,770
Total	$ 31,252	$ 27,181

Research and development expenses increased by $4.1 million in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to increased clinical studies and outside services costs driven primarily by costs related to three Phase 3 clinical trials for JZP-110.

For 2016 and beyond, we expect that our research and development expenses will continue to increase from historical levels particularly as we initiate additional clinical trials and related development work and potentially acquire rights to additional product candidates. A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of our product candidates, and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Acquired In-Process Research and Development

Acquired in-process research and development expense in the three months ended March 31, 2016 related to an upfront payment of $8.8 million we made in connection with the acquisition of intellectual property and know-how related to recombinant crisantaspase.

Intangible Asset Amortization

Intangible asset amortization decreased in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to the impact of foreign exchange rates on euro-denominated assets and the cessation of amortization of certain intangible assets that were fully amortized in 2015. Intangible asset amortization is not expected to change materially in 2016 compared to 2015.

Interest Expense, Net

In June 2015, we terminated our previous credit agreement and entered into a new credit agreement, which we refer to as the June 2015 credit agreement. Interest expense, net decreased by $4.1 million in the three months ended March 31, 2016 compared to the same period in 2015, primarily due to a reduction in interest rates on borrowings under the June 2015 credit agreement compared to our previous credit agreement and a lower average debt balance. We expect interest expense will be lower in 2016 compared to 2015 due to the reduction in interest rates on borrowings under the June 2015 credit agreement compared to our previous credit agreement and a decrease in our average debt balance.

Foreign Currency Gain (Loss)

The foreign currency loss in the three months ended March 31, 2016 primarily related to the translation of euro-denominated net monetary liabilities, including intercompany balances, held by subsidiaries with a U.S. dollar functional currency.

Income Tax Provision

Our income tax provision was $34.0 million and $32.1 million in the three months ended March 31, 2016 and 2015, respectively. The effective tax rates were 31.5% and 31.2% for the three months ended March 31, 2016 and 2015, respectively. The increase in the effective tax rate for the three months ended March 31, 2016 compared to the same period in 2015 was primarily due to the impact of changes in tax rates in certain jurisdictions in which we operate and a decrease in originating tax credits, partially offset by changes in income mix among the various jurisdictions in which we operate. The effective tax rate for the three months ended March 31, 2016 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, unrecognized tax benefits, and various expenses not deductible for tax purposes, partially offset by originating tax credits and deductions available in relation to subsidiary equity.

Non-GAAP Financial Measures

To supplement our financial results presented in accordance with U.S. generally accepted accounting principles, or GAAP, we use certain non-GAAP (also referred to as adjusted or non-GAAP adjusted) financial measures as shown in the table below. We believe that each of these non-GAAP financial measures provides useful information to management, investors and analysts by excluding items that may not be indicative of our core operating results and business outlook. We regularly use these non-GAAP financial measures internally to understand, manage and evaluate our business and to make operating decisions, and compensation of executives is based in part on certain of these non-GAAP financial measures. In addition, we believe that these non-GAAP financial measures are useful to investors because they enhance investors' ability to compare our results from period to period; allow for greater transparency with respect to key financial metrics we use in making operating decisions; and are regularly used by investors and analysts to model and track our financial performance. These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our condensed consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used in this Quarterly Report on Form 10-Q have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Reconciliations of GAAP reported net income to non-GAAP adjusted net income and the related per share amounts are as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2016	2015
GAAP reported net income	$ 74,121	$ 70,700
Intangible asset amortization	22,642	24,677
Share-based compensation expense	24,183	20,819
Upfront and milestone payments	8,750	—
Expenses related to certain legal proceedings and restructuring	6,060	553
Transaction and integration related costs	—	155
Non-cash interest expense	5,362	6,016
Income tax adjustments (1)	(123)	2,148
Non-GAAP adjusted net income	$ 140,995	$ 125,068
GAAP reported net income per diluted share	$ 1.19	$ 1.12
Non-GAAP adjusted net income per diluted share	$ 2.26	$ 1.99
Weighted-average ordinary shares used in diluted per share calculations	62,474	62,964

(1) Tax adjustments to convert the income tax provision to the estimated amount of taxes payable in cash.

Liquidity and Capital Resources

As of March 31, 2016, we had cash, cash equivalents and investments of $980.5 million, borrowing availability under our revolving credit facility of $748.9 million and long-term debt of $1.3 billion. Our long-term debt included our $731.3 million aggregate principal amount term loan, $575.0 million principal amount of the 2021 Notes and other borrowings of $0.5 million. We generated cash flows from operations of $143.7 million during the three months ended March 31, 2016 and we expect to continue to generate positive cash flows from operations during 2016.

In March 2016, we recorded a $150.0 million milestone payable to Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, that was triggered by the FDA approval of Defitelio on March 30, 2016. The milestone was capitalized as an intangible asset in March 2016 and we paid the milestone to Sigma-Tau in April 2016.

We believe that our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future, including our obligations under the June 2015 credit agreement. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses, as well as the other factors set forth in Part II, Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q under the headings "*Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business,*

financial condition, results of operations and growth prospects," "If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected," "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk evaluation and mitigation strategy, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem," and *"To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business."* Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources and we may not be able to generate sufficient cash to service our debt obligations which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue new operations or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders, and the consent of the lenders under the June 2015 credit agreement could be required for certain financings.

In November 2015, our board of directors authorized a share repurchase program pursuant to which we are authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300 million, exclusive of any brokerage commissions. Under this share repurchase program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. In the three months ended March 31, 2016, we spent a total of $134.4 million to purchase 1.1 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $123.77 per share. All ordinary shares repurchased by us were canceled.

The following table presents a summary of our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2016	2015
Net cash provided by operating activities	$ 143,716	$ 96,555
Net cash provided by (used in) investing activities	(11,995)	18,293
Net cash used in financing activities	(144,520)	(3,261)
Effect of exchange rates on cash and cash equivalents	3,794	(13,026)
Net increase (decrease) in cash and cash equivalents	$ (9,005)	$ 98,561

Net cash provided by operating activities of $143.7 million for the three months ended March 31, 2016 related to net income of $74.1 million, adjusted for non-cash items of $56.1 million primarily related to intangible asset amortization and share-based compensation expense, and a net cash inflow of $13.5 million related to changes in operating assets and liabilities. Net cash provided by operating activities of $96.6 million for the three months ended March 31, 2015 related to net income of $70.7 million, adjusted for non-cash items of $28.9 million primarily related to intangible asset amortization and share-based compensation expense. This was partially offset by $3.0 million of net cash outflow related to changes in operating assets and liabilities which included an increase of $15.7 million in our prepaid expenses primarily due to upfront payments to a clinical research organization and a decrease in accrued liabilities of $17.5 million primarily driven by employee-related expenses, partially offset by an increase in income taxes payable.

Net cash used in investing activities for the three months ended March 31, 2016 primarily related to an upfront payment of $8.8 million we made in connection with the acquisition of intellectual property and know-how related to recombinant crisantaspase and purchases of property and equipment of $2.5 million primarily related to the construction of a manufacturing and development facility in Ireland. Net cash provided by investing activities for the three months ended March 31, 2015 primarily related to net proceeds of $32.7 million from the sale of certain products that we originally acquired as part of the EUSA Acquisition, partially offset by purchases of property and equipment of $14.4 million primarily related to the construction of a manufacturing and development facility in Ireland.

Net cash used in financing activities for the three months ended March 31, 2016 primarily related to $134.4 million used to repurchase our ordinary shares under our share repurchase program, payment of employee withholding taxes of $12.5 million related to share-based awards and repayments of long-term debt of $9.4 million, partially offset by proceeds of $3.8 million from employee equity incentive plans. Net cash used in financing activities for the three months ended March 31, 2015 primarily related to payment of employee withholding taxes of $14.8 million related to share-based awards and $10.3 million used to repurchase our ordinary shares under our prior share repurchase program, partially offset by proceeds of $13.5 million from employee equity incentive plans.

Credit Agreement

On June 18, 2015, Jazz Pharmaceuticals plc, as guarantor, and certain of its wholly owned subsidiaries, as borrowers, entered into the June 2015 credit agreement, which provides for a $750.0 million principal amount term loan, which was drawn in full at closing, and a $750.0 million revolving credit facility, of which $160.0 million was drawn at closing and subsequently repaid. We used the proceeds from initial borrowings under the June 2015 credit agreement to repay in full the $893.1 million principal amount of term loans outstanding under the 2012 credit agreement and to pay related fees and expenses. The 2012 credit agreement was terminated upon repayment of the term loans under this agreement.

Under the June 2015 credit agreement, the term loan matures on June 18, 2020 and the revolving credit facility terminates, and any loans outstanding thereunder become due and payable, on June 18, 2020.

Borrowings under the June 2015 credit agreement bear interest, at our option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 1.50% to 2.25% per annum, based upon our secured leverage ratio, or (b) the prime lending rate, plus an applicable margin ranging from 0.50% to 1.25% per annum, based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio.

As of March 31, 2016, the interest rate on the term loan was 2.38%. As of March 31, 2016, we had undrawn revolving credit facilities totaling $750.0 million of which $1.1 million was committed for an outstanding letter of credit.

Jazz Pharmaceuticals plc and certain of our wholly-owned subsidiaries are borrowers under the June 2015 credit agreement. The borrowers' obligations under the credit agreement, and any hedging or cash management obligations entered into with a lender, are guaranteed on a senior secured basis by Jazz Pharmaceuticals plc and certain of its subsidiaries (including the issuer of the 2021 Notes as described below) and are secured by substantially all of Jazz Pharmaceuticals plc's, the borrowers' and the guarantor subsidiaries' assets.

We may make voluntary prepayments of principal at any time without payment of a premium. We are required to make mandatory prepayments of the term loan (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), and (3) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the term loan, which are due quarterly, began in December 2015 and are equal to 5.0% per annum of the original principal amount of $750.0 million during the first two years, 7.5% per annum during the third year, 10.0% per annum during the fourth year and 12.5% per annum during the fifth year, with any remaining balance payable on the maturity date.

The June 2015 credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to us and our restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The June 2015 credit agreement contains financial covenants that require us to (a) not exceed a maximum secured net leverage ratio or (b) not fall below a cash interest coverage ratio. We were, as of March 31, 2016, and are currently in compliance with these financial covenants.

Exchangeable Senior Notes

In August 2014, Jazz Pharmaceuticals plc, through its wholly-owned finance subsidiary Jazz Investments I Limited, completed a private placement of $575.0 million principal amount of the 2021 Notes. The 2021 Notes are the senior unsecured obligations of Jazz Investments I Limited and are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. Interest on the 2021 Notes is payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2015, at a rate of 1.875% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2021 Notes. The 2021 Notes mature on August 15, 2021, unless earlier exchanged, repurchased or redeemed.

The holders of the 2021 Notes have the ability to require us to repurchase all or a portion of their 2021 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from The NASDAQ Global Select Market. Prior to August 15, 2021, we may redeem the 2021 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2021 Note additional amounts as a result of certain tax-related events. We also may redeem the 2021 Notes on or after August 20, 2018, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2021 Notes are exchangeable at an initial exchange rate of 5.0057 ordinary shares per $1,000 principal amount of 2021 Notes, which is equivalent to an initial exchange price of approximately $199.77 per ordinary share. Upon exchange, the 2021 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2021 Notes in cash upon exchange. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2021 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2021 Notes who elect to exchange their 2021 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to February 15, 2021, the 2021 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

Contractual Obligations

The table below presents a summary of our contractual obligations as of March 31, 2016 (in thousands):

	Payments Due By Period				
Contractual Obligations (1)	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 years**
Term and other loans - principal	$ 731,759	$ 37,592	$ 112,698	$ 581,469	$ —
Term and other loans - interest (2)	64,803	17,338	31,495	15,970	—
2021 Notes - principal	575,000	—	—	—	575,000
2021 Notes - interest (3)	59,298	10,781	21,563	21,563	5,391
Revolving credit facility - commitment fee (4)	9,611	2,278	4,556	2,777	—
Purchase obligations (5)	54,803	53,443	410	452	498
Operating and facility lease obligations (6)	111,321	12,138	20,573	13,729	64,881
Total	$ 1,606,595	$ 133,570	$ 191,295	$ 635,960	$ 645,770

(1) This table does not include potential future milestone payment or royalty obligations to third parties under asset purchase, product development, license and other agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable. In 2014, we signed a definitive agreement with Aerial under which we acquired worldwide development, manufacturing and commercial rights to JZP-110 (other than in certain jurisdictions in Asia where SK retains rights). Aerial and SK are currently eligible to receive milestone payments up to an aggregate of $270.0 million based on development, regulatory and sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales of JZP-110. In 2014, we entered into a definitive agreement to acquire rights to defibrotide in the U.S. and all other countries in the Americas from Sigma-Tau. In March 2016, the FDA granted marketing approval for Defitelio for the treatment of adult and pediatric patients with VOD, also known as SOS, with renal or pulmonary dysfunction following HSCT and, as a result, a milestone of $150.0 million to Sigma-Tau was included within accrued liabilities as of March 31, 2016. The milestone payment was made in April 2016. Potential future milestone payments to other third parties under other agreements could be up to an aggregate of $257.0 million, of which up to $120.0 million will become due and payable to Perrigo Company plc (formerly Elan Pharmaceuticals, Inc.) in tiered contingent payments, with the first such payment becoming due if net sales of Prialt of at least $75.0 million are achieved in a calendar year. The remainder would become due and payable to other third parties upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones, the timing and likelihood of which are not known. We are also obligated under these agreements to pay royalties on net sales of certain products at specified rates, which royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.

(2) Estimated interest was calculated based on the interest rates in effect as of March 31, 2016. The interest rate for our term loan was 2.38% at March 31, 2016.
(3) We used the fixed interest rate of 1.875% to estimate interest owed on the 2021 Notes as of March 31, 2016 until the final maturity date in August 2021.
(4) Our revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.30% and assumed undrawn amounts of $748.9 million as of March 31, 2016 to estimate commitment fees owed. Undrawn borrowing capacity does not include an amount of $1.1 million committed under an outstanding letter of credit.
(5) Consists primarily of non-cancelable commitments to third party manufacturers.
(6) Includes automobile lease payments for our sales force and the minimum lease payments for our office buildings, including a lease agreement we entered into in January 2015 to lease office space located in Palo Alto, California. We expect to occupy this office space by the end of 2017. We are obligated to make lease payments totaling approximately $88 million over the initial term of the lease. Not included in the table above are our estimated costs of approximately $20 million associated with the design, development and construction of tenant improvements under this lease agreement, which estimate does not include a tenant improvement allowance to be provided by the landlord. Operating expenses associated with our leased office buildings are also not included in table above.

We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries. In addition, our liability for unrecognized tax benefits has been excluded from the above contractual obligations table as the nature and timing of future payments, if any, cannot be reasonably estimated. We do not anticipate that the amount of our existing liability for unrecognized tax benefits will significantly change in the next twelve months.

Critical Accounting Estimates

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in determining the amounts to be deducted from gross revenues, in particular estimates of government rebates, which include Medicaid and TRICARE rebates, and estimated product returns. Significant estimates and assumptions are also required to determine whether to capitalize intangible assets, the amortization periods for identifiable intangible assets, the potential impairment of goodwill and other intangible assets, income taxes and share-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable. Although we believe our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2015. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's current plans, objectives, estimates, expectations and intentions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "propose," "intend," "continue," "potential," "possible," "foreseeable," "likely," "unforeseen" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under Part II, Item 1A "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our plans, objectives, estimates, expectations and intentions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results and the timing of events may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we undertake no obligation to update or supplement any forward-looking statements publicly, or to update or supplement the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2016, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risk" in our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2016.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting. During the quarter ended March 31, 2016, there have been no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

Xyrem ANDA Matters. On October 18, 2010, we received a notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it had submitted an abbreviated new drug application, or ANDA, to the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane's initial notice alleged that all five patents then listed for Xyrem in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, on the date of the notice are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's initial notice in the U.S. District Court for the District of New Jersey, or the District Court, seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA was stayed for 30 months, or until April 2013. That stay has expired. Additional patents covering Xyrem have been issued since December 2010, and after receiving Paragraph IV Certification notices from Roxane with respect to those patents, we have filed additional lawsuits against Roxane to include these additional patents in the litigation. All of the lawsuits filed against Roxane between 2010 and 2012 have been consolidated by the District Court into a single case, which we refer to as the first Roxane consolidated case. In the first Roxane consolidated case, we allege that 10 of our patents covering Xyrem are or will be infringed by Roxane's ANDA and seek a permanent injunction to prevent Roxane from launching a generic version of Xyrem that would infringe these patents.

After receiving additional Paragraph IV Certification notices from Roxane, we filed three actions against Roxane in the District Court on February 20, 2015, June 1, 2015 and January 27, 2016 that have since been consolidated, which we refer to as the second Roxane consolidated case. In the second Roxane consolidated case, we allege that five of our patents covering Xyrem are or will be infringed by Roxane's ANDA and seek a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe those patents.

In December 2013, the District Court permitted Roxane to amend its answer in the first Roxane consolidated case to allege certain equitable defenses, and the parties were given additional time for discovery on those new defenses. In addition, in March 2014, the District Court granted our motion to bifurcate and stay the portion of the first Roxane consolidated case regarding patents related to the distribution system for Xyrem. Although no trial date has been scheduled, we anticipate that trial on the patents in the first Roxane consolidated case that are not subject to the stay could occur as early as the third quarter of 2016. We do not have any estimate of a possible trial date on the patents in the first Roxane consolidated case that are currently subject to the stay or for the second Roxane consolidated case.

In April 2015, Roxane moved in the second Roxane consolidated case to dismiss claims involving our patent covering a part of the Xyrem label that instructs prescribers on adjusting the dose of Xyrem when it is being co-administered with divalproex sodium (also known as valproate or valproic acid) on the grounds that this patent does not cover patentable subject matter. In October 2015, the District Court administratively terminated this motion to dismiss (without prejudice) pending the outcome of *inter partes* review, or IPR, proceedings before the Patent Trial or Appeal Board, or PTAB, relating to the patent that was the subject of Roxane's motion. Such IPR proceedings were filed by Par, Ranbaxy and Amneal and are discussed below.

The actual timing of events in our litigation with Roxane may be significantly earlier or later than we currently anticipate. We cannot predict the specific timing or outcome of events in these matters or the impact of these matters on other ongoing proceedings with any ANDA filer.

On December 10, 2012, we received notice of Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On January 18, 2013, we filed a lawsuit against Amneal in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. On November 21, 2013, we received notice of Paragraph IV Certification from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 27, 2013, we filed a lawsuit against Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents.

In April 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request in May 2014. The order consolidating the cases provides that Amneal's 30-month stay period will be extended to coincide with the date of Par's 30-month stay period. As a result, the FDA's approval of both Amneal's and Par's ANDAs is stayed until the earlier of (i) May 20, 2016, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

Additional patents covering Xyrem have issued since April 2014 and have been listed in the Orange Book for Xyrem. Amneal and Par have given us additional notices of Paragraph IV Certifications regarding such patents, and we have filed additional lawsuits against Amneal and Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's and Par's ANDAs and seeking a permanent injunction to prevent Amneal and Par from introducing a generic version of Xyrem that will infringe these patents.

On June 4, 2014, we received a notice of Paragraph IV Certification from Ranbaxy Laboratories Limited, or Ranbaxy, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On July 15, 2014, we filed a lawsuit against Ranbaxy in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that will infringe these patents. Since June 2014, we have received additional notices of Paragraph IV Certification from Ranbaxy regarding newly issued patents for Xyrem listed in the Orange Book, and we have filed additional lawsuits against Ranbaxy in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that will infringe these patents.

On October 30, 2014, we received a notice of Paragraph IV Certification from Watson Laboratories, Inc., or Watson, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Watson in the District Court alleging that our patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents. In March 2015, Watson moved to dismiss the portion of the case based on our Orange Book-listed patents covering the distribution system for Xyrem on the grounds that these patents do not cover patentable subject matter. In November 2015, the District Court administratively terminated this motion to dismiss (without prejudice) pending the outcome of IPR proceedings before the PTAB relating to the patents that were the subject of Watson's motion. Since March 2015, we have received an additional notice of Paragraph IV Certification from Watson regarding newly issued patents for Xyrem listed in the Orange Book, and we have filed an additional lawsuit against Watson in the District Court alleging that our patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents.

In April 2015, the District Court issued an order that consolidated all then-pending lawsuits against Amneal, Par, Ranbaxy and Watson into one case.

On June 8, 2015, we received a Paragraph IV Certification from Wockhardt Bio AG, or Wockhardt, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On July 17, 2015, we filed a lawsuit in the District Court alleging that our patents covering Xyrem were or would be infringed by Wockhardt's ANDA and seeking a permanent injunction to prevent Wockhardt from introducing a generic version of Xyrem that would infringe our patents. On November 26, 2015, we received an additional notice of Paragraph IV Certification from Wockhardt regarding newly issued patents listed in the Orange Book, and we filed an additional lawsuit against Wockhardt in the District Court alleging that our patents covering Xyrem were or would be infringed by Wockhardt's ANDA and seeking a permanent injunction to prevent Wockhardt from introducing a generic version of Xyrem that would infringe these patents.

On July 23, 2015, we received a Paragraph IV Certification from Lupin Inc., or Lupin, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On September 2, 2015, we filed a lawsuit in the District Court alleging that our patents covering Xyrem are or will be infringed by Lupin's ANDA and seeking a permanent injunction to prevent Lupin from introducing a generic version of Xyrem that would infringe our patents.

In January 2016, the District Court issued an order consolidating all of the cases then pending against Amneal, Par, Ranbaxy, Watson, Wockhardt and Lupin into a single case for all purposes. In April 2016, the District Court issued orders consolidating two cases against Amneal and Ranbaxy relating to later-issued patents with the previously consolidated case against Amneal, Par, Ranbaxy, Watson and Lupin.

We entered into settlement agreements with Wockhardt and Ranbaxy on April 18, 2016 and May 9, 2016, respectively, that resolved our patent litigation against Wockhardt and Ranbaxy. Under the settlement agreements, we granted each of Wockhardt and Ranbaxy a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events. The specific terms of the settlement agreements are confidential.

The settlements with Wockhardt and Ranbaxy do not resolve the litigation against Amneal, Par, Watson and Lupin, which is ongoing. We cannot predict the specific timing or outcome of events in this matter with respect to the remaining defendants or the impact of developments involving any specific parties or patents on other ongoing proceedings with any ANDA filer.

Xyrem Post-Grant Patent Review Matters. In January 2015, certain of the ANDA filers filed petitions for IPR with respect to the validity of six patents covering the distribution system for Xyrem. In July 2015, the PTAB issued decisions instituting IPR trials with respect to these petitions, and we expect the PTAB to issue final decisions on the validity of the patents in July 2016. In September 2015, certain of the ANDA filers filed a petition for IPR with respect to the validity of an

additional patent covering the distribution system for Xyrem. In March 2016, the PTAB issued a decision instituting an IPR trial with respect to three claims of the patent subject to this petition, and we expect the PTAB to issue final decisions on the validity of these claims in March 2017. The PTAB denied the petition with respect to the other 25 claims of the patent.

In October 2015, Ranbaxy and Par filed petitions for IPR with respect to the validity of one of our patents covering a method for prescribing Xyrem when it is being co-administered with divalproex sodium, and Amneal filed an IPR petition on the same patent in February 2016. In April 2016, the PTAB denied Par's petition in its entirety and issued a decision on Ranbaxy's petition, instituting an IPR trial with respect to 16 of the claims under the patent subject to this petition and denying the petition with respect to the other 18 claims. We expect a decision on the Amneal petition in August 2016. In March 2016, Ranbaxy filed a petition for IPR with respect to the validity of the second of our patents covering a method for prescribing Xyrem when it is being co-administered with divalproex sodium. In connection with settlement of our litigation with Ranbaxy in May 2016, we expect to file a joint motion with Ranbaxy to terminate both of the IPR petitions filed by Ranbaxy.

In December 2015, Wockhardt filed a petition for IPR with respect to the validity of one of our patents covering the formulation of Xyrem. In April 2016, following settlement of our patent litigation against Wockhardt, we and Wockhardt filed a joint motion to terminate the IPR petitions filed or joined by Wockhardt.

We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, whether the PTAB will terminate the IPRs as requested by the parties, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our ordinary shares 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 Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and accompanying notes.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2015.

Risks Related to Xyrem and the Significant Impact of Xyrem Sales

Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

Xyrem is our largest selling product, and our financial results are significantly influenced by sales of Xyrem, which accounted for 75% of our net product sales for the three months ended March 31, 2016 and 73% of our net product sales for the year ended December 31, 2015. Our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2012 to 2015, we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in February 2016, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

In addition to other risks described herein, our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, the most important of which are discussed in more detail below, including those related to:

- the potential introduction of a generic version of Xyrem or an alternative sodium oxybate product for treating cataplexy and/or excessive daytime sleepiness, or EDS, in narcolepsy;
- changed or increased regulatory restrictions, including changes to our Xyrem risk evaluation and mitigation strategy, or REMS, the development of a single shared REMS for sodium oxybate with potential generic competitors or other regulatory actions by the FDA;
- our suppliers' ability to obtain sufficient quotas from the U.S. Drug Enforcement Administration, or DEA, to satisfy our needs for Xyrem;

- any supply, manufacturing or distribution problems arising with any of our suppliers or distributors, all of whom are sole source providers for us;
- any increase in pricing pressure from or restrictions on reimbursement imposed by third party payors;
- changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement and coverage by federal healthcare programs;
- continued acceptance of Xyrem by physicians and patients, even in the face of negative publicity that surfaces from time to time;
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem; and
- operational disruptions at the central pharmacy or any failure to comply with our REMS obligations to the satisfaction of the FDA.

These and the other risks described below related to Xyrem product sales and protection of our proprietary rights could have a material adverse effect on our ability to maintain or increase sales of Xyrem.

If sales of Xyrem were to decline significantly, we might need to reduce our operating expenses or seek to raise additional funds, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects, or we might not be able to acquire, in-license or develop new products in the future to grow our business.

If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.*

Although Xyrem is covered by patents covering its manufacture, formulation, distribution system and method of use, seven third parties have filed ANDAs seeking FDA approval of generic versions of Xyrem, and additional third parties may also seek to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy. If one or more companies receive FDA approval of an ANDA for a generic version of Xyrem or a new drug application, or NDA, for other sodium oxybate products, it is possible that such company or companies could introduce generic versions of Xyrem or other sodium oxybate products before our patents expire if they do not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch a sodium oxybate product at risk of potentially being held liable for damages for patent infringement.

Seven companies have sent us notices that they have filed ANDAs with the FDA seeking approval to market a generic version of Xyrem. We have filed lawsuits against each of these companies seeking to prevent the introduction of a generic version of Xyrem that would infringe our patents, but we cannot assure you that any of the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. In the second quarter of 2016, we settled two of these lawsuits. Additional ANDAs could also be filed requesting approval to market generic versions of Xyrem. If any of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Although no trial date has been set in any of the current ANDA suits, we anticipate that trial on some of the patents in the Roxane case could occur as early as the third quarter of 2016. However, the actual timing of events may be significantly earlier or later than we currently anticipate, and we cannot predict the timing or outcome of events in this or the other ANDA litigation.

Certain ANDA filers have filed petitions for IPR with respect to the validity of certain distribution, method of use and formulation patents covering Xyrem. The PTAB has issued decisions instituting IPR trials with respect to patents and patent claims that are the subject of certain of these petitions, and we expect the PTAB to issue final decisions in the first of these trials in July 2016. For a description of these matters, see “Legal Proceedings” in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

In accordance with the Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane’s ANDA was stayed until April 2013, but that stay has expired. We do not know the status of Roxane’s ANDA and cannot predict what actions the FDA or Roxane may take with respect to Roxane’s ANDA. If Roxane’s ANDA is approved by the FDA, Roxane may seek to launch a generic version of Xyrem prior to a District Court, or potential appellate court, decision in our ongoing patent litigation. While, in the event of such commercialization, Roxane would be liable to us for damages in the event we ultimately prevail in the patent litigation, we expect that the introduction of generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects. For more information, see the risk factor under the heading “*The manufacture, distribution and sale of Xyrem are subject to significant*

regulatory oversight and restrictions and the requirements of a risk evaluation and mitigation strategy, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Other companies could also develop products that are similar, but not identical, to Xyrem, such as an alternative formulation or an alternative formulation combined with a different delivery technology, and seek approval in the U.S. by referencing Xyrem and relying, to some degree, on the FDA's approval of Xyrem and related determinations of safety and efficacy. For example, a company that is using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients has stated that it anticipates commencing a Phase 3 pivotal trial in 2016 that is expected to run through mid-2017. If this company is successful in developing a sodium oxybate formulation that could be effectively used with its delivery technology and is able to obtain FDA or other regulatory approval for its product to treat narcolepsy patients, we expect the launch of such a product would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

A generic manufacturer or manufacturer of an alternative sodium oxybate product would need to obtain quotas from the DEA in order to manufacture in the U.S. both the active pharmaceutical ingredient and the finished product to compete with Xyrem. The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the U.S. in any given calendar year through a quota system. DEA quotas are required for our sodium oxybate supplier to supply us with sodium oxybate and for our Xyrem supplier to obtain sodium oxybate in order to supply us with Xyrem. Because the DEA typically grants quotas on an annual basis, our sodium oxybate supplier and our Xyrem supplier are required to request and justify allocation of sufficient annual DEA quotas as well as additional DEA quotas if our commercial or clinical requirements exceed the allocated quotas throughout the year. For the last few years, our suppliers were allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. Consequently, a generic manufacturer or manufacturer of an alternative sodium oxybate product may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In the past, we have also had to engage in lengthy efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2016, both our sodium oxybate supplier and our Xyrem supplier have been allocated most, but not all, of their respective requested quotas. If, in the future, we and our suppliers cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

After any introduction of a generic competitor, a significant percentage of the prescriptions written for Xyrem may be filled with the generic version, resulting in a loss in sales of Xyrem. Generic competition often also results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, certain U.S. state laws allow for, and in a few instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products where a generic version is available. We expect that generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk evaluation and mitigation strategy, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.*

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management and controlled distribution system, or Xyrem Risk Management Program, in conjunction with Xyrem's approval by the FDA to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. The Xyrem Risk Management Program included elements such as patient and physician education, a database of information to track and report certain information, and the use of a single central pharmacy to distribute Xyrem. The Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, was deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act, or FDAAA. The FDAAA, which amended the Federal Food, Drug and Cosmetic Act, or FDCA, required that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. Pursuant to the FDCA, we engaged with the FDA starting in 2008 to finalize our REMS documents for Xyrem, including initiating dispute resolution procedures with the FDA in February 2014. On February 27, 2015, the FDA notified Jazz Pharmaceuticals, Inc., our wholly owned subsidiary, of (i) the FDA's approval of the REMS for Xyrem in the form submitted by us in November 2014, which includes provisions requiring distribution through a single pharmacy, and (ii) the FDA's denial of our dispute resolution appeal as moot as a result of approval of the Xyrem REMS.

The Xyrem REMS approval letter included statements from the FDA that (i) the approval action should not be construed or understood as agreement with what the FDA stated was our position that dispensing through a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh its risks, and that the FDA has continuing concerns that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system, and (ii) as with

all REMS, the FDA intends to evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. We cannot predict whether the FDA will seek to require or ultimately require modifications to the Xyrem REMS, including with respect to the distribution system, or seek to otherwise impose or ultimately impose additional requirements to the Xyrem REMS, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could potentially make it easier for ANDA applicants to obtain FDA approval of their ANDAs, make it more difficult or expensive for us to distribute Xyrem, make distribution easier for future generic competitors, impair the safety profile of Xyrem and/or negatively affect sales of Xyrem.

In late August 2015, we implemented the final Xyrem REMS, which was approved by the FDA in February 2015, and we have submitted and expect to continue to submit ongoing assessments as set forth in the FDA's Xyrem REMS approval letter. The process under which enrolled patients receive Xyrem is complex, and we are continuing to transition prescribers and patients to the final Xyrem REMS process and documentation requirements. We cannot guarantee that we will be able to complete the transition of prescribers and patients to the final Xyrem REMS in a timely manner, that our ongoing assessments will be satisfactory to the FDA or that the Xyrem REMS will satisfy the FDA's expectations in its evaluation of the Xyrem REMS on an ongoing basis. Any failure to comply with the REMS obligations could result in enforcement action by the FDA; lead to changes in our Xyrem REMS obligations; negatively affect sales of Xyrem; result in additional costs and expenses for us; and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

While we have an exclusive agreement with Express Scripts, the central pharmacy for Xyrem, through June 2017, if the central pharmacy does not fulfill its contractual obligations to us, fails to meet the requirements of the Xyrem REMS applicable to the central pharmacy, provides timely notice that it wants to terminate our agreement, refuses or fails to adequately serve patients, or fails to promptly and adequately address operational challenges, whether expected or unexpected, the fulfillment of Xyrem prescriptions and our sales would be adversely affected. If we change to a new central pharmacy, new contracts might be required with government and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under the Xyrem REMS. Transitioning to a new pharmacy could result in product shortages, which would negatively affect sales of Xyrem, result in additional costs and expenses for us and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Section 505-1(i)(1) of the FDCA generally provides that (i) an ANDA that references a drug subject to a REMS with elements to assure safe use, or ETASU, is required to have a REMS with the same elements as the referenced drug, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and approve an ANDA with a separate REMS with differing but comparable aspects of ETASU if the FDA either determines that the burden of creating a single shared system outweighs its benefit, or if the ANDA applicant certifies that it has been unable to obtain a license to any aspects of the REMS for the referenced drug that are covered by a patent or a trade secret. The FDCA provides that the FDA may seek to negotiate a license between the ANDA applicant and the sponsor of the referenced drug before granting a waiver of the single shared system requirement.

We and the ANDA applicants had interactions with respect to developing a single shared REMS for several years. The ANDA applicants are not currently engaging in single shared REMS discussions with us, but we are seeking to continue the interactions with the goal of developing a single shared REMS. However, we cannot predict whether, or to what extent, our interactions with the ANDA applicants will continue or whether we will develop a single shared REMS. We are aware that, separate from the discussions with us, the FDA and ANDA applicants have exchanged communications regarding a REMS for sodium oxybate. If we and the ANDA applicants do not develop a single shared REMS, or we do not license or share intellectual property pertinent to our Xyrem REMS with generic competitors within a time frame or on terms that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to approve the ANDA of one or more generic competitors with a separate REMS that differs in some aspects from our approved Xyrem REMS. The FDA has exercised this waiver authority in two instances of which we are aware, including most recently in connection with the May 2015 approval of Roxane Laboratories' ANDA for alosetron hydrochloride tablets as generic versions of Lotronex tablets. This waiver was subject to the condition that the waiver-granted REMS system be open to all current and future sponsors of ANDAs or NDAs for alosetron hydrochloride products, and the FDA limited the grant of the waiver to a term of three years, subject to potential extension by the FDA. We also may face pressure to develop a single shared REMS with potential generic competitors for Xyrem that is different from the approved Xyrem REMS or to license or share intellectual property pertinent to the Xyrem REMS, or elements of the Xyrem REMS, including proprietary data required for safe distribution of sodium oxybate, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared REMS for sodium oxybate, licensing or sharing intellectual property pertinent to our Xyrem REMS or elements of the Xyrem REMS, or the FDA's response to a request by one or more ANDA applicants for a waiver of the requirement for a single shared REMS, including in connection with a certification that the applicant had been unable to obtain a license. The FDA's response to any such request could include approval of one or more ANDAs. In

addition, federal legislation, including the Fair Access for Safe and Timely Generics Act of 2015, has been proposed to amend the statutory criteria regarding the development of a shared REMS and the standards for granting a waiver of the requirement of a shared REMS. We cannot predict whether this legislation will be enacted. For more information, see the risk factors under the headings "*If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected*" and "*We have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products"* in Part II, Item 1A of this Quarterly Report on Form 10-Q.

The Federal Trade Commission, or FTC, has been paying increasing attention to the use of REMS by companies selling branded products, in particular to whether a REMS may be deliberately being used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC, other governmental authorities or others could claim or determine that we are using the Xyrem REMS in an anticompetitive manner (including in light of the FDA's statement in the Xyrem REMS approval letter that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the FDCA) or have engaged in other anticompetitive practices. The FDCA further states that a REMS ETASU shall not be used by an NDA holder to block or delay generic drugs from entering the market. Several of the ANDA applicants have asserted that our patents covering the distribution system for Xyrem should not have been listed in the Orange Book and that the Xyrem REMS is blocking competition. We cannot predict the outcome of these claims in the ongoing litigation, or the impact of any similar claims that may be made in the future.

As required by the FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to the FDA and could result in the FDA requiring changes to Xyrem labeling or taking or requiring us to take other actions that could have an adverse effect on Xyrem's commercial success. Our Xyrem REMS includes unique features that provide more extensive information about adverse events, including deaths, than is generally available for other products that are not subject to similar REMS requirements.

Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the satisfaction of the FDA or any other regulatory authority could result in such regulatory authorities taking actions in the future, which could have a material adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth prospects. For more information, see the risk factor under the heading "*We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

The FDA has required that Xyrem's labeling include a boxed warning regarding the risk of central nervous system depression and misuse and abuse. A boxed 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 boxed warning also means, among other things, that the product cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. We cannot predict whether the FDA will require additional warnings, including boxed warnings, to be included on Xyrem's labeling. Warnings in the Xyrem labeling and any limitations on our ability to advertise and promote Xyrem may have affected, and could in the future negatively affect, Xyrem sales and therefore our business, financial condition, results of operations and growth prospects.

Risks Related to Our Business

While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

In addition to Xyrem, we are commercializing a portfolio of products, including our other lead marketed products, Erwinaze and Defitelio.

Erwinaze

Erwinaze (called Erwinase in markets outside the U.S.), a biologic product, is used in conjunction with chemotherapy to treat patients with acute lymphoblastic leukemia, or ALL, with hypersensitivity to *E. coli*-derived asparaginase. Erwinaze was approved by the FDA under a biologics license application, or BLA, and was launched in the U.S. in November 2011. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere.

Erwinaze represents an important part of our strategy to grow sales of our existing products. However, our ability to successfully and sustainably maintain or grow sales of Erwinaze is subject to a number of challenges, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that

population and our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries. Another significant challenge to our ability to maintain current sales levels and to increase sales is our extremely limited inventory of Erwinaze and our need to avoid supply interruptions of Erwinaze due to capacity constraints, production delays, quality or regulatory challenges or other manufacturing difficulties. See the discussion regarding Erwinaze supply issues in the risk factor under the heading "*We depend on single source suppliers for each of our products, product candidates and their active pharmaceutical ingredients. The loss of any of these suppliers, or delays or problems in the supply 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*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

We also face numerous other risks that may impact Erwinaze sales, including regulatory risks, the development of new asparaginase treatments or treatment protocols that could reduce the rate of hypersensitivity in patients with ALL, the development of new treatment protocols for ALL that may not include asparaginase-containing regimens, difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements, and potential competition from future biosimilar products. In addition, if we fail to comply with our obligations under our agreement with the licensor and supplier of Erwinaze or lose exclusive rights to Erwinaze, or otherwise fail to maintain or grow sales of Erwinaze, our growth prospects could be negatively affected.

Defitelio

We made a significant investment in Defitelio in 2014, adding the product to our portfolio as a result of our acquisition of Gentium S.r.l, or Gentium, which we refer to as the Gentium Acquisition, and then securing worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. We launched Defitelio in certain European countries in 2014 and continue to launch in additional European countries on a rolling basis. On March 30, 2016, the FDA approved our NDA for Defitelio for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, or SOS, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT. We launched Defitelio in the U.S. shortly after FDA approval. Our ability to realize the anticipated benefits from this investment is subject to risks and uncertainties, including:

- the acceptance of Defitelio in the U.S. by hospital pharmacy and therapeutics committees and the availability of adequate coverage and reimbursement by government programs and third party payors;
- U.S. market acceptance of Defitelio at its commercial price now that it is no longer available to new patients under an expanded access treatment protocol;
- the lack of experience of U.S. physicians in diagnosing and treating VOD, particularly in adults, and the possibility that physicians may delay initiation of treatment or terminate treatment before the end of the recommended dosing schedule;
- our ability to successfully maintain or grow sales of Defitelio in Europe;
- delays or problems in the supply or manufacture of the product;
- the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in HSCT treatment protocols reduce the incidence of VOD);
- our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA for Defitelio; and
- our ability to obtain marketing approval in other countries and to develop the product for additional indications.

We are in the process of making pricing and reimbursement submissions with respect to Defitelio in certain European countries where Defitelio is not yet launched, including in countries where pricing and reimbursement approvals are required for launch. We cannot predict the timing of Defitelio's launch in European countries where we are engaged in pricing and reimbursement submissions. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected European countries will be delayed, which could negatively impact anticipated revenue from Defitelio. The process for obtaining pricing and reimbursement approvals is complex and can vary from country to country. In addition, orphan products that have significant impact on patient survival, such as Defitelio, may be budgeted on a local rather than national level. The balance of all of these factors will determine our ability to ultimately obtain favorable pricing and reimbursement approvals in the EU. Many European countries periodically review their reimbursement classes, which could have an adverse impact on the reimbursement status of Defitelio. We have developed estimates of anticipated pricing in the EU, which are based on our research and understanding of the product and target market. However, due to efforts to provide for containment of health care costs, one or more countries may not support our estimated level of governmental pricing and reimbursement for Defitelio, particularly in light of the budget crises faced by a number of countries in the EU, which would negatively impact anticipated revenue from Defitelio. Furthermore, after initial pricing and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors,

including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced countries. If any of these events occurs, our anticipated revenue from Defitelio in the EU would be negatively affected. If we are unable to obtain and maintain favorable pricing and reimbursement approvals in European countries that represent significant markets, especially where a country's reimbursed price influences other countries, our anticipated revenue from and growth prospects for Defitelio in the EU could be negatively affected. In addition, our ability to commercialize Defitelio successfully in the U.S. will depend on, among other things, the availability of adequate coverage or reimbursement by U.S. government programs and third party payors.

The European Commission, or EC, granted marketing authorization to Defitelio under "exceptional circumstances" because it was not possible to obtain complete information about the product due to the rarity of the disease and because ethical considerations prevented conducting a study directly comparing Defitelio with best supportive care or a placebo. A marketing authorization granted under exceptional circumstances is subject to approval conditions and an annual reassessment of the risk-benefit balance by European Medicines Agency, or EMA. As a result, if we fail to meet the approval condition for Defitelio established by the EC, which requires that we set up a patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use, or if it is determined that the balance of risks and benefits of using Defitelio changes materially, the EMA could vary, suspend or withdraw the marketing authorization for Defitelio. In addition, the FDA imposed several post-marketing commitments and requirements in connection with its approval of our NDA for Defitelio in March 2016, including the requirement that we conduct a clinical trial to analyze the safety of defibrotide versus best supportive care in the prevention of VOD in adult and pediatric patients. We may be unable to comply with these or other post-marketing obligations imposed as part of the marketing approvals for Defitelio. If we fail to meet any of these post-marketing obligations, our sales of and revenues from Defitelio could be materially adversely affected, and our potential future maintenance and growth of the market for this product may be limited.

The size of the population of VOD patients who are indicated for treatment with Defitelio is limited, and changes in HSCT treatment protocols could reduce the incidence of VOD. Changes in treatment protocols that reduce the incidence of VOD could adversely affect our anticipated revenues from Defitelio and our business, financial condition, results of operations and growth prospects.

We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in additional indications. We cannot know when, if ever, defibrotide will be approved in any other country or under what circumstances, and what, if any, additional clinical or other development activities will be required in order to potentially obtain such regulatory approval and the cost associated with such required activities, if any. If we fail to obtain approval for defibrotide in other countries or for new indications, or if any future approvals we receive are for narrower indications than we expect, our anticipated revenue from defibrotide and our growth prospects would be negatively affected.

Due to the limited amount of historical sales data from commercialization of Defitelio, our Defitelio sales will be difficult to predict from period to period. As a result, Defitelio sales results or trends in any period are not necessarily indicative of future performance. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from Defitelio would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we fail to maintain or increase prescriptions and revenue from sales of our products, including Erwinaze and Defitelio, our business, financial condition, results of operations and growth prospects could be materially adversely affected. We may choose to increase the price of our products, and price adjustments may negatively affect our sales volumes. Also, sales of Erwinaze and Defitelio may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the availability of supply to meet the demand for the product, the dosing requirements of treated patients and other factors. The market price of our ordinary shares may decline if sales of our products do not continue or grow at the rates anticipated by financial analysts or investors.

In addition, if we fail to obtain approvals for certain of our products in new indications or formulations, we will be unable to commercialize our products in new indications or formulations, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We cannot predict whether historical revenues from named patient programs for our hematology/oncology products will continue or whether we will be able to continue to distribute those products on a named patient basis.

In certain European countries, reimbursement for products that have not yet received marketing authorization may be provided through national named patient programs. Erwinase and Defitelio are available on a named patient basis in many countries where they are not commercially available. Such reimbursement may cease to be available if authorization for a named patient program expires or is terminated. While we generate revenue from the distribution of these products through named patient programs, we cannot predict whether historical revenues from these programs will continue, whether we will be able to continue to distribute our products on a named patient basis in these countries, whether we will be able to

commercialize our products in countries where the products have historically been available on a named patient basis, or whether commercial revenues will exceed revenues historically generated from sales on a named patient basis. Any failure to maintain revenues from sales of Erwinase and/or Defitelio on a named patient basis and/or to generate revenues from commercial sales of these products exceeding historical sales on a named patient basis could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We depend on single source suppliers for each of our products, product candidates and their active pharmaceutical ingredients. The loss of any of these suppliers, or delays or problems in the supply 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.*

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredient and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. If we or any of our third party suppliers encounter these or any other manufacturing, quality or compliance difficulties with respect to any of our products, particularly Xyrem and Erwinaze since we maintain limited inventories for these products, we may be unable to meet commercial demand for such products, which could adversely affect our business, financial condition, results of operations and growth prospects.

We have completed construction of a manufacturing and development facility in Ireland and expect to begin commercial operations at the facility in 2016. Currently, however, other than the manufacturing plant in Italy where we produce some active pharmaceutical ingredients, including the defibrotide drug substance, we do not currently have our own commercial manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. The availability of our products for commercial sale depends upon our ability to procure the ingredients, raw materials, packaging materials and finished products we need from third parties. In part due to the limited market size for our products and product candidates, we have entered into supply and manufacturing agreements with suppliers, each of which is currently our single source for each of our marketed products and for the active pharmaceutical ingredients used in some of these products. These single source arrangements put us at risk of interruption in supply in the event of manufacturing, quality or compliance difficulties at our suppliers.

We maintain limited inventories of Xyrem and Erwinaze, as well as the ingredients or raw materials used to make them. Our limited inventory puts us at significant risk of not being able to meet product demand, and we have experienced Erwinaze supply interruptions that have adversely affected sales volumes. In addition, the DEA limits the quantity of certain Schedule I controlled substances that may be produced in the U.S. in any given calendar year through a quota system. The active pharmaceutical ingredient of Xyrem, sodium oxybate, is a Schedule I controlled substance, production quantities of which are limited by the DEA through a quota system. DEA quotas are required for our sodium oxybate supplier to supply us with sodium oxybate and for our Xyrem supplier to obtain sodium oxybate in order to supply us with Xyrem. Because the DEA typically grants quotas on an annual basis, our sodium oxybate supplier and our Xyrem supplier are required to request and justify allocation of sufficient annual DEA quotas as well as additional DEA quotas if our commercial or clinical requirements exceed the allocated quotas throughout the year. In the past, we have had to engage in lengthy efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2016, both our sodium oxybate supplier and our Xyrem supplier have been allocated most, but not all, of their respective requested quotas. If, in the future, we and our third party suppliers cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

Siegfried (USA) Inc., subsequently renamed Siegfried USA, LLC, or Siegfried, has been our sole supplier of sodium oxybate since 2012. We expect that Siegfried will continue to be our sole supplier of sodium oxybate for the foreseeable future, and we cannot assure you that Siegfried can or will continue to supply on a timely basis, or at all, sufficient quantities of active pharmaceutical ingredient to enable the manufacture of the quantities of Xyrem that we need.

Erwinaze is licensed from and manufactured by a single source, which was Public Health England, or PHE, through March 31, 2015. As of April 1, 2015, the facility at which Erwinaze is manufactured was transferred to Porton Biopharma Limited, or PBL, which is wholly owned by the U.K. Secretary of State for Health. The FDA's approval of the BLA for Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze. In March 2016, the FDA conducted an inspection of the PBL manufacturing facility and issued an FDA Form 483 to PBL that included observations related to a range of operational systems and processes. PBL has responded to the FDA Form 483 with its plan to address the observations made in the FDA Form 483, which will require remediation activities. Inability to comply with regulatory requirements, including failure by PBL to timely remediate the observations included in the FDA Form 483 or failure by us to demonstrate compliance with our obligations under the BLA, in each case to the FDA's satisfaction, and compliance with

manufacturing-related post-marketing commitments that are part of the BLA approval, as well as other requirements monitored by the FDA, could adversely affect Erwinaze supply, particularly in light of our extremely limited product inventory, and could result in FDA approval being revoked, product release being delayed or product recalls, any of which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. In addition, if the FDA or any non-U.S. regulatory authority mandates any changes to the specifications for Erwinaze, we may face challenges having product produced to meet such specifications, and our supplier may increase its price to supply Erwinaze meeting such specifications, which may result in additional costs to us and may decrease any profit we would otherwise achieve with Erwinaze.

The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product. We are working with PBL to evaluate potential expansion of its production capacity to increase the supply of Erwinaze over the longer term. As a consequence of constrained manufacturing capacity, we have had an extremely limited or no ability to build product inventory levels that can be used to absorb disruptions to supply resulting from quality, regulatory or other issues, and we have experienced product quality, manufacturing and inventory challenges that have resulted in disruptions in our ability to supply certain markets and caused us to implement batch-specific, modified product use instructions. We expect that we will continue to experience inventory challenges. If capacity constraints or supply disruptions continue, whether as a result of continued quality or other manufacturing issues, regulatory issues or otherwise, we may be unable to build a desired excess level of product inventory, our ability to supply the market may continue to be compromised and physicians' decisions to use Erwinaze in the future may be negatively impacted. If quality or other manufacturing issues or regulatory difficulties occur and result in a disruption to supply or capacity constraints, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach or the cessation of manufacturing by our supplier. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming, might not be successful and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinaze. If we fail to obtain a sufficient supply of Erwinaze, our sales of and revenues from Erwinaze, our potential future maintenance and growth of the market for this product, and/or our business, financial condition, results of operations and growth prospects could be materially adversely affected.

We are our sole supplier of, and we believe that we are currently the sole worldwide producer of, the defibrotide drug compound. We manufacture the defibrotide drug compound in a single facility located in Villa Guardia, near Como, Italy. Patheon currently processes the defibrotide compound into its finished vial form, and Patheon is the sole provider of our commercial and clinical supply of Defitelio. In 2015, the FDA issued an FDA Form 483 to Patheon Italia that included observations related to the Ferentino, Italy facility that manufactures Defitelio. Although we are advised that Patheon Italia remediated the observations to the FDA's satisfaction, the FDA will continue to inspect and evaluate facilities for ongoing compliance with applicable requirements. If Patheon does not or is not able to supply us with Defitelio for any reason, it may take time and resources to implement and execute the necessary technology transfer to another processor, and such delay could negatively impact our anticipated revenues from Defitelio and could potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need.

In addition, the active pharmaceutical ingredient in Defitelio is derived from porcine DNA. If our porcine DNA supplier experiences safety or other issues that impact its ability to supply porcine materials to us as needed, we may not be able to find alternative suppliers in a timely fashion, which could negatively impact our supply of Defitelio.

In order to conduct and complete our clinical program for JZP-110 or to potentially conduct future clinical trials for other product candidates, if any, we need to have sufficient quantities of clinical product manufactured and available for use. There can be no assurance that our suppliers will be able to produce or provide sufficient clinical supplies of JZP-110 or other product candidates in a timely manner. Any delay in receiving adequate supplies of JZP-110 or other product candidates for our studies could negatively impact our development programs.

Failure by us or our third party suppliers to comply with regulatory requirements could adversely affect our or their ability to supply products or ingredients. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with applicable current Good Manufacturing Practices, or cGMP, requirements. DEA regulations also govern facilities where controlled substances such as sodium oxybate are manufactured. Our manufacturing facilities and manufacturing facilities of our suppliers have been and are subject to periodic unannounced inspection by the FDA, the EMA, the DEA, the Italian Health Authority and other regulatory authorities, including state authorities and similar authorities in other jurisdictions, to confirm compliance with cGMP and other requirements. We and our third party 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. Failure to comply with applicable legal and regulatory requirements subjects us and our suppliers to possible legal or regulatory action, including restrictions on supply or shutdown, which may adversely affect our or a supplier's ability to supply the ingredients or finished products we need. Moreover, our or our third party suppliers' facilities could be damaged by fire, flood, earthquake, power loss, telecommunication and information system failure, terrorism or

similar events. Any of these events could cause a delay or interruption in manufacturing and potentially a supply shortage of our products, which could negatively impact our anticipated revenues.

If, for any reason, our suppliers, including any new suppliers, do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to 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, which could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, if one of our suppliers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. The loss of one of our suppliers 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 up to two years, or longer in certain cases, to qualify a new supplier, and we may not be able to obtain active pharmaceutical ingredients or finished products from new suppliers on acceptable terms and at reasonable prices, or at all. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to obtain a sufficient quota from the DEA, if required, or to otherwise meet FDA or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, particularly since we do not have secondary sources for supply and manufacture of the active pharmaceutical ingredients for our products or backup suppliers for our finished products.

Our ability to develop and deliver products in a timely and competitive manner depends on our third party suppliers being able to continue to meet our ongoing commercial needs. Any delay in supplying, or failure to supply, products or product candidates 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.

We have substantially expanded our international footprint and operations, and we may expand further in the future, but we do not yet have substantial historical experience in international markets and may not achieve the results that we, our shareholders or analysts who cover our business expect.*

We are headquartered in Dublin, Ireland and have multiple offices in the U.S., the United Kingdom, Italy and other countries in Europe. Our headcount has grown to approximately 920 in May 2016. This includes employees in 14 countries in North America and Europe, a European commercial presence, a complex distribution network for products in Europe and additional territories, and manufacturing facilities in Italy and Ireland. In addition, we may expand our international operations into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations, financial condition and growth prospects, including, among other things:

- the increased complexity and costs inherent in managing international operations;
- diverse regulatory, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- country-specific tax, labor and employment laws and regulations;
- applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions and any changes to them;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations, as well as maintaining positive interactions with unionized employees in one of our international locations;
- liabilities for activities of, or related to, our international operations, products or product candidates;
- changes in currency rates; and
- regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

As a result of our rapid growth, our business and corporate structure has become substantially more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage the increased complexity of our company, and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In recent years, the global economy has been impacted by the effects of an ongoing global financial crisis, including the European sovereign debt crisis, which has caused extreme disruption in the financial markets, including severely diminished

liquidity and credit availability. In addition, we expect to continue to grow our product sales in Europe. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe and the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, has led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our revenues and profitability.

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

Physicians may not prescribe our products, in which case we would not generate the revenues we anticipate from product sales. Market acceptance of any of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved, including any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry or labeling restrictions;
- the 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;
- physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the Xyrem REMS;
- 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 conditions for reimbursement required by, and appropriate pricing and availability of reimbursement from, third party payors.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse events resulting from the use or misuse of our products or any similar products distributed by other companies, including generic versions of our products, could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, from time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. 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. Patients, physicians and regulators may therefore view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of its connection to GHB. Xyrem's label includes information about adverse events from GHB.

In addition, we have periodically increased the price of Xyrem and may do so again in the future. We also have made and may in the future make similar price increases on our other products. Price increases on our products and negative publicity regarding pricing and price increases generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of our products. For additional discussion about payor acceptance, see the risk factor under the heading "*Price approvals and reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably"* in Part II, Item 1A of this Quarterly Report on Form 10-Q.

We may not be able to successfully identify and acquire, in-license or develop additional products or product candidates to grow our business, and, even if we are able to do so, we may not be able to successfully manage the risks associated with integrating any products or product candidates we may acquire in the future into our product portfolio, or we may otherwise fail to realize the anticipated benefits of these acquisitions.*

We intend to grow our business over the long term by acquiring or in-licensing and developing additional products and product candidates that we believe have significant commercial potential. Future growth through acquisition or in-licensing will depend upon the availability of suitable products and product candidates for acquisition or in-licensing on acceptable prices, terms and conditions.

Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities. In order to compete successfully to acquire attractive products or product candidates in the current business climate, we may have to pay higher prices for assets than may have been paid historically, which may make it more difficult for us to realize an adequate return on any acquisition. See also the

discussion under the heading "*We are subject to a requirement under Irish law to periodically obtain new authorities from our shareholders to issue ordinary shares, which we may be unable to obtain"* in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Even if we are able to successfully identify and acquire, in-license or develop additional products or product candidates, we cannot assure you that we will be able to successfully manage the risks associated with integrating any products or product candidates or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing. We may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including if:

- we are unable to obtain and maintain adequate funding to complete the development of, obtain regulatory approval for and commercialize a product candidate;
- a product candidate proves not to be safe or effective in later clinical trials;
- a product fails to reach its forecasted commercial potential as a result of pricing pressures;
- we experience negative publicity regarding actual or potential future price increases for that product or otherwise; or
- the integration of a product or product candidate gives rise to unforeseen difficulties and expenditures.

Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business.

In addition, product and product candidate acquisitions create other uncertainties and risks, particularly when the acquisition takes the form of a merger or other business consolidation. Our business acquisitions have required, and any similar future transactions will also require, significant efforts and expenditures, including with respect to transition activities and integrating the acquired business with our historical business. We may encounter unexpected difficulties, or incur unexpected costs, in connection with potential acquisitions and similar transactions, which include:

- high acquisition costs;
- the need to incur substantial debt or engage in dilutive issuances of equity securities to pay for acquisitions;
- the potential disruption of our historical core business;
- the strain on, and need to continue to expand, our existing operational, technical, financial and administrative infrastructure;
- the difficulties in assimilating employees and corporate cultures;
- the failure to retain key managers and other personnel;
- the challenges in controlling additional costs and expenses in connection with and as a result of any acquisition;
- the need to write down assets or recognize impairment charges;
- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures; and
- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

If any of these or other factors impair our ability to integrate any acquired business efficiently and successfully, we may be required to spend time or money on integration activities that otherwise would be spent on the development and expansion of our business. If we fail to integrate or otherwise manage an acquired business successfully and in a timely manner, resulting operating inefficiencies could increase costs and expenses more than we planned, could negatively impact the market price of our ordinary shares and could otherwise distract us from the execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures during and after integration of an acquired business could also impact our ability to produce timely and accurate financial statements.

Conducting clinical trials is costly and time-consuming, and the outcomes are uncertain. A failure to prove that our product candidates are safe and effective in clinical trials, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.*

Since 2014, we have made significant investments into expanding our product development pipeline and expect to continue to increase our research and development organization. Significant clinical, development and financial resources will be required to progress product candidates through clinical trials and the regulatory approval process to develop them into commercially viable products. We have a number of product candidates under development. We also intend to pursue clinical development of other product candidates that we may acquire or in-license in the future. 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.

As a condition to regulatory approval, each product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. Results of limited preclinical studies, including studies of our product candidates in animal models, may not predict the results of human clinical trials of those product candidates. Similarly, 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. In that case, the FDA or any equivalent non-U.S. regulatory agency may determine our data is not sufficiently compelling to warrant marketing approval and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. 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 preclinical studies or earlier clinical trials. For example, in the second quarter of 2015, we initiated patient enrollment in three Phase 3 clinical trials for JZP-110, a late-stage investigational compound being developed for potential treatment of EDS in patients with narcolepsy and EDS in patients with obstructive sleep apnea, or OSA. We are targeting preliminary data from these trials by the end of the fourth quarter of 2016. However, our ability to meet this goal for each trial depends on an acceleration of enrollment rates. Further, these results may not be positive, and we may be unable to complete these clinical trials in a timely manner or submit an NDA on our anticipated timeline, or at all. If a product candidate, including JZP-110, fails at any stage of development, it will not receive regulatory approval, we will not be able to commercialize it, and we will not receive any return on our investment in that product candidate.

Our development pipeline projects may not be successful, and any adverse events or other information generated during the course of studies related to existing products could result in action by the FDA or a non-U.S. regulatory agency, which may restrict our ability to sell, or adversely affect sales of, currently marketed products, or such events or other information could otherwise have a material adverse effect on a related commercial product. Any failure or delay in completing clinical trials for line extensions or the generation of additional clinical data could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

In addition to issues relating to the results generated in clinical trials, clinical trials can be delayed or halted for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, also known as Ethics Committees in Europe, to conduct a clinical trial at a prospective study site;
- delays or failures in recruiting patients to participate in a clinical trial;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA and other regulatory agencies' good clinical practice guidelines;
- unforeseen safety issues, including negative results from ongoing preclinical studies and clinical trials and adverse events associated with product candidates;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- failure of our third party clinical trial managers to satisfactorily perform their contractual duties, comply with regulations or meet expected deadlines; or
- insufficient funds to complete the trials.

We rely on third parties to conduct our clinical trials, 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 rely on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical 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 a high priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and non-U.S. regulatory agencies' requirements, 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. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us 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 or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies 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 cGMP regulations and similar regulations outside of the U.S. Our failure, or the failure of our product suppliers, to comply with these regulations may require us to repeat or redesign 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, including dosing requirements, 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 or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have.

The commercial potential of our current products and any future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, have fewer side effects, are easier to administer or are less expensive than our products. The pharmaceutical industry is highly competitive and dominated by a number of large, established pharmaceutical companies, as well as specialty pharmaceutical companies that market products and develop product candidates in sleep, hematology/oncology, pain and other therapeutic areas. Many of our competitors, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. They can spend more on, and have more expertise in, research and development, regulatory, manufacturing, distribution and sales activities. As a result, our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may and may market their products more effectively than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through focused development programs and collaborative arrangements with large, established companies.

While there is currently no direct competition to Erwinaze to treat ALL patients with hypersensitivity to *E. coli*-derived asparaginase, other companies have developed or are developing new treatments for ALL, including new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL, and new treatment protocols are being developed for ALL that may not include asparaginase-containing regimens. For example, a number of companies are developing new immunotherapy treatments for relapsed or refractory ALL patients, including one treatment that was recently approved, and a company recently announced positive efficacy and safety results from its completed Phase 2/3 pivotal trial in Europe for an alternative asparaginase treatment consisting of L-asparaginase encapsulated inside donor-derived red blood cells. The development of these new treatments could negatively impact our ability to maintain and grow sales of Erwinaze in patient populations where the benefit of an asparaginase-containing regimen is not well established.

In addition, many of our competitors are able to deploy more personnel to market and sell their products than we do. We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. In particular, we compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in hematology/oncology markets, and our failure to compete effectively in this area could negatively affect our sales of Erwinaze, Defitelio and other products. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of our products. If our

specialty sales force and sales organization are not appropriately sized to adequately promote any current or potential future products, the commercial potential of our current products and any future products may be diminished.

We also face competition, and may in the future face additional competition, from manufacturers of generic drugs. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the U.S. allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. Other companies could also develop products that are similar, but not identical, to our marketed products, such as an alternative formulation of our product or an alternative formulation combined with a different delivery technology, and seek approval in the U.S. by referencing our products and relying, to some degree, on the FDA's finding that our products are safe and effective. For more information, see the risk factor under the heading *"If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected"* in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Our products and product candidates may also compete in the future with new products currently under development by others. 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.

Our ability to continue to grow further requires that we compete successfully with specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. These competitors include established companies that may have a competitive advantage over us due to their size and financial resources.

If we fail to attract, retain and motivate key personnel or to retain the members of our executive management team, our operations and our future growth may be adversely affected.

Our success and our ability to grow depend 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 and other critical personnel, all of whom work on many complex matters that are essential to our success. We do not carry "key person" insurance. The loss of services of one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities. Any employee may terminate his or her employment at any time without notice or with only short notice and without cause or good reason. The resulting loss of institutional knowledge may negatively impact our operations and future growth.

In addition, to grow our company we will need additional personnel. Competition for qualified personnel in the pharmaceutical industry is very intense. If we are unable to attract, retain and motivate quality individuals, including in our research and development operations, which are continuing to expand, our business, financial condition, results of operations and growth prospects could be adversely affected.

We also depend on the unique abilities, industry experience and institutional knowledge of the members of our board of directors to efficiently set company strategy and effectively guide our executive management team. We cannot be certain that future board turnover will not negatively affect our business.

Significant disruptions of information technology systems or data security breaches could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. From time to time, our systems have been subject to cyber-attacks.

Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or

employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

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 depends in part on obtaining and maintaining patent protection of our products and product candidates and their use and the methods used to manufacture and distribute them, as well as successfully defending these patents against third party challenges, and successfully protecting our trade secrets. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents or have trade secrets that cover these activities. We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents, that the patents we own and license, or any additional patents we may own or license, will prevent other companies from developing similar or therapeutically equivalent products, or 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.

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal, regulatory and factual questions. We own a portfolio of U.S. and non-U.S. patents and patent applications and have licensed rights to a number of issued patents and patent applications that cover or relate to our products and product candidates, including Xyrem and Defitelio. Changes in either the patent laws or in interpretations of patent laws in the U.S. 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, potentially including by FDA approval of an ANDA that avoids infringement of our intellectual property.

On September 16, 2011, the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law. The final substantive provisions of the America Invents Act, including the first to file system, became effective on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as IPR and other post grant reviews. These proceedings are conducted before the PTAB. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. The IPR process permits any person (except a party who has sued on the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We cannot predict what impact, if any, amendments to the America Invents Act or other patent-related legislation, or judicial decisions interpreting such legislation, will have on such uncertainties and costs.

Although Xyrem is covered by patents covering its formulation, distribution system and method of use, third parties are seeking to introduce generic versions of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy. If one or more companies receive FDA approval of an ANDA for generic versions of Xyrem or an NDA for other sodium oxybate products, it is possible that such company or companies could introduce generic versions of Xyrem or other sodium oxybate products before our patents expire, if it is determined that our patents are invalid, unenforceable or non-infringed, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch competition to Xyrem at risk of potentially being held liable for damages for patent infringement.

Seven companies have sent us notices that they have filed ANDAs with the FDA seeking approval to market a generic version of Xyrem. We have filed lawsuits seeking to prevent the introduction of a generic version of Xyrem that would infringe our patents, but we cannot assure you that any of the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. In the second quarter of 2016, we settled two of these lawsuits. Additional ANDAs could also be filed requesting approval to market generic versions of Xyrem. If any of these applications is approved,

and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Although no trial date has been set in any of the current ANDA suits, we anticipate that trial on some of the patents in the Roxane case could occur as early as the third quarter of 2016. However, the actual timing of events may be significantly earlier or later than we currently anticipate, and we cannot predict the timing or outcome of events in this or the other ANDA litigation.

Certain ANDA filers have filed petitions for IPR with respect to the validity of certain distribution, method of use and formulation patents covering Xyrem. The PTAB has issued decisions instituting IPR trials with respect to patents and patent claims that are the subject of certain of these petitions, and we expect the PTAB to issue final decisions in the first of these trials in July 2016. For a description of these matters, see "Legal Proceedings" in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

A company that is using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients has stated that it anticipates commencing a Phase 3 pivotal trial in 2016 that is expected to run through early 2017. For more information, see the risk factor under the heading "*If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

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 invent or file, as appropriate, subject matters covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- 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;
- our issued patents may not cover our competitors' products;
- our issued patents and the issued patents of our licensors or partners may be vulnerable to legal challenges as a result of changes in applicable law;
- 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 U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. We rely on trade secrets and other unpatented proprietary information to protect our commercial position with respect to such products, which we may be unable to do. In some instances, we also rely on regulatory exclusivity. For example, Erwinaze has no patent protection. In addition to protection using trade secrets, Erwinaze has orphan drug exclusivity in the U.S. for a seven-year period from its FDA approval, which precludes approval of another product with the same principal molecular structure for the same indication until November 2018. Erwinaze, as a biologic product approved under a BLA, is also subject to the U.S. Biologics Price Competition and Innovation Act, or BPCIA. We believe that Erwinaze is protected by exclusivity that prevents approval of a biosimilar in the U.S. through late 2023 under the BPCIA. Because the BPCIA is a relatively new law, we anticipate that its impact on both reference product sponsors and biosimilar applicants will evolve over a period of years. Its implementation likely will be shaped by a variety of factors, including FDA issuance of guidance documents, proposed regulations, and decisions in the course of considering specific applications. As a result, it is possible that a potential competing drug product might obtain FDA approval before the orphan drug and expected BCPIA exclusivity periods have expired, which would adversely affect sales of Erwinaze. In the EU, the regulatory data protection and thus regulatory exclusivity period for Erwinase has lapsed. This also means that any new marketing authorizations for Erwinase in other EU member states will not receive any regulatory data protection. If a biosimilar product to Erwinaze is approved as interchangeable to Erwinaze in the U.S. or in other countries where Erwinaze is sold, a significant percentage of the prescriptions that would have been written for Erwinaze may be filled with the biosimilar version, resulting in a loss in sales of Erwinaze, and there may be a decrease in the price at which Erwinaze can be sold. Competition from a biosimilar product to Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, 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 non-U.S. counterparts, and may file additional U.S. and non-U.S. patent applications. 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, for a variety of reasons, including the existence of relevant prior research performed and the existence of conflicting 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 a third party from infringing our patents, our licensed patents or our partners' patents, that third party has the right to ask the court, or to argue in front of an administrative agency, to rule that these patents are invalid and/or should not be enforced. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. There is also a risk that a court will decide that these patents are not valid or infringed, or that the PTAB will decide that certain patents are not valid, and that we do not have the right to stop a third party from using the patented subject matter. Litigation involving patent matters is frequently settled between the parties, rather than continuing to a court ruling. If we were to settle a patent lawsuit with a generic pharmaceutical company, we could be subject to investigations by the FTC or other antitrust enforcement agencies or government or private-party lawsuits. The FTC has publicly stated that, in its view, certain types of agreements between brand and generic pharmaceutical companies related to the settlement of patent litigation or the manufacture, marketing and sale of generic versions of branded drugs violate the antitrust laws and has commenced investigations and brought actions against some companies that have entered into such agreements. In particular, the FTC has expressed its intention to take aggressive action to challenge settlements that include an alleged transfer of value from the brand company to the generic company (so-called "pay for delay" patent litigation settlements) and to call on legislators to pass stronger laws prohibiting such settlements. Because there is currently no precise legal standard with respect to the lawfulness of such settlements, there could be extensive

litigation over whether any settlement that we might enter into constitutes a reasonable and lawful patent settlement. Any such investigations or lawsuits, and the outcome thereof, could have a material adverse effect on our business.

Seven companies have sent us notices that they have filed ANDAs with the FDA seeking approval to market a generic version of Xyrem. We have filed lawsuits seeking to prevent the introduction of a generic version of Xyrem that would infringe our patents, but we cannot assure you that any of the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. In the second quarter of 2016, we settled two of these lawsuits. Additional ANDAs could also be filed requesting approval to market generic versions of Xyrem. If any of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Although no trial date has been set in any of the current ANDA suits, we anticipate that trial on some of the patents in the Roxane case could occur as early as the third quarter of 2016. However, the actual timing of events may be significantly earlier or later than we currently anticipate, and we cannot predict the timing or outcome of events in this or the other ANDA litigation. Certain ANDA filers have also filed petitions for IPR with respect to the validity of certain distribution, method of use and formulation patents covering Xyrem. The PTAB has issued decisions instituting IPR trials with respect to patents and patent claims that are the subject of certain of these petitions, and we expect the PTAB to issue final decisions in the first of these trials in July 2016. For a description of these matters, see “Legal Proceedings” in Part II, Item 1 of this Quarterly Report on Form 10-Q. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business. In addition, the IPR process under the America Invents Act permits any person, whether they are accused of infringing the patent at issue or not, to challenge the validity of certain patents. As a result, entities associated with hedge funds have challenged valuable pharmaceutical patents through the IPR process. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business. For more information, see the risk factor under the heading “*It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection”* in Part II, Item 1A of this Quarterly Report on Form 10-Q. We cannot assure you that our pending lawsuits, other lawsuits or proceedings we may file in the future, or our defense against any lawsuits or other proceeding that have been or will be brought against us will be successful in stopping the infringement of our patents, that any such litigation or other proceedings will be cost-effective, or that any of them will have a satisfactory result for us.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party’s patent rights, or that we or such partners are infringing, misappropriating or otherwise violating other intellectual property rights, and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Such 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, misappropriating or otherwise violating third party patent or other intellectual property rights, which could be very costly to us and have a material adverse effect on our business.

In the pharmaceutical and life sciences industry, like other industries, 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, which we may not be able to do.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. and many non-U.S. jurisdictions are typically not published until 18 months after their priority date, 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 or our licensors’ 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 USPTO to determine priority of invention in the U.S. 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. Patent interferences are limited or unavailable for patent applications filed after March 16, 2013.

Some of our competitors may be able to sustain the costs of complex patent and other intellectual property 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.

We own patents that cover, among other things, the formulation and method of use covering the administration for Xyrem. In July 2014, the USPTO issued us a new method of use patent relating to the safe and effective use of Xyrem by decreasing the dose of Xyrem when used concomitantly with divalproex sodium. In June 2015, the USPTO issued us another new method of use patent relating to decreasing the dose of Xyrem when used concomitantly with divalproex sodium. Both of these patents have been listed in the Orange Book. We have filed lawsuits against each of the Xyrem ANDA filers alleging infringement of these patents and seeking a permanent injunction to prevent these Xyrem ANDA filers from introducing a generic version of Xyrem that would infringe these patents. While we believe the additional safety information is critical for the safe use of Xyrem and should be required to be included in the label for any proposed generic form of Xyrem, we do not know whether the FDA will require any proposed generic form of Xyrem to include this information in its product label or whether we will be successful in maintaining the validity of the applicable patents and protecting the patents from infringement.

We also own method of use patents and trade secrets that cover elements of the Xyrem REMS, including patents that cover the use of a single central pharmacy to distribute Xyrem. The Xyrem REMS approval letter includes statements from the FDA that (i) the approval action should not be construed or understood as agreement with us that dispensing through a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh its risks, and that the FDA has continuing concerns that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system and (ii) as with all REMS, the FDA intends to evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. We cannot predict whether the FDA will seek to require or ultimately require modifications to the Xyrem REMS, including with respect to the Xyrem distribution system, or seek to otherwise impose or ultimately impose additional requirements to the Xyrem REMS, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could potentially make it easier for future generic competitors, make it more difficult or expensive for us to distribute Xyrem and/or negatively affect sales of Xyrem. In particular, depending on the nature of any such modifications or additional requirements, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced. In addition, the extent of protection provided by our method of use patents covering the distribution of Xyrem depends on the nature of the distribution system that may be used by any generic competitor, including whether the distribution system is as restricted as the distribution system set forth in the Xyrem REMS. If a generic competitor is able to obtain ANDA approval for a generic version of Xyrem based on a REMS that does not fall within the scope of any of the claims of our distribution patents, those patents will not be a barrier to the generic version's entry into the market. We cannot be certain whether our existing distribution patents or patents that may be granted in the future will be construed to cover any generic REMS or risk management plan that might be approved by the FDA. The interpretation of intellectual property protections and the effect of these protections are extremely complex, and we cannot predict the impact of any of these matters on our business.

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 manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, record keeping, importing and exporting of our products and our research and development activities are subject to extensive regulation by the FDA, the EC, the competent authorities of the EU member states and other regulatory authorities. Regulations differ from country to country. As a result of these regulations, product development, approval and commercialization processes are expensive and time-consuming. For example, we are not permitted to market a pharmaceutical product in the U.S. or in the EU member states until we receive approval from the FDA, the EC or the competent authorities of the EU member states, as applicable. An application for marketing approval must contain information demonstrating the quality, safety and efficacy of the pharmaceutical product, including data from preclinical and clinical trials, information pertaining to the preparation and manufacture of the active pharmaceutical ingredient, analytical methods, product formulation, details on the manufacture and stability of the finished pharmaceutical product and proposed product packaging and labeling. Submission of an application for marketing authorization does not assure approval for marketing in any jurisdiction, and we may encounter significant difficulties or costs in our efforts to obtain approval to market products. 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. Any delay or failure in obtaining approval of a drug candidate, or receipt of approval for narrower indications than sought, can have a negative impact on our financial performance.

If the FDA, the EC or the competent authorities of the EU member states determine that a REMS or the imposition of post-marketing obligations is necessary to ensure that the benefits of the drug outweigh the risks, we may be required to include a proposed REMS as part of an NDA or BLA or to propose post-marketing obligations to be included in the marketing authorization for our products in the EU. We may also be required to include a patient package insert or a medication guide to provide information to consumers about the product's risks and benefits, a plan for communication to healthcare providers, and restrictions on the product's distribution. For example, the FDA requires a REMS for Xyrem, discussed in detail in the risk

factor under the heading "*The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk evaluation and mitigation strategy, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem*" in Part II, Item 1A of this Quarterly Report on Form 10-Q, and other products that we sell are or may become subject to a REMS specific to our product or shared with other products in the same class of drug. We cannot predict the impact that any new REMS requirements applicable to any of our products would have on our business.

The FDA approved the BLA for Erwinaze in the U.S. in November 2011, subject to certain post-marketing requirements, which have been completed, and compliance with multiple post-marketing commitments, including certain commitments that must be met by the product's manufacturer with respect to product manufacturing, which are outside of our control. While activities are underway to complete the post-marketing commitments, any inability to comply with regulatory requirements, including compliance with manufacturing-related post-marketing commitments that are part of the BLA approval, as well as other requirements monitored by the FDA, could adversely affect Erwinaze supply, particularly in light of our extremely limited product inventory, and could result in FDA approval being revoked, product release being delayed or product recalls, any of which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product.

As another example, the marketing authorization in the EU for Defitelio requires us to comply with a number of post-marketing obligations, including obligations relating to the establishment of a patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use, and the FDA imposed several post-marketing commitments and requirements in connection with its approval of our NDA for Defitelio in March 2016, including the requirement that we conduct a clinical trial to analyze the safety of defibrotide versus best supportive care in the prevention of VOD in adult and pediatric patients. If we fail to meet any of these post-marketing obligations, our sales of and revenues from Defitelio could be materially adversely affected, and our potential future maintenance and growth of the market for this product may be limited.

Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition.*

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, together, the Healthcare Reform Act, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, or the 340B program, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Details of the changes to the Medicaid Drug Rebate program and the 340B program are discussed in the risk factor under the heading "*If we fail to comply with our reporting and payment obligations under the Medicaid Drug 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*" in Part II, Item 1A of this Quarterly Report on Form 10-Q. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Healthcare Reform Act, including the employer mandate. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

Moreover, legislative changes to the Healthcare Reform Act remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved.

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third party payors to keep healthcare costs down while expanding individual healthcare benefits.

Likewise, in the countries in the EU, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Further, an increasing number of EU member states and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement for our products in some countries, including some EU member states, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our products will obtain favorable reimbursement status in any country.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem free product voucher program and co-pay coupon programs for Xyrem and certain other products. Additionally, we make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. Co-pay coupon programs, including our program for Xyrem, have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives. In recent years, other pharmaceutical manufacturers were named in class action lawsuits challenging the legality of their co-pay programs under a variety of federal and state laws. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar lawsuits or insurer actions. In addition, in November 2013, the Centers for Medicare and Medicaid Services, or CMS, issued guidance to the issuers of qualified health plans sold through the Healthcare Reform Act's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the Office of Inspector General, or OIG, of the U.S. Department of Health and Human Services, or HHS, issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Medicare Part D beneficiaries from using co-pay coupons. In 2015, the OIG refined existing guidance with respect to manufacturer grants to independent charitable foundations that provide financial support to financially needy patients, and has issued new or revised advisory opinions containing updated guidance on the government's view of such programs. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, including Xyrem, and therefore could have a material adverse effect on our sales, business and financial condition.

We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.*

Oversight by FDA and Equivalent Non-U.S. Regulatory Authorities

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, record keeping, importing and exporting of our products are, and any of our product candidates that may be approved by the FDA, the EC, the competent authorities of the EU member states and other non-U.S. regulatory authorities will be, subject to extensive and ongoing regulatory requirements. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. Failure by us or any of our third party partners, including suppliers, distributors and our central pharmacy for Xyrem, to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to

approve a product candidate, withdrawal, suspension or variation of product approval, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall, withdrawal or seizure, total or partial suspension of production or distribution, interruption of manufacturing or clinical trials, operating restrictions, injunctions; suspension of licenses, civil penalties and/or criminal prosecution, any of which could have a significant impact on our sales, business and financial condition.

We monitor adverse events resulting from the use of our commercial products, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The authorities review these events and reports, and if they determine that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing and/or require or conduct other actions, potentially including withdrawal or suspension of the product from the market, any of which could result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The FDA and the competent authorities of the EU Member States on behalf of the EMA also periodically inspect the company records related to safety reporting. Following such inspections, the FDA may issue notices on FDA Form 483 and warning letters that could cause us to modify certain activities. The EMA's Pharmacovigilance Risk Assessment Committee, or the PRAC, may propose to the Committee for Human Medicinal Products, or the CHMP, that the marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended, or withdrawn. An FDA Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated relevant FDA regulations or guidance. Failure to adequately and promptly correct the observation(s) can result in further regulatory enforcement action. For example, in April 2014, we received an FDA Form 483 at the conclusion of a pharmacovigilance inspection conducted by the FDA. The FDA Form 483 included observations relating to certain aspects of our adverse drug experience, or ADE, reporting system for all of our products, including Xyrem. We responded to the FDA Form 483 with a description of the corrective actions and improvements we had implemented before or shortly following the inspection and additional improvements that we planned to implement, and have now implemented, to address the observations in the FDA Form 483. In August 2014, the FDA issued an Establishment Inspection Report to us, which indicates that the inspection is closed. Although we have implemented improvements to our ADE reporting system, there can be no assurance that the FDA or other regulatory agencies will not identify additional matters in future pharmacovigilance inspections or that we will be able to adequately address any matters identified by the FDA or other regulatory agencies in the future, and the failure to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we receive regulatory approvals to sell our products, the FDA, the EC, the competent authorities of the EU member states and other non-U.S. regulatory authorities where our products are approved 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 commercial potential of the product. If we become aware of problems with any of our products in the U.S., the EU or elsewhere in the world or at our third party suppliers' facilities, a regulatory agency may impose restrictions on our products, our suppliers, our other partners or us. In such an instance, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits. For example, in April 2015, Medtronic Inc., or Medtronic, announced a consent decree with the FDA related to Medtronic's SynchroMed® II implantable infusion pump systems. Our product Prialt is approved for administration to patients via that pump. While the Medtronic consent decree does not impact existing patients with the pump, physicians who want to implant the pump in new patients are required to complete a certification process to document medical necessity. While the approved indication for Prialt is one of the conditions eligible to support a showing of medical necessity provided by the consent decree, we cannot predict the impact of this new certification requirement on sales of Prialt.

EU legislation related to pharmacovigilance, or the assessment and monitoring of the safety of medicinal products enhanced the authority of the EMA and the competent authorities of the EU member states to require companies to conduct additional post-approval clinical efficacy and safety studies and increased the burden on companies with respect to additional monitoring, adverse event management and reporting. Under the legislation and its related regulations and guidelines, we may be required to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and may be required to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time-consuming and expensive and could impact our profitability. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

The FDA approved the BLA for Erwinaze in the U.S. in November 2011, subject to certain post-marketing requirements, which have been completed, and compliance with multiple post-marketing commitments, including certain commitments that must be met by the product's manufacturer with respect to product manufacturing, which are outside of our control. While

activities are underway to complete the post-marketing commitments, any inability to comply with regulatory requirements, including compliance with manufacturing-related post-marketing commitments that are part of the BLA approval, as well as other requirements monitored by the FDA, could adversely affect Erwinaze supply and could result in FDA approval being revoked or product recalls, either of which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product.

The marketing authorization in the EU for Defitelio requires us to comply with a number of post-marketing obligations, including obligations relating to the establishment of a patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use, and the FDA imposed several post-marketing requirements and commitments in connection with its March 2016 approval of our NDA for Defitelio, including the requirement that we conduct a clinical trial to analyze the safety of defibrotide versus best supportive care in the prevention of VOD in adult and pediatric patients. We may be unable to comply with these or other post-marketing obligations. If we fail to meet any of these post-marketing obligations, our sales of and revenues from Defitelio could be materially adversely affected, and our potential future maintenance and growth of the market for this product may be limited.

Erwinase and defibrotide are available on a named patient basis in many countries where they are not commercially available. While we believe we have satisfied the regulations regarding our communications and medical affairs activities in those countries, if any such country's regulatory authorities determine that we are promoting Erwinase or defibrotide without proper authorization, we could be found to be in violation of pharmaceutical advertising law or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties.

The FDA, the competent authorities of the EU member states and other governmental authorities require advertising and promotional labeling to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. The FDA routinely provides its interpretations of that authority in informal communications and also in more formal communications such as untitled letters or warning letters, and although such communications may not be considered final agency decisions, companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful.

The FDA, the competent authorities of the EU member states and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. A company that is found to have promoted an approved product for off-label uses may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. For all of our products, it is important that we maintain a comprehensive compliance program. Failure to maintain a comprehensive and effective compliance program, and to integrate the operations of acquired businesses into a combined comprehensive and effective compliance program on a timely basis, could subject us to a range of regulatory actions that could affect our 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.

Other Regulatory Authorities

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the U.S. Department of Justice, or DOJ, the FTC, the DOC, the OIG and other regulatory bodies, as well as governmental authorities in those non-U.S. countries in which we commercialize our products. In addition to the FDCA, other federal, state and non-U.S. 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, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our partners, including our suppliers and distributors and the central pharmacy for Xyrem, are subject to many of the same requirements.

These requirements include obtaining sufficient quotas from the DEA each year to manufacture sodium oxybate and Xyrem in the U.S. In addition to quota requirements, the DEA imposes various registration, importing, exporting, record keeping and reporting requirements, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the Controlled Substances Act, or CSA. The states also impose similar requirements for handling controlled substances. The U.S. and the EU member states are parties to the Convention on Psychotropic Substances (1971), or the 1971 Convention. In October 2012, the World Health Organization sent a recommendation to the United Nations Commission on Narcotic Drugs, or CND, to reschedule GHB under the 1971 Convention from Schedule IV status to Schedule II status. In March 2013, the CND voted to reschedule GHB from Schedule

IV to Schedule II under the 1971 Convention. While the DEA imposes its own scheduling requirements in the U.S. under the CSA, the U.S. is obligated as a signatory to the 1971 Convention to ensure that drug scheduling in the U.S. is consistent with its obligations under the international treaties. The change in international scheduling did not result in a change in the U.S. control of GHB. Failure by us or any of our partners, including suppliers and distributors, to comply with the requirements of the CSA and other regulatory bodies could result in, among other things, additional operating costs to us, delays in shipments outside or into the U.S. and adverse regulatory actions.

The U.S. federal healthcare program anti-kickback 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 or recommending the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. The Healthcare Reform Act amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability, and therefore would be subject to a facts and circumstances analysis.

The False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false statement to get a false claim paid. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Many pharmaceutical and other healthcare companies have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company’s products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, in recent years the government and private whistleblowers have pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

In addition, the Physician Payment Sunshine Act, or Sunshine provisions, require extensive tracking of payments and transfers of value to physicians and teaching hospitals and public reporting of the data collected. On September 30, 2014, CMS published the first set of data collected under the Sunshine provisions. On or before the 90th day of each calendar year starting in 2015, manufacturers covered under the Sunshine provisions are required to submit a report disclosing payments and transfers of value made in the preceding calendar year, and CMS then will publish the reported data on or before June 30 of the reporting year. It is widely anticipated that public reporting under the Sunshine provisions will result in increased scrutiny of the financial relationships between industry, teaching hospitals and physicians, and such scrutiny may negatively impact our ability to engage with physicians on matters of importance to us. In addition, if the data reflected in our reports are found to be in violation of any of the Sunshine provisions or any other U.S. federal, state or local laws or regulations that may apply, or if we otherwise fail to comply with the Sunshine provisions, we may be subject to significant civil, criminal and administrative penalties, damages or fines.

The majority of states also have statutes or regulations similar to the federal anti-kickback 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. A number of states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Outside the U.S., we are subject to similar regulations in those countries where we market and sell products.

In May 2016, we received a subpoena from the U.S. Attorney’s Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, and, for Xyrem, documents concerning our provision of financial assistance to Medicare patients. Other companies have disclosed similar inquiries. We intend to cooperate with this subpoena. We are unable to predict how long this investigation will

continue or its outcome, but it is possible that we will incur significant costs in connection with the investigation, regardless of the outcome. We may also become subject to similar investigations by other state or federal governmental agencies. The investigation by the U.S. Attorney's Office and any additional investigations of our patient assistance programs or other business practices may result in damages, fines, penalties or other administrative sanctions against us, negative publicity or other negative actions that could harm our reputation, reduce demand for Xyrem and/or reduce coverage of Xyrem, including by federal health care programs and state health care programs. If any or all of these events occur, our business and stock price could be materially and adversely affected.

In the EU, the advertising and promotion of our products are subject to EU member states' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU member states may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the EU. The applicable laws at EU level and in the individual EU member states also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU member states. One example is the U.K. Bribery Act. As further discussed below, the U.K. Bribery Act applies to any company incorporated in or "carrying on business" in the U.K., irrespective of where in the world the alleged bribery activity occurs, which could have implications for our interactions with physicians both in and outside of the U.K. Violation of these laws could result in substantial fines and imprisonment. Certain EU member states require that payments made to physicians must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Our business activities outside of the U.S. are subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including both U.K. and non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the U.K. may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, in another country by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but having in place adequate procedures designed to prevent bribery is an available defense. Furthermore, under the U.K. Bribery Act there is no exception for facilitation payments. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the U.S. Securities and Exchange Commission, or SEC, and the DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures and internal controls. However, there is no certainty that all employees and third party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of suppliers and other third party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which

could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

We are also subject to laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations, could create liability for us (including the imposition of significant penalties), result in adverse publicity and negatively affect our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, EU member states and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the U.S., which are not considered by the EC to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the U.S., a recent decision of the European Court of Justice that invalidated the safe harbor framework on which we have relied has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it will no longer be possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. In addition, data protection authorities from the different EU member states may interpret the EU Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. In February 2016, the EC announced an agreement with the United States Department of Commerce, or DOC, to replace the invalidated Safe Harbor framework with a new EU-US “Privacy Shield.” The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its recent ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and FTC, and making commitments on the part of public authorities regarding access to information. However, the Privacy Shield is still under review, and a formal vote of the EC will be required before it will go into effect. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the U.S. (or other countries not considered by the EC to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the EC. The EU General Data Protection Regulation, which was officially adopted in April 2016 and will be applicable in May 2018, will introduce new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

The number and complexity of both U.S. federal and state laws continue to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In addition, we expect private plaintiffs to continue to file lawsuits against pharmaceutical manufacturers under the whistleblower provisions of the False Claims Act and state equivalents and to seek out new theories of liability under those statutes. We also expect government enforcement agencies to continue to “intervene” in private whistleblower lawsuits, effectively converting the private lawsuit into a lawsuit by the government, which typically increases the likelihood that the lawsuit will result in increased expense for the company and/or a burdensome settlement. For example, federal enforcement agencies recently have shown interest in pharmaceutical companies’ product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements. Other private whistleblowers have proceeded without government invention, causing considerable expense to targeted companies.

Recent changes in the law have reinforced and facilitated these trends. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government’s ability to pursue anti-kickback and false claims cases against

pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, and amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations, such as defining a "false" claim to include any claim based on a violation of the anti-kickback statute. While we cannot say with certainty what effect these changes have had or will have on our business, we anticipate that increased enforcement and litigation, including through government intervention in whistleblower lawsuits and private whistleblowers proceeding on their own, will continue for the foreseeable future. Responding to a whistleblower lawsuit, government investigation or enforcement action, defending any claims raised, and paying any resulting fines, damages, penalties or settlement amounts would be expensive and time-consuming, and could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects.

Compliance with U.S. federal and state, EU and EU member state national laws that apply to pharmaceutical manufacturers is difficult and time-consuming, and companies that violate these laws may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and, in some cases, the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. For example, the FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular to whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC, other governmental authorities or others could claim or determine that we are using the Xyrem REMS in an anticompetitive manner (including in light of the FDA's statement in the Xyrem REMS approval letter that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the FDCA) or have engaged in other anticompetitive practices. The FDCA further states that a REMS shall not be used by an NDA holder to block or delay generic drugs from entering the market. Several of the ANDA applicants have asserted that our patents covering the distribution system for Xyrem should not have been listed in the Orange Book, and that the Xyrem REMS is blocking competition. We cannot predict the outcome of these claims in the ongoing litigation, or the impact of any similar claims that may be made in the future. Such a challenge or any other challenge that we or our business partners have failed to comply with applicable laws and regulations could have a material adverse effect on our business, financial condition, results of operations and growth prospects. If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our 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.

We manufacture certain active pharmaceutical ingredients, including the defibrotide drug substance, at our manufacturing facilities in Italy. In addition, we have engaged a third party supplier to process defibrotide into the finished product in Italy. Our manufacturing facilities and those of our third party manufacturer are subject to continuing regulation by the Italian Health Authority and other Italian regulatory authorities with respect to the manufacturing of active pharmaceutical ingredients and drug products, including the defibrotide drug substance and its finished form. These facilities are also subject to inspection and regulation by the EMA. Also, part of the process to obtain approval for defibrotide is to pass a pre-approval inspection by the EMA, Italian Health Authority and the FDA to ensure that these facilities are in compliance with cGMP. Following initial approval in a jurisdiction, the applicable authorities will continue to inspect our manufacturing facilities and those of our third party supplier, in some cases, unannounced, to confirm ongoing compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our third party suppliers will need to ensure that all of our processes, methods and equipment are compliant with cGMP. If these authorities determine that either our facilities or our third party supplier's facility in Italy do not meet the standards of compliance required under applicable regulations, they may deny approval to manufacture our products, require us to stop manufacturing our products, deny approval to the sale of our products or suspend the sale of our products.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug 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 and have certain price reporting obligations to the Medicaid Drug Rebate program, several state Medicaid supplemental rebate programs and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program.

Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates

are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Such data previously have not been submitted for Quadramet® (samarium sm 153 lexidronam injection) and ProstaScint® (capromab pendetide), which are radiopharmaceutical products. We engaged in interactions with CMS and a trade group, the Council on Radionuclides and Radiopharmaceuticals, or CORAR, regarding the reporting of Medicaid pricing data and paying Medicaid rebates for radiopharmaceutical products. In addition to the discussions with CMS as part of CORAR, we have had separate discussions with CMS directly regarding Quadramet. We sold Quadramet to a third party in December 2013, but we retained any liabilities related to sales of the product during prior periods. Similarly, we sold ProstaScint to a third party in May 2015, but we retained any liabilities related to sales of the product during prior periods. We are currently unable to predict whether price reporting and rebates will be required for Quadramet and ProstaScint and, if so, for what period they will be required. We are currently unable to reasonably estimate an amount or range of a potential contingent loss related to the payment of rebates for Quadramet or ProstaScint. Any material liability resulting from radiopharmaceutical price reporting and rebates would negatively impact our financial results.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well and changing the definition of average manufacturer price. The Healthcare Reform Act also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The Healthcare Reform Act expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs" from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. For example, the initiation of any reporting of Medicaid pricing data for ProstaScint and Quadramet could result in retroactive 340B ceiling price liability for these two products. We are currently unable to reasonably estimate an amount or range of a contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Healthcare Reform Act obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. In 2015, the Health Resources and Services Administration, or HRSA, issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program. HRSA is currently expected to issue additional proposed regulations in 2016. Any final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Statutory or

regulatory changes or CMS binding guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B drug discount program.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DoD, Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information. These obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DoD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Price approvals and 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 non-U.S. 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 U.S., governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. In many countries, price approvals must be obtained before products can be placed on the market or submitted for reimbursement. Third party payors, including government payors, decide which drugs can be reimbursed and establish reimbursement and co-pay levels and conditions for reimbursement. 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 and co-pay policies. We may need to conduct expensive pharmacoeconomic and/or clinical studies in order to demonstrate the cost-effectiveness of our products. Even with such studies, our products may be considered less safe, less effective or less cost-effective than other products, and third party payors may not provide and maintain price approvals, coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. 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 impact our ability to sell our products profitably. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies and reforms intended to curb healthcare costs, particularly given the current atmosphere of mounting criticism of prescription costs in the U.S. These cost containment measures may include controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; pharmaceutical cost transparency bills that aim to require drug companies to justify their prices; controls on healthcare providers; challenges to the pricing of drugs, or limits or prohibitions

on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third party payors to make coverage and payment decisions. For example, in March 2016, CMS proposed to conduct a demonstration project that would reduce the Medicare payment rates for most Part B drugs from average sales price plus 6% to average sales price plus 2% for approximately half of the country. CMS indicated that it intends to implement this model in 2016. Additionally, drug pricing by pharmaceutical companies has recently come under close scrutiny, particularly with respect to companies that have increased the price of products after acquiring those products from other companies. For example, in late 2015 the U.S. House of Representatives formed an Affordable Drug Pricing Task Force to advance legislation intended to control pharmaceutical drug costs and investigate pharmaceutical drug pricing. Since then, both the U.S. House of Representatives and the U.S. Senate have conducted numerous hearings with respect to pharmaceutical drug pricing practices, including in connection with the investigation of specific price increases by several pharmaceutical companies. If we become the subject of government investigation with respect to our drug pricing or other business practices, we could incur significant expense and could be distracted from execution of our strategy. Any such investigation could also result in reduced market acceptance and demand for our products, could harm our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In May 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, and, for Xyrem, documents concerning our provision of financial assistance to Medicare patients. For more information, see the risk factor under the heading *"We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products"* in Part II, Item 1A of this Quarterly Report on Form 10-Q. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products, including Xyrem, may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

In addition, much attention has been paid to legislation proposing federal rebates on Medicare Part D and Medicare Advantage utilization for drugs issued to certain groups of lower income beneficiaries and the desire to change the provisions that treat these dual-eligible patients differently from traditional Medicare patients. Any such changes could have a negative impact on revenues from sales of our products.

Further, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

Third party payors' practices may affect the conditions required for reimbursement and the availability of reimbursement for our products, including Xyrem and Defitelio. Our business could be materially harmed if the Medicaid program, Medicare program or other third party payors in the U.S. or elsewhere were to deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms. This risk is particularly significant with respect to Xyrem and Defitelio, in part due to payor sensitivity to the price of these products. Third party payors often require prior authorization for, require reauthorization for continuation of, or refuse to provide reimbursement for our products, and others may do so in the future. As a result of such practices, patients may not be able to obtain prescribed medications due to an inability to afford the medication. For example, we are experiencing increasingly restrictive conditions for reimbursement required by some third party payors for Xyrem, which may have a material effect on the overall level of reimbursement coverage for Xyrem. In addition, increases in reimbursement-related activities have extended the time required to fill prescriptions and could continue to do so in the future. Further, increasing consolidation among third party payors has led to fewer and larger third party payors with increased negotiating power. In particular, a small number of third party payors cover a significant portion of Xyrem patients. We have experienced and expect to continue to experience increasing pressure from third party payors to agree to discounts, rebates or other restrictive pricing terms for Xyrem. If we are unsuccessful in maintaining reimbursement for our products in a timely manner and at acceptable levels, if reimbursement for our products by third party payors is subject to restrictive pricing terms or overly restrictive reimbursement conditions, or if third party payors limit the indications for which our products will be reimbursed or refuse to provide reimbursement, the level of reimbursement for our products would be negatively impacted, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In many countries, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing approval. We launched Defitelio in certain European countries in 2014 and continue to launch in additional European countries on a rolling basis. We are in the process of making pricing and reimbursement submissions with respect to Defitelio in those European countries where Defitelio is not yet launched, including in countries where pricing and

reimbursement approvals are required for launch. We cannot predict the timing of Defitelio's launch in countries where we are engaged in pricing and reimbursement submissions. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected countries would be delayed, or, if we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected. In addition, on March 30, 2016, the FDA approved our NDA for defibrotide for the treatment of adult and pediatric patients with VOD, also known as SOS, with renal or pulmonary dysfunction following HSCT. We launched Defitelio in the U.S. shortly after FDA approval. Our ability to commercialize Defitelio successfully in the U.S. will depend on, among other things, the availability of adequate coverage or reimbursement by U.S. government programs and third party payors. For more information, see the risk factor under the heading "*While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

We cannot predict actions third party payors may take, or whether they will limit the price approvals, coverage and level of reimbursement for our products or refuse to provide and maintain any approvals or coverage at all. For example, because some of our products compete in a market with both branded and generic products, obtaining and maintaining price approvals and reimbursement coverage by government and private payors may be more challenging than for new chemical entities for which no therapeutic alternatives exist. Additionally, in many countries, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness to prescribe our products. For example, the U.S. federal government follows a Medicare severity diagnosis-related group, or MS-DRG, payment system for certain institutional services provided under Medicare, which some states also use for Medicaid. The MS-DRG system entitles a healthcare facility to a fixed reimbursement based on discharge diagnoses rather than actual costs incurred in providing inpatient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many healthcare products. For our products used in the inpatient setting, there may not be sufficient reimbursement under the MS-DRG to fully cover the cost of our products. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to effectively commercialize our products.

Third party payors frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices or include other restrictive pricing terms. We have experienced increasing pressure from third party payors to agree to discounts, rebates or other restrictive pricing terms for products such as Xyrem. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce our sales and harm our results of operations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Any such requirements could have a negative impact on revenues from sales of our products.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. Certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover our products appropriately, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the federal marketplace. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs, including as a result of legislative changes to these programs, would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the U.S. in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations, additional legislative proposals to curb healthcare costs and negative publicity regarding pricing and price increases generally, which could limit the prices that we charge for our products, including Xyrem, limit our commercial opportunity and/or negatively impact revenues from sales of our products. In various EU member states we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. 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. We have periodically increased the price of Xyrem, most recently in February 2016, and we have made and may in the future make similar price increases on

our other products. We cannot assure you that such price adjustments will not negatively affect our ability to secure and maintain reimbursement coverage for our products, which could negatively impact our sales volumes and revenue.

Health Care Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states. These EU member states include the United Kingdom, France, Germany, Ireland, Italy, Spain, and Sweden. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products, as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between EU member states and cannot be determined or anticipated in relation to our products at the present time. If we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

In the EU, our products are marketed through various channels and within different legal frameworks. In certain EU member states, reimbursement for unauthorized products may be provided through national named patient programs. Such reimbursement may no longer be available if authorization for named patient programs expire or are terminated or when marketing authorization is granted. In other EU member states, authorization and reimbursement policies may also delay commercialization of our products, or may adversely affect our ability to sell our products on a profitable basis. After initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced member states.

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 negatively affect our growth prospects in Europe.

There also continue to be legislative proposals to amend U.S. laws to allow the importation into the U.S. of prescription drugs, which can be sold at prices that are regulated by the governments of various non-U.S. countries. The potential importation of prescription drugs could pose significant safety concerns for patients, increase the risk of counterfeit products becoming available in the market, and could also have a negative impact on prescription drug prices in the U.S. For example, the potential importation of Xyrem without the safeguard of our Xyrem REMS could harm patients and could also negatively impact Xyrem revenues.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products are associated with significant risks of product liability claims or recalls. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Some of our products, including Xyrem and Prialt, have boxed warnings in their labels. In addition, in the EU, Defitelio's label includes an inverted black triangle that indicates the product is subject to additional monitoring to permit quick identification of new safety information, as a condition of authorization of Defitelio under "exceptional circumstances." In many countries, including in EU member states, national laws provide for strict (no-fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party.

Product liability claims may be brought by individuals seeking relief for themselves or by groups seeking to represent a class of injured patients. Further, third party payors, either individually or as a putative class, may bring actions seeking to recover monies spent on one of our products. The risk of product liability claims may also increase if a company receives a warning letter from a regulatory agency. Product liability claims are an inherent risk in our business, but 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, or at all. 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, 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. A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the EMA, or the competent authorities of the EU member states. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension, variation, or withdrawal of approval. Any such regulatory action by the FDA, the EC or the competent authorities of the EU member states could lead to product liability lawsuits as well.

We use hazardous materials in our manufacturing facilities, and any claims relating to the improper handling, storage, release or disposal of these materials could be time-consuming and expensive.

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in Italy and Ireland where we have manufacturing facilities. Environmental and health and safety authorities in the relevant jurisdictions administer laws, which implement EU directives and regulations governing, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. In certain cases, such laws, directives and regulations may impose strict liability for pollution of the environment and contamination resulting from spills, disposals or other releases of hazardous substances or waste or any migration of such hazardous substances or waste. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us or at off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination. Our manufacturing activities in Italy and Ireland involve the controlled storage, use and disposal of chemicals and solvents. Our environmental policy is designed to comply with current EU laws and regulations on environmental protection, to provide for continuous improvement of our manufacturing performance, to protect our employees' health and safety and to respect the safety of people living close to our plant and in the surrounding community. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by these EU laws and regulations, we cannot completely eliminate the risk of contamination or injury from hazardous materials. If an accident occurs, an injured party could seek to hold us liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future EU environmental laws and regulations.

Risks Related to Our Financial Condition

We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position.*

As of March 31, 2016, we had total indebtedness of approximately $1.3 billion, which included $731.3 million of outstanding secured indebtedness under a credit agreement that we entered into in June 2015, which we refer to as our credit agreement, and $575.0 million of outstanding indebtedness under our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, which were issued in August 2014. Our debt may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for working capital, capital expenditures, acquisitions or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- result in dilution to our existing shareholders in the event exchanges of our 2021 Notes are settled in our ordinary shares;

- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

Our ability to meet our debt service obligations will depend on our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control. If we do not have sufficient funds to meet our debt service obligations, we may be required to refinance or restructure 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.

Covenants in our credit agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.

Our credit agreement provides for a $750.0 million principal amount term loan due in June 2020 and a $750.0 million revolving credit facility, with loans under such revolving credit facility due in June 2020, subject to early mandatory repayments under certain circumstances. Our credit agreement contains various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

Our credit agreement also includes financial covenants that require us to maintain a maximum secured leverage ratio and a minimum interest coverage ratio. Our ability to comply with these financial covenants may be affected by events beyond our control. In addition, the covenants under our credit agreement could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the credit agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the revolving credit facility. A default under our credit agreement could also lead to a default under agreements governing our current or future indebtedness, including the indenture governing our 2021 Notes.

In addition, the holders of our 2021 Notes have the ability to require us to repurchase their notes for cash if we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution, or the delisting of our ordinary shares from The NASDAQ Global Select Market. Moreover, upon exchange of the 2021 Notes, unless we elect to cause to be delivered solely ordinary shares to settle such exchange, we will be required to make cash payments in respect of the 2021 Notes being exchanged. In this regard, it is our intent and policy to settle the principal amount of the 2021 Notes in cash upon exchange. However, we may not have enough available cash or be able to obtain financing at the time we are required to make any required repurchases of surrendered 2021 Notes or to pay cash upon exchanges of 2021 Notes. Our failure to repurchase 2021 Notes at a time when the repurchase is required by the indenture governing the 2021 Notes or to pay any cash payable on future exchanges of the 2021 Notes as required by the indenture governing the 2021 Notes would constitute a default under that indenture. A default under that indenture could also lead to a default under agreements governing our current or future indebtedness, including our credit agreement. If the repayment of the related indebtedness were to be accelerated, we may not have sufficient funds to repay the related indebtedness, which could have a material adverse effect on our financial condition and our business. In this regard, if we are unable to repay amounts under our credit agreement, the lenders under the credit agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business.

We may not be able to generate sufficient cash to service our debt obligations.

Our ability to make payments on and to refinance our debt will depend on our future financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to maintain a level of positive cash flows from operating activities sufficient to permit us to pay the principal and interest on our debt.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, seek additional capital or restructure or refinance our debt. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations. In the absence of such cash flows and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. Our credit agreement restricts our ability to dispose of assets, use the proceeds from any disposition of assets and refinance our indebtedness. We may not be able to consummate or obtain proceeds from such dispositions, and any such proceeds may not be adequate to meet any debt service obligations then due.

In addition, our borrowings under our credit agreement are, and are expected to continue to be, at variable rates of interest and expose us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even if the amount borrowed remained the same, and our net income would decrease.

To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.

The scope of our business and operations has grown substantially since 2012 through a series of transactions, including the business combination between Jazz Pharmaceuticals, Inc. and Azur Pharma, which we refer to as the Azur Merger, our acquisition of EUSA Pharma Inc., or EUSA Pharma, which we refer to as the EUSA Acquisition, and the Gentium Acquisition. To continue to grow our business over the longer term, we will need to commit substantial additional resources to in-licensing and/or acquiring new products and product candidates, and to costly and time-consuming product development and clinical trials of our product candidates. We also intend to continue to invest in our commercial operations in an effort to grow sales of our current products. Our future capital requirements will depend on many factors, including many of those discussed above, such as:

- the revenues from our commercial products, which may be affected by many factors, including the extent of generic competition for our products;
- the costs of our commercial operations;
- the costs of integration activities related to any future strategic transactions we may engage in;
- the cost of acquiring and/or in-licensing any new products and product candidates;
- the scope, rate of progress, results and costs of our development and clinical activities;
- the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost of investigations, litigation and/or settlements related to regulatory oversight and third party claims; and
- changes in laws and regulations, including, for example, healthcare reform legislation.

Our strategy includes the expansion of our business through the acquisition or in-licensing and development of additional marketed products or product candidates that are in late-stage development. We cannot assure you that we will continue to identify attractive opportunities. Even if appropriate opportunities are available, in order to compete successfully to acquire attractive products or product candidates in the current business climate, we may have to pay higher prices for assets than may have been paid historically, and we may not have the financial resources necessary to pursue them. As a result, we may be unable to expand our business if we do not have sufficient capital or cannot borrow or raise additional capital on attractive terms. In particular, our substantial indebtedness may limit our ability to borrow additional funds for acquisitions or to use our cash flow or obtain additional financing for future acquisitions. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.*

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. We expect to opportunistically seek access to the capital and credit markets to supplement our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility to satisfy our needs for working capital, capital expenditures and debt service requirements or to continue to grow our business over the longer term through product acquisition and in-licensing, product development and clinical trials of product candidates, and expansion of our commercial operations. In the event of adverse capital and credit market conditions, we may not be able to obtain capital market financing or credit on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. Changes in our credit ratings issued by nationally recognized credit rating agencies could adversely affect our cost of financing and have an adverse effect on the market price of our securities. See also the discussion under the heading "*We are subject to a requirement under Irish law to periodically*

obtain new authorities from our shareholders to issue ordinary shares, which we may be unable to obtain" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

We may not be able to successfully maintain our tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.*

We are incorporated in Ireland and maintain subsidiaries in North America and a number of other foreign jurisdictions. We are able to achieve a low average tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, together with intra-group service and transfer pricing agreements, each on an arm's length basis. However, changes in tax laws in any of these jurisdictions could adversely affect our ability to do so in the future. Taxing authorities, such as the U.S. Internal Revenue Service, or the IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We are subject to reviews and audits by the IRS and other taxing authorities from time to time, and the IRS or other taxing authority may challenge our structure and transfer pricing arrangements through an audit or lawsuit. For example, in December 2015, we received proposed tax assessment notices from the French tax authorities for 2012 and 2013 relating to certain transfer pricing adjustments. The notices propose additional taxes of approximately $43.3 million, including interest and penalties, through the date of the assessment translated at the foreign exchange rate at March 31, 2016. Responding to or defending against this and other challenges from taxing authorities could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We generally cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes.*

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. Because we indirectly acquired all of Jazz Pharmaceuticals, Inc.'s assets through the acquisition of the shares of Jazz Pharmaceuticals, Inc. common stock in the Azur Merger, the IRS could assert that we should be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874. For us to be treated as a foreign corporation for U.S. federal tax purposes under Section 7874 of the Code, either (1) the former stockholders of Jazz Pharmaceuticals, Inc. must have owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Jazz Pharmaceuticals, Inc. (the "ownership test"), or (2) we must have substantial business activities in Ireland after the Azur Merger (taking into account the activities of our expanded affiliated group). The Jazz Pharmaceuticals, Inc. stockholders owned less than 80% of our share capital immediately after the Azur Merger by reason of their ownership of shares of Jazz Pharmaceuticals, Inc. common stock. As a result, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes under current law. It is possible that the IRS could disagree with the position that the ownership test is satisfied and assert that Section 7874 of the Code applies to treat us as a U.S. corporation following the Azur Merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. The IRS continues to scrutinize transactions that are potentially subject to Section 7874, and has issued several sets of final and temporary regulations under Section 7874 since 2012. Most recently, in April 2016, the IRS issued temporary regulations under Section 7874 reflecting guidance that the IRS previously announced in notices dated September 2014 and November 2015, as well as additional guidance. We do not expect these regulations to affect the U.S. tax consequences of the Azur Merger. Nevertheless, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have retroactive application to us, Jazz Pharmaceuticals, Inc., our respective shareholders and/or the Azur Merger. For more information, see the risk factor under the heading "*Future changes to the tax laws under which we expect to be treated as a foreign corporation for U.S. federal tax purposes or in other tax laws relating to multinational corporations could adversely affect us,*" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Section 7874 of the Code limits Jazz Pharmaceuticals, Inc.'s ability to utilize its U.S. tax attributes to offset certain U.S. taxable income, if any, generated by certain taxable transactions.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code can limit the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses, or NOLs, to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, this limitation applies to us. As a result, after the Azur Merger, Jazz Pharmaceuticals, Inc. has not been able and will continue to be unable, for a period of time, to utilize its U.S. tax attributes to offset its U.S. taxable income, if any, resulting from certain taxable transactions. Notwithstanding this limitation, we plan to fully utilize Jazz Pharmaceuticals, Inc.'s U.S. NOLs prior to their expiration. As a result of this limitation, however, it may take Jazz Pharmaceuticals, Inc. longer to use its NOLs. Moreover, contrary to these plans, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Jazz Pharmaceuticals, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Jazz Pharmaceuticals, Inc. does not generate sufficient taxable income.

Jazz Pharmaceuticals, Inc.'s ability to use its net operating losses to offset potential taxable income and related income taxes that would otherwise be due could be subject to further limitations if we do not generate taxable income in a timely manner or if the "ownership change" provisions of Sections 382 and 383 of the Code result in further annual limitations.*

Jazz Pharmaceuticals, Inc. has a significant amount of NOLs. Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, Jazz Pharmaceuticals, Inc. will generate sufficient taxable income to use all of the NOLs. In addition, realization of NOLs to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of Sections 382 and 383 of the Code and similar state provisions, which may result in the expiration of additional NOLs before future utilization. In general, an "ownership change" occurs if, during a three-year rolling period, there is a change of 50% or more in the percentage ownership of a company by 5% shareholders (and certain persons treated as 5% shareholders), as defined in the Code and the U.S. Treasury Department regulations, or Treasury Regulations, promulgated thereunder. In this regard, we currently estimate that, as a result of these ownership change provisions, we have an annual limitation on the utilization of certain NOLs and credits of $28.9 million, before tax effect, for 2016 and a combined total of $29.7 million, before tax effect, for 2017 to 2026.

However, Sections 382 and 383 of the Code are extremely complex provisions with respect to which there are many uncertainties, and we have not requested a ruling from the IRS to confirm our analysis of the ownership change limitations related to the NOLs generated by Jazz Pharmaceuticals, Inc. Therefore, we have not established whether the IRS would agree with our analysis regarding the application of Sections 382 and 383 of the Code. If the IRS were to disagree with our analysis, or if Jazz Pharmaceuticals, Inc. experiences additional ownership changes in the future, we could be subject to further annual limitations on the use of the NOLs to offset potential taxable income and related income taxes that would otherwise be due.

Future changes to the tax laws under which we expect to be treated as a foreign corporation for U.S. federal tax purposes or in other tax laws relating to multinational corporations could adversely affect us.

As described above, under current law, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes. However, changes to the Code or the Treasury Regulations or other IRS guidance promulgated thereunder, including under Section 7874 of the Code, could adversely affect our status as a foreign corporation for U.S. federal tax purposes or could otherwise affect our effective tax rate, and any such changes could have prospective or retroactive application. In addition, recent legislative proposals have aimed to expand the scope of U.S. corporate tax residence. This legislation, if passed, could adversely affect us.

In addition, the U.S. Congress, the Organization for Economic Co-operation and Development and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting," where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

We have significant intangible assets and goodwill. Consequently, the future impairment of our intangible assets and goodwill may significantly impact our profitability.*

Our intangible assets and goodwill are significant. As of March 31, 2016, we had recorded $2.0 billion of intangible assets and goodwill related to our past acquisitions. Intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. For example, in January 2016, we terminated a pivotal Phase 2 clinical trial of JZP-416 (pegcrisantaspase), a PEGylated recombinant *Erwinia chrysanthemi* L-asparaginase being developed for the treatment of patients with ALL who are hypersensitive to *E. coli*-derived asparaginase. As a result, in the fourth quarter of 2015, we recorded an impairment charge of $31.5 million to our acquired in-process research and development. Our results of operations and financial position in future periods could be negatively impacted should similar or other future impairments of intangible assets or goodwill occur.

Our financial results have been and may continue to be adversely affected by foreign currency exchange rate fluctuations.

We have significant operations in Europe as well as in the U.S., but we report revenues, costs and earnings in U.S. dollars. Our primary currency translation exposure relates to our subsidiaries that have functional currencies denominated in the euro. Exchange rates between the U.S. dollar and the euro have fluctuated and are likely to continue to fluctuate from period to period. Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the functional currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. To the extent that revenue and expense transactions are not denominated in the functional currency, we are also subject to the risk of transaction losses. For example, because our Defitelio and Erwinase product sales outside of the U.S. are primarily denominated in the euro, our sales of those products have been and may continue to be adversely affected by fluctuations in foreign currency exchange rates. In this regard, when the U.S. dollar strengthens against a foreign currency, the relative value of sales made in the foreign currency decreases. Conversely, when the U.S. dollar weakens against a foreign currency, the relative value of such sales increases. Accordingly, increases in the value of the U.S. dollar relative to foreign currencies, primarily the euro, could adversely affect our foreign revenues, perhaps significantly. In addition, as we continue to expand our international operations, we will conduct more transactions in currencies other than the U.S. dollar, which could increase our foreign currency exchange risk. Given the volatility of exchange rates, continued concerns regarding European sovereign debt and instability of the euro, as well as our expanding operations, we cannot assure you that we will be able to effectively manage currency transaction and/or translation risks. We have not entered into derivative instruments to offset the impact of foreign currency exchange rate fluctuations. Fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations and financial condition.

Risks Related to Our Ordinary Shares

The market price of our ordinary shares has been volatile and may continue to be volatile in the future, and the value of your investment could decline significantly.*

The market price for our ordinary shares has fluctuated significantly from time to time, for example, varying between a high of $194.73 on July 31, 2015 and a low of $108.50 on February 11, 2016 during the period from December 31, 2014 through March 31, 2016. The market price of our ordinary shares is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market, industry and other factors, including the risk factors described above. The stock market in general, including the market for life sciences companies, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. In particular, recent negative publicity regarding pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the market for life sciences companies. These broad market and industry factors have harmed, and in the future may seriously harm, the market price of our ordinary shares, regardless of our operating performance.

Our share price may be dependent upon the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, the market price of our ordinary shares could decline. Our ability to meet analysts' forecasts, investors' expectations and our financial guidance is substantially dependent on our ability to maintain or increase sales of Xyrem. In addition, we will need to minimize future supply interruptions of Erwinaze in order to meet revenue expectations for Erwinaze. The risks and uncertainties associated with our ability to maintain or increase sales of Xyrem and Erwinaze include those discussed elsewhere in these risk factors. In the past, following periods of volatility in the market or significant price decline, 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.

In addition, the market price of our ordinary shares may decline if the effects of our past transactions, including the Gentium Acquisition and/or potential future acquisitions, on the financial results of our company are not consistent with the expectations of financial analysts or investors. The market price of our ordinary shares could also be affected by possible sales of our ordinary shares by holders of our 2021 Notes who may view the 2021 Notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity involving our ordinary shares by the holders of these notes.

Future sales of our ordinary shares in the public market could cause our share price to fall.*

Sales of a substantial number of our ordinary shares in the public market, including sales by members of our management or board of directors, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity or equity-related securities. As of May 3, 2016, we had 60,421,794 ordinary shares outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144. In addition, future issuances by us of our ordinary shares upon the exercise or settlement of equity-based awards and exchanges of our 2021 Notes would dilute existing shareholders' ownership interests in our company, and any sales in the public market of these ordinary shares, or the perception that these sales might occur, could also adversely affect the market price of our ordinary shares.

Moreover, we have in the past and may in the future grant rights to some of our shareholders that require us to register the resale of our ordinary shares on behalf of these shareholders and/or facilitate offerings of ordinary shares held by these shareholders, including in connection with potential future acquisitions of additional products, product candidates or companies. For example, consistent with our obligations under then-existing registration rights agreements, we entered into underwriting agreements with certain underwriters and selling shareholders pursuant to which selling shareholders sold an aggregate of approximately 13 million ordinary shares in two separate registered public offerings in March 2012 and in March 2013. We have also filed registration statements to register the sale of our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and we intend to file additional registration statements to register any shares automatically added each year to the share reserves under these plans.

We are subject to Irish law, which differs from the laws in effect in the U.S. and may afford less protection to holders of our securities.*

It may not be possible to enforce court judgments obtained in the U.S. against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liability provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Act 2014, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company are generally owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the U.S.

Provisions of our articles of association, Irish law and the indenture governing our 2021 Notes could delay or prevent a takeover of us by a third party.*

Our articles of association could delay, defer or prevent a third party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. For example, our articles of association:

- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes;
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association; and
- permit our board of directors to issue one or more series of preferred shares with rights and preferences, as our shareholders may determine by ordinary resolution.

In addition, several mandatory provisions of Irish law could prevent or delay an acquisition of us. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent, and the shareholder approval requirements for certain types of transactions differ from those in the U.S., and in some cases are greater, under Irish law. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our shares in certain circumstances. Furthermore, the indenture governing our 2021 Notes requires us to repurchase the notes for cash if we undergo certain fundamental changes and, in certain circumstances, to

increase the exchange rate for a holder of 2021 Notes. A takeover of us may trigger the requirement that we purchase our 2021 Notes and/or increase the exchange rate, which could make it more costly for a potential acquiror to engage in a business combination transaction with us.

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors other than the candidates nominated by our board.

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

Other than funds we have allocated for the purposes of supporting our share repurchase program authorized in November 2015, we anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs, acquire or in-license additional products and product candidates, and pursue other opportunities. If we propose to pay dividends in the future, we must do so in accordance with Irish law, which provides that distributions including dividend payments, share repurchases and redemptions be funded from "distributable reserves." In addition, our ability to pay cash dividends on or repurchase our ordinary shares is restricted under the terms of our credit agreement. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our credit agreement and other factors our board of directors deems relevant. Accordingly, holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future.

A transfer of our ordinary shares may be subject to Irish stamp duty.

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0% of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the U.S., an exemption from this stamp duty is available to transfers by shareholders who hold our ordinary shares beneficially through brokers which in turn hold those shares through the Depositary Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by a record holder who holds our ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Irish Companies Act 2014 or any other applicable law permit, may, or may provide that a subsidiary of ours will, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of our ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of our subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

Dividends paid by us may be subject to Irish dividend withholding tax.

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the U.S., EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

We are subject to a requirement under Irish law to periodically obtain new authorities from our shareholders to issue ordinary shares, which we may be unable to obtain.*

Under Irish law, we must have authority from our shareholders to issue any shares, including shares that are part of our authorized but unissued share capital. Moreover, when an Irish company issues shares for cash to new shareholders, it is required first to offer those shares on the same or more favorable terms to existing shareholders on a pro-rata basis unless otherwise authorized by its existing shareholders. While we are currently authorized to issue all shares that are part of our authorized but unissued share capital on a non-pre-emptive basis, these share issuance authorities are scheduled to expire in January 2017. If we are unable to obtain renewal of our existing share issuance authorities from our shareholders, or are otherwise limited by the terms of new share issuance authorities approved by our shareholders, our ability to use our unissued share capital to effect or to fund in-licensing or acquisition opportunities, or to otherwise raise capital, could be adversely affected after expiration of our existing share issuance authorities in January 2017.

Our auditor, like other independent registered public accounting firms operating in Ireland and a number of other European countries, is not currently permitted to be subject to inspection by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, our investors currently do not have the benefits of PCAOB oversight.

As an auditor of companies that are publicly-traded in the U.S. and as a firm registered with the PCAOB, our independent registered public accounting firm is required by the laws of the U.S. to undergo regular inspections by the PCAOB to assess its compliance with the laws of the U.S. and the professional standards of the PCAOB. However, because our auditor is located in Ireland, a jurisdiction where the PCAOB is currently unable to conduct inspections, our auditor is not currently inspected by the PCAOB. Inspections of other auditors conducted by the PCAOB outside of Ireland have at times identified deficiencies in those auditor's audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in Ireland prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. In addition, the inability of the PCAOB to conduct auditor inspections in Ireland makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors located outside of Ireland that are subject to regular PCAOB inspections. As a result, our investors are deprived of the benefits of PCAOB inspections, and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our "affiliated purchasers" as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934, as amended, during each fiscal month during the three-month period ended March 31, 2016:

	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (3)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (4)
January 1 - January 31, 2016	96,101	$ 128.57	96,101	$ 247,404,017
February 1 - February 29, 2016	136,330	$ 121.18	136,330	$ 230,887,452
March 1 - March 31, 2016	853,142	$ 123.65	853,142	$ 125,423,636
Total	1,085,573	$ 123.77	1,085,573	

(1) This table does not include ordinary shares that we withheld in order to satisfy minimum tax withholding requirements in connection with the vesting or exercise of restricted stock units.

(2) Average price paid per ordinary share includes brokerage commissions.

(3) The ordinary shares reported in the table above were purchased pursuant to our publicly announced share repurchase program. In November 2015, we announced that our board of directors authorized the use of up to $300 million to repurchase our ordinary shares. This authorization has no expiration date.

(4) The dollar amount shown represents, as of the end of each period, the approximate dollar value of ordinary shares that may yet be purchased under our publicly announced share repurchase program, exclusive of any brokerage commissions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under our credit agreement, corporate and regulatory requirements and market conditions, and may be modified, suspended or otherwise discontinued at any time without prior notice.

Item 6. Exhibits

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and between Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
2.5	Tender Offer Agreement, dated December 19, 2013, by and among Jazz Pharmaceuticals Public Limited Company, Jazz Pharmaceuticals Italy S.r.l. and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K/A (File No. 001-33500), as filed with the SEC on December 20, 2013).
2.6†	Asset Purchase Agreement, dated January 13, 2014, by and among Jazz Pharmaceuticals International III Limited, Aerial BioPharma, LLC and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 13, 2014).
2.7†	Assignment Agreement, dated July 1, 2014, by and among Jazz Pharmaceuticals International II Limited, Sigma-Tau Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 5, 2014).
2.8	Amended and Restated Agreement for the Acquisition of the Topaz Portfolio Business of Jazz Pharmaceuticals plc, dated March 20, 2015, between Jazz Pharmaceuticals plc and Essex Bidco Limited (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on March 23, 2015).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.2B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.2C	Indenture, dated as of August 13, 2014, by and among Jazz Pharmaceuticals plc, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.2D	Form of 1.875% Exchangeable Senior Note due 2021 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
10.1+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement.
10.2+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.

Exhibit Number	Description of Document
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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+ Indicates management contract or compensatory plan.
† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the SEC.
* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 10, 2016

Jazz Pharmaceuticals plc
(Registrant)

/s/ Bruce C. Cozadd

Bruce C. Cozadd

Chairman and Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Matthew P. Young

Matthew P. Young

Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

/s/ Karen J. Wilson

Karen J. Wilson

Senior Vice President, Finance
(Principal Accounting Officer)

EXHIBIT INDEX

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2.7†	Assignment Agreement, dated July 1, 2014, by and among Jazz Pharmaceuticals International II Limited, Sigma-Tau Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 5, 2014).
2.8	Amended and Restated Agreement for the Acquisition of the Topaz Portfolio Business of Jazz Pharmaceuticals plc, dated March 20, 2015, between Jazz Pharmaceuticals plc and Essex Bidco Limited (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on March 23, 2015).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.2B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.2C	Indenture, dated as of August 13, 2014, by and among Jazz Pharmaceuticals plc, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.2D	Form of 1.875% Exchangeable Senior Note due 2021 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
10.1+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement.
10.2+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement.

31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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+ Indicates management contract or compensatory plan.
† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the SEC.
* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.1

JAZZ PHARMACEUTICALS PLC
2011 EQUITY INCENTIVE PLAN

NON-U.S. OPTION GRANT NOTICE

Jazz Pharmaceuticals plc (the "***Company***"), pursuant to its 2011 Equity Incentive Plan (the "***Plan***"), hereby grants to Optionholder an option to purchase the number of Ordinary Shares specified and on the terms set forth below. This option is subject to all of the terms and conditions as set forth in this Non-U.S. Option Grant Notice (the "***Grant Notice***") and in the Non-U.S. Option Agreement, including any country-specific Appendix (the "***Agreement***"), and the Plan, both of which are attached hereto and incorporated herein in their entirety.

Optionholder:	_____
Option #:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Ordinary Shares Subject to Option:	_____
Exercise Price (Per Ordinary Share):	_____
Total Exercise Price:	_____
Expiration Date:	_____

Type of Grant: ☐ Incentive Stock Option ☒ Nonstatutory Stock Option

Vesting Schedule:

Payment: By one or a combination of the following items (described in the Option Agreement):

☒ By cash, check, bank draft or money order payable to the Company
☒ Pursuant to a Regulation T Program if the Ordinary Shares are publicly traded
☐ By delivery of already-owned Ordinary Shares if the Ordinary Shares are publicly traded
☒ If and only to the extent this option is a Nonstatutory Stock Option, and subject to the Company's consent at the time of exercise, by a "net exercise" arrangement

Additional Terms/Acknowledgements: The undersigned Optionholder acknowledges receipt of, and understands and agrees to, this Grant Notice, the Agreement and the Plan. Optionholder further acknowledges that as of the Date of Grant, this Grant Notice, the Agreement and the Plan set forth the entire understanding between Optionholder and the Company regarding the acquisition of Ordinary Shares and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionholder under the Plan, (ii) any other specific written agreement between Optionholder and the Company and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law. By accepting this option, Optionholder consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

JAZZ PHARMACEUTICALS PLC	**OPTIONHOLDER:**
By: _____	_____
Signature	Signature
Title: _____	Date: _____
Date: _____	

ATTACHMENTS: Non-U.S. Option Agreement and 2011 Equity Incentive Plan

* * * * *

Based on the form of Non-U.S. Option Grant Notice for the 2011 Equity Incentive Plan as approved by the Compensation Committee of the Board of Directors of Jazz Pharmaceuticals plc on July 31, 2013.

ATTACHMENT I

NON-U.S. OPTION AGREEMENT

Jazz Pharmaceuticals plc
2011 Equity Incentive Plan

Non-U.S. Option Agreement
(Nonstatutory Stock Option)

Pursuant to your Non-U.S. Option Grant Notice (the "***Grant Notice***") and this Non-U.S. Option Agreement, including any country-specific Appendix (the "***Agreement***"), Jazz Pharmaceuticals plc (the "***Company***") has granted you an option under its 2011 Equity Incentive Plan (the "***Plan***") to purchase the number of Ordinary Shares indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). Except as otherwise explicitly provided in the Grant Notice or this Agreement, in the event of any conflict between the terms in the Grant Notice or this Agreement and the Plan, the terms of the Plan shall control. Capitalized terms not explicitly defined in the Grant Notice or this Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. Vesting. Subject to Section 9 and the limitations contained herein, your option will vest as provided in your Grant Notice, provided that vesting will cease upon the termination of your Continuous Service.

2. Number of Shares and Exercise Price. The number of Ordinary Shares subject to your option and your exercise price per Ordinary Share referenced in your Grant Notice may be adjusted from time to time for Capitalization Adjustments.

3. Method of Payment. You must pay the full amount of the exercise price for the Ordinary Shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company (subject to Section 4) or in any other manner ***permitted by your Grant Notice,*** which may include one or more of the following:

(a) Provided that at the time of exercise the Ordinary Shares are publicly traded, pursuant to a program developed under Regulation T as promulgated by the U.S. Federal Reserve Board that, prior to the issuance of Ordinary Shares, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise," "same day sale," or "sell to cover."

(b) Provided that at the time of exercise the Ordinary Shares are publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned Ordinary Shares that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of such Ordinary Shares in a form approved by the Company. You may not exercise your option by delivery

to the Company of Ordinary Shares if doing so would violate the provisions of any law, regulation or agreement applicable to the or restricting the redemption of the Ordinary Shares.

(c) If this option is a Nonstatutory Stock Option, subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of Ordinary Shares issued upon exercise of your option by the largest whole number of Ordinary Shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Ordinary Shares will no longer be outstanding under your option and will not be exercisable thereafter if those Ordinary Shares (i) are used to pay the exercise price pursuant to the "net exercise," (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy any Tax-Related Items (defined below).

4. Payment of Par (Nominal) Value. To the extent that any Ordinary Shares issued upon exercise of your option are newly issued Ordinary Shares, you must pay in cash or by check, bank draft or money order payable to the Company an amount equal to the par value of such number of newly issued Ordinary Shares (rounded up to the nearest whole cent).

5. Whole Shares. You may exercise your option only for whole Ordinary Shares.

6. Securities Law Compliance. Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the Ordinary Shares issuable upon such exercise are then registered under the Securities Act or, if such Ordinary Shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations. The Company shall have no liability to you should your option expire unexercised as a result of the Company's determination that the exercise of your option does not comply with the applicable laws and regulations governing the option or that the exercise is not in material compliance with such laws and regulations.

7. Term. You may not exercise your option before the commencement or after the expiration of its term. The term of your option commences on the Date of Grant and expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

(a) three (3) months after the termination of your Continuous Service for any reason other than Cause or your Disability or death (except as otherwise provided in Section 7(c) below); *provided, however,* that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service;

(b) twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 7(c) below);

(c) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

(d) five (5) days following the termination of your Continuous Service for Cause;

(e) the Expiration Date indicated in your Grant Notice; or

(f) the day before the tenth (10th) anniversary of the Date of Grant.

For purposes of this Agreement, "***Cause***" shall mean the occurrence of any of the following events that has a material negative impact on the business or reputation of the Company or an Affiliate: (i) your conviction for any criminal offence (other than an offence under any road traffic legislation for which a fine or non-custodial penalty is imposed) or any offence under any regulation or legislation relating to insider dealing, fraud or dishonesty; (ii) your attempted commission of, or participation in, a fraud or act of dishonesty against the Company or an Affiliate; (iii) your intentional, material violation of any contract or agreement between you and the Company or an Affiliate, or of any statutory duty owed to the Company or an Affiliate; (iv) your unauthorized use or disclosure of the Company's or an Affiliate's confidential information or trade secrets; or (v) your gross misconduct. The determination that a termination of your Continuous Service is either for Cause or without Cause shall be made by the Company in its sole discretion. Any determination by the Company that your Continuous Service was terminated with or without Cause for the purposes of this Agreement shall have no effect upon any determination of the rights or obligations of the Company or an Affiliate or you for any other purpose.

8. Exercise.

(a) You may exercise the vested portion of your option during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable Tax-Related Items to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any Tax-Related Items arising by reason of (i) the exercise of your option or (ii) the disposition of Ordinary Shares acquired upon such exercise.

9. Change in Control.

(a) If your Continuous Service terminates either within twelve (12) months following or one (1) month prior to the effective date of a Change in Control due to an Involuntary Termination Without Cause, the vesting and exercisability of your option shall be accelerated in full.

(b) For purposes of this Agreement, "***Involuntary Termination Without Cause***" means the involuntary termination of your Continuous Service for reasons other than death, Disability, or Cause. Any determination by the Company that your Continuous Service was terminated with or without Cause for the purposes of this Agreement shall have no effect upon any determination of the rights or obligations of the Company or an Affiliate or you for any other purpose.

10. Parachute Payments.

(a) If you are a U.S. taxpayer and any payment or benefit you would receive from the Company or otherwise in connection with a Change in Control or other similar transaction ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax, or (y)

the largest portion, up to and including the total, of the Payment, whichever amount ((x) or (y)), after taking into account all applicable federal, state, foreign and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for you.

(b) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the event described in Section 280G(b)(2)(A)(i) of the Code shall perform the foregoing calculations. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting such Change in Control or similar transaction, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

(c) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and you within thirty (30) calendar days after the date on which your right to a Payment is triggered (if requested at that time by the Company or you) or such other time as reasonably requested by the Company or you. Any good faith determinations of the independent registered public accounting firm made hereunder shall be final, binding and conclusive upon the Company and you.

11. Transferability. Your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

12. Option Not a Service Contract. Your option is not an employment or service contract, and nothing in your option shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment and shall not in any way restrict the Company or an Affiliate to terminate your Continuous Service or employment. In addition, nothing in your option shall obligate the Company or an Affiliate, their respective shareholders, Boards of Directors, Officers or Employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

13. Tax Withholding Obligations.

You acknowledge that, regardless of any action taken by the Company or, if different, your employer (the "***Employer***"), the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to your participation in the Plan and legally applicable to you ("***Tax-Related Items***"), is and remains your responsibility and may exceed the amount actually withheld by the Company or the Employer. You further acknowledge that the Company and/or the Employer (i) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the option, including, but not limited to, the grant, vesting or exercise of the option, the subsequent sale of Ordinary Shares acquired pursuant to such exercise and the receipt of any dividends; and (ii) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the option to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. Further, if you are subject to Tax-Related Items in more than one jurisdiction between the Date of Grant and the date of any relevant taxable or tax withholding event, as applicable, you acknowledge that the Company and/or the

Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to the relevant taxable or tax withholding event, as applicable, you agree to make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Items.

In this regard, you authorize the Company and/or the Employer, or their respective agents, at their discretion, to satisfy the obligations with regard to all Tax-Related Items by (i) withholding from proceeds of the sale of Ordinary Shares acquired at exercise of the option either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization) without further consent or (ii) withholding in Ordinary Shares to be issued at exercise of the option.

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding amounts or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Ordinary Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding in Ordinary Shares, for tax purposes, you are deemed to have been issued the full number of Ordinary Shares subject to the exercised options, notwithstanding that a number of the Ordinary Shares are held back solely for the purpose of paying the Tax-Related Items.

Finally, you agree to pay to the Company or the Employer, including through withholding from your wages or other cash compensation paid to you by the Company and/or the Employer, any amount of Tax-Related Items that the Company or the Employer may be required to withhold or account for as a result of your participation in the Plan that cannot be satisfied by the means previously described. The Company may refuse to issue or deliver the Ordinary Shares or the proceeds of the sale of Ordinary Shares, if you fail to comply with your obligations in connection with the Tax-Related Items.

14. Nature of Grant. In accepting the option, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature, and may be amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the option is voluntary and occasional and does not create any contractual or other right to receive future grants of options, or benefits in lieu of options, even if options have been granted in the past;

(c) all decisions with respect to future option or other grants, if any, will be at the sole discretion of the Company;

(d) you are voluntarily participating in the Plan;

(e) the option and any Ordinary Shares acquired under the Plan, and the income and value of same, are not intended to replace any pension rights or compensation;

(f) the option and any Ordinary Shares acquired under the Plan, and the income and value of same, are not part of normal or expected compensation for any purpose, including, without limitation, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) the future value of the Ordinary Shares underlying the option is unknown, indeterminable, and cannot be predicted with certainty;

(h) if the underlying Ordinary Shares do not increase in value, the option will have no value;

(i) if you exercise the option and acquire Ordinary Shares, the value of such Ordinary Shares may increase or decrease in value, even below the exercise price;

(j) no claim or entitlement to compensation or damages shall arise from forfeiture of the option resulting from the termination of your Continuous Service (for any reason whatsoever, whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any), and in consideration of the grant of the option, you agree not to institute any claim against the Company, any Affiliate or the Employer;

(k) for purposes of the option, your Continuous Service will be considered terminated as of the date you are no longer actively providing services to the Company or any Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any), and unless otherwise expressly provided in this Agreement or determined by the Company, (i) your right to vest in the option under the Plan, if any, will terminate as of such date and will not be extended by any notice period (e.g., your period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any); and (ii) the period (if any) during which you may exercise the option after such termination of your Continuous Service will commence on the date you cease to actively provide services and will not be extended by any notice period mandated under employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any; the Board or the chief executive officer of the Company or an Affiliate, as applicable, shall have the exclusive discretion to determine when you are no longer actively providing services for purposes of your option grant (including whether you may still be considered to be providing services while on a leave of absence);

(l) unless otherwise agreed with the Company, the option and any Ordinary Shares acquired under the Plan, and the income and value of same, are not granted as consideration for, or in connection with, the service you may provide as a director of the Company or any Affiliate;

(m) unless otherwise provided in the Plan or by the Company in its discretion, the option and the benefits evidenced by this Agreement do not create any entitlement to have the option or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the Ordinary Shares; and

(n) neither the Company, the Employer nor any Affiliate shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the option or of any amounts due to you pursuant to the exercise of the option or the subsequent sale of any Ordinary Shares acquired upon exercise.

15. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Ordinary Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

16. **Data Privacy.** ***You hereby explicitly*** and ***unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Agreement and any other option grant materials by and among, as applicable, the Employer, the Company and any Affiliate for the exclusive purpose of implementing, administering and managing your participation in the Plan.***

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, email address, date of birth, social insurance number, passport or other identification number, salary, nationality, job title, any shares of stock or directorships held in the Company, details of all options or any other entitlement to Ordinary Shares awarded, canceled, exercised, vested, unvested or outstanding in your favor ("Data"), for the exclusive purpose of implementing, administering and managing the Plan.

You understand that Data will be transferred to a third party stock plan service provider as may be selected by the Company in the future, which is assisting the Company with the implementation, administration and management of the Plan. You understand that the recipients of the Data may be located in the United States or elsewhere, and that the recipient's country (e.g., the United States) may have different data privacy laws with a lower level of protection than your country. You understand that you may request a list with the names and addresses of any potential recipients of the Data by contacting your local human resources representative. You authorize the Company, and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer the Data, in electronic or other form, for the sole purposes of implementing, administering and managing your participation in the Plan. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. Further, you understand that you are providing the consents herein on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your Continuous Service and career with the Employer will not be affected; the only consequence of refusing or withdrawing your consent is that the Company would not be able to grant you options or other equity awards or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

17. **Governing Law and Venue.** The option grant and the provisions of this Agreement are governed by, and subject to, the laws of the State of Delaware, without regard to its conflict of law provisions.

For purposes of any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, the parties hereby submit to and consent to the sole and exclusive jurisdiction of the courts of Santa Clara County, California, or the federal courts for the United States for the Northern District of California, and no other courts, where this grant is made and/or to be performed.

18. **Language.** If you have received this Agreement, or any other document related to the option and/or the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

19. **Severability.** The provisions of this Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

20. Appendix. Notwithstanding any provisions in this Agreement, the option grant shall be subject to any special terms and conditions set forth in any Appendix to this Agreement for your country. Moreover, if you relocate to one of the countries included in the Appendix, the special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

21. Notices; Electronic Delivery. Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, fourteen (14) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

22. Insider Trading / Market Abuse Laws. Depending on your country, you may be subject to insider trading restrictions and/or market abuse laws, which may affect your ability to acquire or sell Ordinary Shares or rights to Ordinary Shares (*e.g.*, options) under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under the Company's insider trading policy as may be in effect from time to time. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you should speak to your personal advisor on this matter.

23. Foreign Asset/Account, Exchange Control and Tax Reporting. You may be subject to foreign asset/account, exchange control and/or tax reporting requirements as a result of the acquisition, holding and/or transfer of Ordinary Shares or cash (including dividends and the proceeds arising from the sale of Ordinary Shares) derived from your participation in the Plan, to and/or from a brokerage/bank account or legal entity located outside your country. The applicable laws of your country may require that you report such accounts, assets, the balances therein, the value thereof and/or the transactions related thereto to the applicable authorities in such country. You acknowledge that you are responsible for ensuring compliance with any applicable foreign asset/account, exchange control and tax reporting requirements and should consult your personal legal advisor on this matter.

24. Governing Plan Document. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. Except as otherwise explicitly provided herein, in the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control.

25. Amendment. Notwithstanding anything in the Plan to the contrary, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

26. Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan, on the option and on any Ordinary Shares purchased upon exercise of the option, to the extent the Company determines it is necessary or advisable for legal or

administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

27. Waiver. You acknowledge that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by you or any other Participant.

* * * * *

By signing the Non-U.S. Option Grant Notice to which this Non-U.S. Option Agreement is attached, you shall be deemed to have signed and agreed to the terms and conditions of this Non-U.S. Option Agreement.

* * * * *

Based on the form of Non-U.S. Option Agreement for the 2011 Equity Incentive Plan as approved by the Compensation Committee of the Board of Directors of Jazz Pharmaceuticals plc on July 31, 2013. Last revision February 25, 2016.

APPENDIX

TO THE

NON-U.S. OPTION AGREEMENT

Terms and Conditions

This Appendix contains additional terms and conditions that govern the option granted under the Plan to you if you reside and/or work in one of the countries listed below. Certain capitalized terms used but not defined in this Appendix have the meanings set forth in the Plan, the Grant Notice and/or the Agreement.

If you are a citizen or resident of a country other than the one in which you are currently working, transfer employment and/or residency after the option is granted, or are considered a resident of another country for local law purposes, the information contained herein may not be applicable to you and the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to you.

Notifications

This Appendix contains information regarding exchange controls and certain other issues of which you should be aware with respect to participation in the Plan. The information is based on the securities, exchange control and other laws in effect in the respective countries as of February 2016. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information in this Appendix as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time you exercise the option or sell Ordinary Shares acquired pursuant thereto.

The information contained herein is general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of a particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation.

AUSTRIA

Notifications

Consumer Protection Information. You may be entitled to revoke acceptance of the option granted under the Plan on the basis of the Austrian Consumer Protection Act (the "Act") under the conditions listed below, if the Act is considered to be applicable to the Agreement and the Plan:

(i) The revocation must be made within fourteen (14) days after acceptance of the option.

(ii) The revocation must be in written form to be valid. It is sufficient if you return the Agreement to the Company or the Company's representative with language which can be understood as a refusal to conclude or honor the Agreement, provided the revocation is sent within the period discussed above.

Exchange Control Notification. If you hold Ordinary Shares acquired under the Plan outside of Austria, you must submit a report to the Austrian National Bank. An exemption applies if the value of the Ordinary Shares as of any given quarter does not meet or exceed €30,000,000 or if the value of the Ordinary Shares in any given year as of December 31 does not meet or exceed €5,000,000. If the former threshold is exceeded, quarterly obligations are imposed, whereas if the latter threshold is exceeded, annual reports must be given. The annual reporting date is December 31 and the deadline for filing the annual report is March 31 of the following year.

A separate reporting requirement applies when you sell Ordinary Shares acquired under the Plan or receive a dividend payment. In that case, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all accounts abroad meets or exceeds €10,000,000, the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed form (*Meldungen SI-Forderungen und/oder SI-Verpflichtungen*).

BELGIUM

Terms and Conditions

Taxation of Option. The option must be accepted in writing either (i) within 60 days of the offer (for tax at offer), or (ii) after 60 days of the offer (for tax at exercise). You have received a separate offer letter and undertaking form in addition to the Agreement and should refer to the offer letter for a more detailed description of the tax consequences corresponding with when you accept the option. You should consult with your personal tax advisor regarding taxation of the option and completion of the additional forms.

Notifications

Foreign Asset / Account Reporting. Belgian residents are required to report any securities held (*e.g.*, Ordinary Shares) or bank accounts opened and maintained outside of Belgium on your annual tax return. In a separate report, Belgian residents are required to provide the National Bank of Belgium with the account details of any such foreign accounts.

CANADA

Terms and Conditions

Form of Payment. Notwithstanding anything in Sections 3(b) and 13 to the contrary, you are prohibited from surrendering Ordinary Shares that you own or attesting to the ownership of Ordinary Shares to pay the exercise price or any Tax-Related Items in connection with the option.

Involuntary Termination Terms. In the event of involuntary termination of your Continuous Service (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any), vesting will terminate and the period remaining to exercise the option will be measured effective as of the date that is the earlier of: (1) the date you receive notice of termination of employment from the Employer, or (2) the date you are no longer actively rendering services, regardless of any notice period or period of pay in lieu of such notice required under local law (including, but not limited to, statutory law, regulatory law, and/or common law); the Board or the chief executive officer of the Company or an Affiliate, as applicable, shall have the exclusive discretion to determine when you are no longer actively employed or rendering services for purposes of the option.

The following provision applies if you reside in Quebec:

Consent to Receive Information in English. The parties acknowledge that it is their express wish that the Agreement, as well as all documents, notices and legal proceeds entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Les parties reconnaissent avoir exigé la rédaction en anglais de la convention, ainsi que de tous documents, avis et procédures judiciaires, exécutés, donnés ou intentés en vertu de, ou liés directement ou indirectement à, la présente convention.

Data Privacy Notice and Consent. This section supplements Section 16 of the Agreement:

You hereby authorize the Company and the Company's representatives to discuss and obtain all relevant information from all personnel, professional or non-professional, involved in the administration of the Plan. You further authorize the Company, the Employer and any Affiliate to disclose and discuss such information with their advisors. You also authorize the Company, the Employer and any Affiliate to record such information and to keep such information in your file.

Notifications

Foreign Asset / Account Reporting. Canadian residents are required to report any foreign property (including unvested options and Ordinary Shares) annually on Form T1135 (Foreign Income Verification Statement) if the total cost of the foreign property exceeds C$100,000 at any time during the year. The form must be filed by April 30th of the following year. Options must be reported - generally at a nil cost - if the C$100,000 cost threshold is exceeded because of other foreign specified property. When Ordinary Shares are acquired, their cost generally is the adjusted cost base ("***ACB***") of the Ordinary Shares. The ACB would ordinarily equal the fair market value of the Ordinary Shares at the time of acquisition, but if other shares are also owned, this ACB may have to be averaged with the ACB of the other shares. You should consult your personal tax advisor to ensure compliance with applicable reporting obligations.

FRANCE

Terms and Conditions

Language Consent. By accepting the option, you confirm that you have read and understood the documents relating to the option (the Plan and the Agreement, including this Appendix) which were provided in the English language. You accept the terms of these documents accordingly.

Consentement Relatif à la Langue Utilisée. *En acceptant l'option, vous confirmez avoir lu et compris les documents relatifs à l'option (le Plan et le Contrat, y compris cette Annexe) qui ont été communiqués en langue anglaise. Vous acceptez les termes de ces documents en connaissance de cause.*

Notifications

Foreign Asset / Account Reporting. If you hold Ordinary Shares outside of France or maintain a foreign bank account, you are required to report such to the French tax authorities when filing your annual tax return.

GERMANY

Notifications

Exchange Control Information. Cross-border payments in excess of €12,500 must be reported monthly to the German Federal Bank (*Bundesbank*). Effective from September 2013, the report must be filed electronically. The form of report (*Allgemeines Meldeportal Statistik*) can be accessed via the *Bundesbank's* website (www.bundesbank.de) and is available in both German and English. You are responsible for satisfying the reporting obligation.

IRELAND

Data Privacy. The following provision replaces Section 16 of the Agreement:

You acknowledge, understand and agree that, in signing or electronically accepting the Grant Notice and/or this Agreement, you consent to the Company and any Affiliate sharing and exchanging your information held in order to administer and operate the Plan (including personal details, data relating to participation, salary, taxation and employment and sensitive personal data, e.g., data relating to physical or mental health, criminal conviction or the alleged commission of offences) (the "Information") and you further consent to the Company and any Affiliate providing the Company's or Affiliates' agents and/or third parties with the Information for the administration and operation of the Plan. You accept that this may involve the Information being sent to a country outside the European Economic Area which may not have the same level of data protection laws as Ireland. You acknowledge that you have the right to request a list of the names and addresses of any potential recipients of the Information and to review and correct the Information by contacting the local human resources representative. You further acknowledge that the collection, processing and transfer of the Information is important to Plan administration and that failure to consent to same may prohibit participation in the Plan.

Notifications

Director Notification Obligation. If you are a director, shadow director or secretary of the Company or an Irish Affiliate, you must notify the Company or the Irish Affiliate in writing if you receive or dispose of an interest exceeding 1% of the Company (*e.g.*, options, Ordinary Shares), or become aware of the event giving rise to the notification requirement, or if you become a director or secretary if such an interest exceeding 1% of the Company exists at the time. This notification requirement also applies with respect to the interests of a spouse or minor children (whose interests will be attributed to the director, shadow director or secretary, as applicable).

ITALY

Terms and Conditions

Method of Payment. Notwithstanding anything to the contrary in the Grant Notice or Section 3 of the Agreement, due to securities restrictions in Italy, you are required to use a "cashless sell-all" method of exercise pursuant to which you deliver irrevocable instructions to the broker to sell all Ordinary Shares to which you are entitled at exercise and remit the proceeds from sale, less any Tax-Related Items and brokerage fees or commissions, to you in cash. You will not be permitted to hold any Ordinary Shares in connection following the exercise of the option. The Company reserves the right to provide you with additional methods of exercising the option depending upon development of local laws.

Data Privacy Notification. The following provision replaces the "Data Privacy" section of the Agreement:

You understand that the Company, the Employer and any Affiliate may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, email address, date of birth, social insurance (to the extent permitted under Italian law), passport or other identification number, salary, nationality, job title, Ordinary Shares or directorships held in the Company or any Affiliate, details of all options granted, or any other entitlement to Ordinary Shares awarded, canceled, exercised, vested, unvested or outstanding in your favor ("Data"), for the exclusive purpose of implementing, managing and administering the Plan.

You also understand that providing the Company with Data is necessary for the performance of the Plan and that your refusal to provide such Data would make it impossible for the Company to perform its contractual obligations and may affect your ability to participate in the Plan. The Controller of personal data processing is Jazz Pharmaceuticals plc, with registered offices at Fourth Floor, Connaught House, 1 Burlington Road, Dublin 4, Ireland, and, pursuant to Legislative Decree no. 196/2003, its Representative in France for privacy purposes is EUSA Pharma SAS, Les Jardins d'Eole, 3 allér de Séquoias, F-69760, Limonest, France, or, if you are an employee of Gentium S.r.l., is Gentium S.r.l., Piazza XX Settembre 2, 22079 Villa Guardia (Como) Italy. You understand that Data will not be publicized, but it may be transferred to banks, other financial institutions, or brokers involved in the management and administration of the Plan. You understand that Data may also be transferred to the independent registered public accounting firm engaged by the Company. You further understand that the Employer, the Company and/or any Affiliate will transfer Data among themselves as necessary for the purpose of implementing, administering and managing your participation in the Plan, and that the Company and/or any Affiliate may each further transfer Data to third parties assisting the Company in the implementation, administration, and management of the Plan, including any requisite transfer of Data to a broker or other third party with whom you may elect to deposit any Ordinary Shares acquired under the Plan. Such recipients may receive, possess, use, retain, and transfer Data in electronic or other form, for the purposes of implementing, administering, and managing your participation in the Plan. You understand that these recipients may be located in the European Economic Area or elsewhere, such as the United States. Should the Company exercise its discretion in suspending all necessary legal obligations connected with the management and administration of the Plan, it will delete Data as soon as it has completed all the necessary legal obligations connected with the management and administration of the Plan.

You understand that Data processing related to the purposes specified above shall take place under automated or non-automated conditions, anonymously when possible, that comply with the purposes for which Data is collected and with confidentiality and security provisions, as set forth by applicable laws and regulations, with specific reference to Legislative Decree no. 196/2003.

The processing activity, including communication, the transfer of Data abroad, including outside of the European Economic Area, as herein specified and pursuant to applicable laws and regulations, does not require your consent thereto, as the processing is necessary to performance of contractual obligations related to implementation, administration, and management of the Plan. You understand that, pursuant to Section 7 of the Legislative Decree no. 196/2003, you have the right to, including but not limited to, access, delete, update, correct, or terminate, for legitimate reason, the Data processing.

Furthermore, you are aware that Data will not be used for direct-marketing purposes. In addition, Data provided can be reviewed and questions or complaints can be addressed by contacting your local human resources representative.

Acknowledgement. You acknowledge that you have read and specifically and expressly approve the following sections of the Agreement: Section 13 - Tax Withholding Obligations; Section 14 - Nature of Grant; Section 17 - Governing Law and Venue; Section 18 - Language; Section 19 - Severability; Section 21 - Notices; Electronic Delivery; and Section 26 - Imposition of Other Requirements. In addition, you acknowledge that you have read and specifically and expressly approve the Data Privacy Notification above.

Notifications

Foreign Asset / Account Reporting. Italian residents who, at any time during the fiscal year, hold foreign financial assets (including Ordinary Shares) which may generate income taxable in Italy are required to report these assets on their annual tax returns (UNICO Form, RW Schedule) for the year during which the assets

are held, or on a special form if no tax return is due. These reporting obligations will also apply to Italian residents who are the beneficial owners of foreign financial assets under Italian money laundering provisions. You are responsible for complying with this reporting obligation and should speak with your personal legal advisor in this regard.

NETHERLANDS

Insider Trading Notification. You should be aware of Dutch insider trading rules, which may impact the sale of Ordinary Shares acquired under the Plan. In particular, you may be prohibited from effecting certain transactions if you have insider information regarding the Company.

By accepting the grant of the option and participating in the Plan, you acknowledge having read and understood this Insider Trading Notification and further acknowledge that it is your responsibility to comply with the following Dutch insider trading rules.

Under Article 5:56 of the Dutch Financial Supervision Act, anyone who has "insider information" related to an issuing company is prohibited from effectuating a transaction in securities in or from the Netherlands. "Insider information" is defined as knowledge of details concerning the issuing company to which the securities relate that is not public and which, if published, would reasonably be expected to affect the stock price, regardless of the development of the price. The insider could be any person in Continuous Service in the Netherlands who has insider information as described herein.

Given the broad scope of the definition of insider information, certain persons in Continuous Service in the Netherlands may have insider information and, thus, would be prohibited from effectuating a transaction in securities in the Netherlands at a time when in possession of such inside information. If you are uncertain whether the insider trading rules apply to you, you should consult with your personal legal advisor.

POLAND

Notifications

Exchange Control Notification. You are required to file quarterly reports to the National Bank of Poland with information on transactions and balances regarding your rights to Ordinary Shares (such as options) and Ordinary Shares if the total value (calculated individually or together with other assets and liabilities possessed abroad) exceeds PLN 7 million. You also are required to transfer funds through a bank account in Poland if the transferred amount in any single transaction exceeds a specified threshold (currently €15,000). You are required to retain documents connected with foreign exchange transactions for a period of five years from the date the exchange transaction was made.

PORTUGAL

Notifications

Exchange Control Notification. If you acquire Ordinary Shares under the Plan and hold the Ordinary Shares with a U.S. broker that is not a Portuguese financial intermediary, you may need to file a report with the Portuguese Central Bank. If the Ordinary Shares are held by a Portuguese financial intermediary, it will file the report for you.

SPAIN

Terms and Conditions

Nature of Grant. This provision supplements Section 14 of the Agreement:

In accepting the option, you consent to participate in the Plan and acknowledge having received and read a copy of the Plan.

You understand that the Company has unilaterally, gratuitously and discretionally decided to grant an option under the Plan to individuals who may be employees of the Employer, the Company or any Affiliate throughout the world. The decision is a limited decision that is entered into upon the express assumption and condition that any grant will not bind the Company or any Affiliate except as set forth in the Plan or Agreement. Consequently, you understand that your option is granted on the assumption and condition that such option and any Ordinary Shares acquired upon exercise of your option shall not become a part of any employment contract (either with the Employer or the Company or any Affiliate) and shall not be considered a mandatory benefit, salary for any purpose (including severance compensation) or any other right whatsoever. In addition, you understand that your option would not be granted but for the assumptions and conditions referred to above; thus, you acknowledge and freely accept that should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then the grant of your option shall be null and void.

Further, the vesting of your option is expressly conditioned on your Continuous Service, such that if your service or employment terminates for any reason whatsoever, your option ceases vesting immediately effective on the date of termination of your service or employment. This will be the case, for example, even if you (1) are considered to be unfairly dismissed without good cause; (2) are dismissed for disciplinary or objective reasons or due to a collective dismissal; (3) terminate service or employment due to a change of work location, duties or any other employment or contractual condition; (4) terminate service or employment due to the Company's or any Affiliate's unilateral breach of contract; or (5) are terminated from service or employment for any other reason whatsoever. Consequently, upon your termination of service or employment for any of the above reasons, you will automatically lose any rights to your option that were unvested on the date of termination.

Notifications

Securities Law Notification. Your option described in the Plan and the Agreement, including this Appendix, does not qualify under Spanish regulations as a security. No "offer of securities to the public," as defined under Spanish law, has taken place or will take place in the Spanish territory. The Plan and the Agreement, including this Appendix, have not been nor will they be registered with the Comisión Nacional del Mercado de Valores (Spanish Securities Exchange Commission), and they do not constitute a public offering prospectus.

Exchange Control Notification. The acquisition, ownership and sale of Ordinary Shares under the Plan must be declared for statistical purposes to the Spanish Dirección General de Comercio e Inversiones (the "***DGCI***"), the Bureau for Commerce and Investments, which is a department of the Ministry of Economy and Competitiveness. Generally, the declaration must be made each January for Ordinary Shares owned as of December 31 of the prior year; however, if the amount of Ordinary Shares acquired or sold exceeds a specific threshold or if you hold 10% or more of the share capital of the Company or such other amount that would entitle you to join the Company's board of directors, the declaration must be filed also within one month of the acquisition or sale, as applicable.

Foreign Asset / Account Reporting. Spanish residents are required to declare electronically to the Bank of Spain any securities accounts (including brokerage accounts held abroad), as well as the Ordinary Shares held in such accounts if the value of the transactions during the prior tax year or the balances in such accounts as of December 31 of the prior tax year exceed €1,000,000. More frequent reporting is required if such transaction value or account balance exceeds €100,000,000.

In addition, you may be subject to certain tax reporting requirements with respect to assets or rights that you hold outside of Spain, including bank accounts, securities and real estate if the aggregate value for particular category of assets exceeds €50,000 as of December 31 each year. Ordinary Shares acquired under the Plan or other equity programs offered by the Company constitute securities for purposes of this requirement, but unvested awards (*e.g.*, options, etc.) are not considered assets or rights for purposes of this reporting requirement. If applicable, you must report the assets on Form 720 by no later than March 31 following the end of the relevant year. After the rights and/or assets are initially reported, the reporting obligation will apply only if the value of previously-reported rights or assets increases by more than €20,000 as of each subsequent December 31 or if you sell or otherwise dispose of previously-reported rights or assets. You should consult with your personal advisor to determine your obligations in this respect.

SWITZERLAND

Notifications

Securities Law Notification. The grant of the options and the issuance of any Ordinary Shares is not intended to be a public offering in Switzerland. Neither this document nor any other materials relating to the options constitute a prospectus as such term is understood pursuant to article 652a of the Swiss Code of Obligations, and neither this document nor any other materials relating to the options may be publicly distributed nor otherwise made publicly available in Switzerland. Finally, neither this document nor any other offering or marketing material relating to the options have been or will be filed with, or approved or supervised by, any Swiss regulatory authority (in particular, the Swiss Financial Market Supervisory Authority (FINMA)).

UNITED KINGDOM

Terms and Conditions

Tax Withholding Obligations. This provision supplements Section 13 of the Agreement:

If payment or withholding of the income tax due is not made within 90 days of the end of the U.K. tax year in which the event giving rise to the liability or such other period specified in Section 222(1)(c) of the U.K. Income Tax (Earnings and Pensions) Act 2003 (the "***Due Date***"), the amount of any uncollected tax will constitute a loan owed by you to the Employer, effective on the Due Date. You agree that the loan will bear interest at the then-current Her Majesty's Revenue and Customs ("***HMRC***") Official Rate, it will be immediately due and repayable, and the Company or the Employer may recover it at any time thereafter by any of the means referred to in Section 13 of the Agreement. Notwithstanding the foregoing, if you are a director or executive officer of the Company (within the meaning of Section 13(k) of the Exchange Act), you will not be eligible for such a loan to cover the tax liability. In the event that you are a director or executive officer and the income tax due is not collected from or paid by you by the Due Date, the amount of any uncollected income tax may constitute a benefit to you on which additional income tax and national insurance contributions ("***NICs***") may be payable. You will be responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for reimbursing the Employer for the value of any employee NICs due on this additional benefit, which the

Company or the Employer may recover from you at any time thereafter by any of the means referred to in Section 13 of the Agreement.

Joint Election for Transfer of Liability for Employer National Insurance Contributions. As a condition of participation in the Plan, you agree to accept any liability for secondary Class 1 NICs that may be payable by the Company, the Employer or any Affiliate in connection with the option and any event giving rise to Tax-Related Items (the "***Employer NICs***"). Without prejudice to the foregoing, you agree to execute a joint election with the Company, the form of such joint election (the "***Joint Election***") having been approved formally by HMRC, and any other required consent or election prior to exercise of the option. You further agree to execute such other joint elections as may be required between you and any successor to the Company, the Employer or any Affiliate. You further agree that the Company, the Employer and any Affiliate may collect the Employer NICs from you by any of the means set forth in Section 13 of the Agreement.

If you do not enter into a Joint Election prior to the exercise of the option, you will not be entitled to exercise the option unless and until you enter into a Joint Election, and no Ordinary Shares will be issued to you under the Plan, without any liability to the Company, the Employer or any Affiliate.

JAZZ PHARMACEUTICALS PLC

2011 EQUITY INCENTIVE PLAN

ELECTION TO TRANSFER THE EMPLOYER'S SECONDARY CLASS 1 NATIONAL INSURANCE LIABILITY TO THE EMPLOYEE

This Election is between:

A. The individual who has received this Election (the "**Employee**"), who is employed by one of the employing companies listed in the attached schedule (the "**Employer**") and who is eligible to receive stock options and/or restricted stock units (together, the "**Awards**") pursuant to the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (the "**Plan**"), and

B. Jazz Pharmaceuticals plc, Fourth Floor, Connaught House, 1 Burlington Road, Dublin 4, Ireland (the "**Company**"), which may grant Awards under the Plan and is entering into this Election on behalf of the Employer.

1. Introduction

1.1 This Election relates to all Awards granted to the Employee under the Plan on or after January 18, 2012 up to the termination date of the Plan.

1.2 In this Election the following words and phrases have the following meanings:

(a) "**Chargeable Event**" means, in relation to the Awards:

(i) the acquisition of securities pursuant to the Awards (within section 477(3)(a) of ITEPA);

(ii) the assignment (if applicable) or release of the Awards in return for consideration (within section 477(3)(b) of ITEPA);

(iii) the receipt of a benefit in connection with the Awards, other than a benefit within (i) or (ii) above (within section 477(3)(c) of ITEPA);

(iv) post-acquisition charges relating to the Awards and/or ordinary shares of the Company acquired pursuant to the Awards (within section 427 of ITEPA); and/or

(v) post-acquisition charges relating to the Awards and/or ordinary shares of the Company acquired pursuant to the Awards (within section 439 of ITEPA).

(b) "**ITEPA**" means the Income Tax (Earnings and Pensions) Act 2003.

(c) "**SSCBA**" means the Social Security Contributions and Benefits Act 1992.

1.3 This Election relates to the Employer's secondary Class 1 National Insurance Contributions (the "**Employer's Liability**") which may arise on the occurrence of a Chargeable Event in respect of the Awards pursuant to section 4(4)(a) and/or paragraph 3B(1A) of Schedule 1 of the SSCBA.

1.4 This Election does not apply in relation to any liability, or any part of any liability, arising as a result of regulations being given retrospective effect by virtue of section 4B(2) of either the SSCBA, or the Social Security Contributions and Benefits (Northern Ireland) Act 1992.

1.5 This Election does not apply to the extent that it relates to relevant employment income which is employment income of the earner by virtue of Chapter 3A of Part VII of ITEPA (employment income: securities with artificially depressed market value).

2. The Election

The Employee and the Company jointly elect that the entire liability of the Employer to pay the Employer's Liability on the Chargeable Event is hereby transferred to the Employee. The Employee understands that, by signing the award grant notice, he or she will become personally liable for the Employer's Liability covered by this Election. This Election is made in accordance with paragraph 3B(1) of Schedule 1 of the SSCBA.

3. Payment of the Employer's Liability

3.1 The Employee hereby authorises the Company and/or the Employer to collect the Employer's Liability from the Employee at any time after the Chargeable Event:

(i) by deduction from salary or any other payment payable to the Employee at any time on or after the date of the Chargeable Event; and/or

(ii) directly from the Employee by payment in cash or cleared funds; and/or

(iii) by arranging, on behalf of the Employee, for the sale of some of the securities which the Employee is entitled to receive in respect of the Awards, the proceeds from which must be delivered to the Employer in sufficient time for payment to be made to Her Majesty's Revenue & Customs ("**HMRC**") by the due date; and/or

(iv) where the proceeds of the gain are to be made through a third party, the Employee will authorize that party to withhold an amount from the payment or to sell some of the securities which the Employee is entitled to receive in respect of the Award, such amount to be paid in sufficient time to enable the Company and/or the Employer to make payment to HMRC by the due date; and/or

(v) by any other means specified in the applicable Award agreement entered into between the Employee and the Company.

3.2 The Company hereby reserves for itself and the Employer the right to withhold the transfer of any securities to the Employee in respect of the Awards until full payment of the Employer's Liability is received.

3.3 The Company agrees to procure the remittance by the Employer of the Employer's Liability to HMRC on behalf of the Employee within 14 days after the end of the UK tax month during which the Chargeable Event occurs (or within 17 days after the end of the UK tax month during which the Chargeable Event occurs if payments are made electronically).

4. Duration of Election

4.1 The Employee and the Company agree to be bound by the terms of this Election regardless of whether the Employee is transferred abroad or is not employed by the Employer on the date on which the Employer's Liability becomes due.

4.2 Any reference to the Company and/or the Employer shall include that entity's successors in title and assigns as permitted in accordance with the terms of the Plan and relevant award agreement. This Election will continue in effect in respect of any awards which replace the Awards in circumstances where section 483 of ITEPA applies.

4.3 This Election will continue in effect until the earliest of the following:

(i) the date on which the Employee and the Company agree in writing that it should cease to have effect;

(ii) the date on which the Company serves written notice on the Employee terminating its effect;

(iii) the date on which HMRC withdraws approval of this Election; or

(iv) the date on which, after due payment of the Employer's Liability in respect of the entirety of the Awards to which this Election relates or could relate, the Election ceases to have effect in accordance with its own terms.

SCHEDULE OF EMPLOYER COMPANIES

The following are employer companies to which this Election may apply:

For each company, provide the following details:

EUSA Pharma (Europe) Limited

Registered Office:	EUSA Pharma (Europe) Limited Wing B, Building 5700 Spires House John Smith Drive - Oxford Business Park South, Oxford OX4 2RW, United Kingdom
Company Registration Number:	4555273
Corporation Tax Reference:	452/76424 00934
Corporation Tax Address:	HM Revenue & Customs CT Operations (Large & Complex Specialist) 16 North Government Buildings Ty Glas, Llanishen Cardiff, CF14 5 FP
PAYE Reference:	120/WZ72892

ATTACHMENT II

JAZZ PHARMACEUTICALS PLC
2011 EQUITY INCENTIVE PLAN

Exhibit 10.2

JAZZ PHARMACEUTICALS PLC
2011 EQUITY INCENTIVE PLAN

NON-U.S. RESTRICTED STOCK UNIT GRANT NOTICE

Jazz Pharmaceuticals plc (the "***Company***") pursuant to its 2011 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant the number of restricted stock units ("***RSUs***") specified and on the terms set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this Non-U.S. Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and in the Non-U.S. Restricted Stock Unit Award Agreement, including any country-specific Appendix (the "***Agreement***"), and the Plan, both of which are attached hereto and incorporated herein in their entirety.

Participant:	
RSU #:	
Date of Grant:	
Vesting Commencement Date:	
Number of RSUs:	
Consideration:	Participant's Services (payment of par value of newly issued shares)

Vesting Schedule:

Issuance Schedule: One Ordinary Share will be issued for each RSU which vests at the time set forth in Section 6 of the Agreement.

Additional Terms/Acknowledgements: The undersigned Participant acknowledges receipt of, and understands and agrees to, this Grant Notice, the Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Grant Notice, the Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the Award and supersede all prior oral and written agreements on that subject, with the exception of: (i) any employment or severance arrangement that would provide for vesting acceleration of the Award upon the terms and conditions set forth therein and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law. By accepting this Award, Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

JAZZ PHARMACEUTICALS PLC

By: _____
Signature

Title: _____

Date: _____

PARTICIPANT:

_____
Signature

Date: _____

ATTACHMENTS: Non-U.S. Restricted Stock Agreement, 2011 Equity Incentive Plan

* * * * *

Based on the form of Non-U.S. Restricted Stock Unit Award Grant Notice for the 2011 Equity Incentive Plan as approved by the Compensation Committee of the Board of Directors of Jazz Pharmaceuticals plc on July 31, 2013.

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ATTACHMENT I

NON-U.S. RESTRICTED STOCK UNIT AGREEMENT

Jazz Pharmaceuticals plc
2011 Equity Incentive Plan

Non-U.S. Restricted Stock Unit Award Agreement

Pursuant to your Non-U.S. Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and this Non-U.S. Restricted Stock Unit Award Agreement, including any country-specific Appendix (the "***Agreement***"), and in consideration of your services, Jazz Pharmaceuticals plc (the "***Company***") has awarded you a Restricted Stock Unit Award (the "***Award***") under its 2011 Equity Incentive Plan (the "***Plan***") for the number of restricted stock units (the "***RSUs***") indicated in your Grant Notice. The Award is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). Except as otherwise explicitly provided in the Grant Notice or this Agreement, in the event of any conflict between the terms in the Grant Notice or this Agreement and the Plan, the terms of the Plan shall control. Capitalized terms not explicitly defined in the Grant Notice or this Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your Award, in addition to those set forth in the Grant Notice and the Plan, are as follows.

1. Grant of the Award. This Award represents your right to be issued on a future date the number of Ordinary Shares that is equal to the number of RSUs indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "Account") the number of RSUs subject to the Award. This Award was granted in consideration of your services to the Company or one of its Affiliates. Except as otherwise provided herein, you will not be required to make any payment to the Company (other than past and future services to the Company or its Affiliates) with respect to your receipt of the Award, the vesting of the RSUs or the delivery of the Ordinary Shares to be issued in respect of the Award; provided, however, that to the extent that any Ordinary Shares issued upon settlement of your Award are newly issued Ordinary Shares, a payment must be received by the Company of an amount equal to the par value of such number of newly issued Ordinary Shares (rounded up to the nearest whole cent) in cash, by check, bank draft or money order payable to the Company.

2. Vesting. Subject to Section 11 and the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the RSUs credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such RSUs or the Ordinary Shares to be issued in respect of such portion of the Award.

3. Number of RSUs and Ordinary Shares.

(a) The number of RSUs subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan.

(b) Any additional RSUs that become subject to the Award pursuant to this Section 3 shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other RSUs covered by your Award.

Notwithstanding the provisions of this Section 3, no fractional Ordinary Shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 3. The Board shall, in its

discretion, determine an equivalent benefit for any fractional Ordinary Shares or fractional Ordinary Shares that might be created by the adjustments referred to in this Section 3.

4. Securities Law Compliance. You may not be issued any Ordinary Shares in respect of your Award unless either (i) the Ordinary Shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other applicable laws and regulations governing the Award, and you will not receive such Ordinary Shares if the Company determines that such receipt would not be in material compliance with such laws and regulations. The Company shall not be liable if Ordinary Shares cannot be issued to you as a consequence of the Company's determination that the issuance of Ordinary Shares does not comply with applicable laws and regulations governing the Award.

5. Transfer Restrictions. Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Ordinary Shares subject to the Award until the Ordinary Shares are issued to you in accordance with Section 6 of this Agreement. After the Ordinary Shares have been issued to you, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such Ordinary Shares provided that any such actions are in compliance with the provisions herein (including the country-specific Appendix hereto) and applicable securities laws.

6. Date of Issuance.

(a) To the extent your Award is exempt from application of Section 409A of the Code and any state or foreign law of similar effect (collectively "***Section 409A***"), the Company will deliver to you a number of Ordinary Shares equal to the number of vested RSUs subject to your Award, including any additional RSUs received pursuant to Section 3 above that relate to those vested RSUs on the applicable vesting date(s). However, if a scheduled delivery date falls on a date that is not a U.S. business day, such delivery date shall instead fall on the next following U.S. business day. Notwithstanding the foregoing, in the event that (i) you are subject to the Company's Policy Regarding Stock Trading by Executive Officers, Directors and Other Designated Employees (or any successor policy) (the "***Policy***"), the Company's Policy Against Trading on the Basis of Inside Information, or you are otherwise prohibited from selling Ordinary Shares in the open market and any Ordinary Shares covered by your Award are scheduled to be delivered on a day (the "***Original Distribution Date***") that does not occur during an open "window period" applicable to you or a day on which you are permitted to sell Ordinary Shares pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Exchange Act, as determined by the Company in accordance with the Policy, or does not occur on a date when you are otherwise permitted to sell Ordinary Shares in the open market, and (ii) the Company elects not to satisfy any Tax-Related Items (defined below) by withholding Ordinary Shares from your distribution, then such Ordinary Shares shall not be delivered on such Original Distribution Date and shall instead be delivered on the first U.S. business day of the next occurring open "window period" applicable to you pursuant to the Policy (regardless of whether you are still providing Continuous Service at such time) or the next U.S. business day when you are not prohibited from selling

Ordinary Shares in the open market, but in no event later than the fifteenth (15th) day of the third calendar month of the calendar year following the calendar year in which the Ordinary Shares covered by the Award vest. Delivery of the Ordinary Shares pursuant to the provisions of this Section 6(a) is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and shall be construed and administered in such manner. The form of such delivery of the Ordinary Shares (*e.g.*, a share certificate or electronic entry evidencing such Ordinary Shares) shall be determined by the Company.

(b) The provisions of this Section 6(b) are intended to apply to the extent you are a U.S. taxpayer and your Award is subject to Section 409A because of the terms of a severance arrangement or other agreement between you and the Company, if any, that provide for acceleration of vesting of your Award upon your termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder)) ("***Separation from Service***") and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4) or 1.409A-1(b)(9) ("***Non-Exempt Severance Arrangement***"). If you are not a U.S. taxpayer, this Section 6(b) shall not apply to you. To the extent your Award is subject to and not exempt from application of Section 409A due to application of a Non-Exempt Severance Arrangement, the following provisions in this Section 6(b) shall supersede anything to the contrary in Section 6(a).

(i) If your Award vests in the ordinary course during your Continuous Service in accordance with the vesting schedule set forth in the Grant Notice, without accelerating vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the Ordinary Shares be issued in respect of your Award any later than the later of: (A) December 31st of the calendar year that includes the applicable vesting date and (B) the 60th day that follows the applicable vesting date.

(ii) If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were in effect as of the Date of Grant of your Award and, therefore, are part of the terms of your Award as of the Date of Grant, then the Ordinary Shares will be earlier issued in respect of your Award upon your Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of your Separation from Service. However, if at the time the Ordinary Shares would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such Ordinary Shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six (6) month period.

(iii) If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were not in effect as of the Date of Grant of the Award and, therefore, are not a part of the terms of your Award on the Date of Grant, then such acceleration of vesting of your Award shall not accelerate the issuance date of the Ordinary Shares, but the Ordinary Shares shall instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during your Continuous Service, notwithstanding the vesting acceleration of the Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).

(c) If you are a U.S. taxpayer and your Award is subject to and not exempt from Section 409A (a "***Non-Exempt Award***"), then the provisions in this Section 6(c) shall apply and supersede anything

to the contrary that may be set forth in the Plan, the Grant Notice or in any other section of this Agreement with respect to the permitted treatment of your Non-Exempt Award:

(i) Any exercise by the Board of discretion to accelerate the vesting of your Non-Exempt Award shall not result in any acceleration of the scheduled issuance dates for the Ordinary Shares in respect of the Non-Exempt Award unless earlier issuance of the Ordinary Shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

(ii) The Company explicitly reserves the right to (A) earlier settle your Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix) and (B) provide that you will receive a cash settlement equal to the Fair Market Value of the Ordinary Shares that would otherwise be issued to you, if applicable and in compliance with the requirements of Section 409A.

(iii) To the extent the terms of your Non-Exempt Award provide that it will be settled upon a Change in Control or Corporate Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Change in Control or Corporate Transaction event triggering settlement must also constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (a "***409A Change of Control***"). To the extent the terms of your Non-Exempt Award provide that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation from Service. However, if at the time the Ordinary Shares would otherwise be issued to you in connection with your Separation from Service, you are subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such Ordinary Shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six (6) month period.

(iv) The provisions in this Agreement for delivery of the Ordinary Shares in respect of the Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the Ordinary Shares to you in respect of your Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.

7. Dividends. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, share dividend or other distribution that does not result from a Capitalization Adjustment as provided in the Plan; *provided*, *however*, that this sentence shall not apply with respect to any Ordinary Shares that are delivered to you in connection with your Award after such Ordinary Shares have been delivered to you.

8. Restrictive Legends. The Ordinary Shares issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

9. Award Not a Service Contract.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award pursuant to the schedule set forth in Section 2 herein or the issuance of the Ordinary Shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate

regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company or its Affiliates, as applicable, of the right to terminate you without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the schedule set forth in Section 2 is earned only by providing Continuous Service (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "reorganization"). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the right of the Company or its Affiliate, as applicable, to terminate your Continuous Service at any time.

10. Tax Withholding Obligations.

(a) On or before the time you receive a distribution of the Ordinary Shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize the Company or, if different, your employer (the "***Employer***") to withhold from the Ordinary Shares issuable to you an amount sufficient to satisfy any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items which arise in connection with your Award ("***Tax-Related Items***"), where the Fair Market Value of the Ordinary Shares is measured as of the date the Ordinary Shares are issued pursuant to Section 6. Additionally, the Company or the Employer may, in its sole discretion, satisfy all or any portion of the Tax-Related Items obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or your Employer; (ii) causing you to tender a cash payment; or (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the Ordinary Shares to be delivered in connection with your Award to satisfy the Tax-Related Items and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax-Related Items directly to the Company and/or its Affiliates. Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding amounts or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Ordinary Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding from Ordinary Shares otherwise issuable to you, for tax purposes, you are deemed to have been issued the full number of Ordinary Shares subject to the vested RSUs, notwithstanding that a number of the Ordinary Shares are held back solely for the purpose of paying the Tax-Related Items. Furthermore, you acknowledge that the Company and/or your Employer make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award grant, including, but not limited to, the grant or vesting of the RSUs, the subsequent sale of Ordinary Shares acquired pursuant to such vesting and the receipt of any dividends, and do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Award to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You further acknowledge

that if you become subject to tax in more than one jurisdiction between the Date of Grant and the date of any relevant taxable event, the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Unless the tax withholding obligations of the Company and/or the Employer are satisfied, the Company and/or the Employer shall have no obligation to deliver to you any Ordinary Shares.

(c) In the event the Company's and/or the Employer's obligation to withhold arises prior to the delivery to you of Ordinary Shares or it is determined after the delivery of Ordinary Shares to you that the amount of the Company's and/or the Employer's withholding obligation was greater than the amount withheld by the Company and/or the Employer, you agree to indemnify and hold the Company harmless from any failure by the Company and/or the Employer to withhold the proper amount.

11. Change in Control.

(a) If your Continuous Service terminates either within twelve (12) months following or one (1) month prior to the effective date of a Change in Control due to an Involuntary Termination Without Cause, the vesting of the RSUs subject to this Award shall be accelerated in full. In order to give effect to the intent of this provision, in the event of your Involuntary Termination Without Cause, notwithstanding anything to the contrary set forth in the Plan or Section 2 of this Agreement, in no event will any portion of this Award be forfeited or terminate any earlier than one (1) month following such termination date.

(b) For purposes of this Agreement, "***Involuntary Termination Without Cause***" means the involuntary termination of your Continuous Service for reasons other than death, Disability, or Cause. For this purpose, "Cause" means the occurrence of any of the following events that has a material negative impact on the business or reputation of the Company or an Affiliate: (i) your conviction for any criminal offence (other than an offence under any road traffic legislation for which a fine or non-custodial penalty is imposed) or any offence under any regulation or legislation relating to insider dealing, fraud or dishonesty; (ii) your attempted commission of, or participation in, a fraud or act of dishonesty against the Company or an Affiliate; (iii) your intentional, material violation of any contract or agreement between you and the Company or an Affiliate, or of any statutory duty owed to the Company or an Affiliate; (iv) your unauthorized use or disclosure of the Company's or an Affiliate's confidential information or trade secrets; or (v) your gross misconduct. The determination that a termination of your Continuous Service is either for Cause or without Cause shall be made by the Company in its sole discretion. Any determination by the Company that your Continuous Service was terminated with or without Cause for the purposes of this Agreement shall have no effect upon any determination of the rights or obligations of the Company or an Affiliate or you for any other purpose.

12. Parachute Payments.

(a) If you are a U.S. taxpayer and any payment or benefit you would receive from the Company or otherwise in connection with a Change in Control or other similar transaction ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax, or (y) the largest portion, up to and including the total, of the Payment, whichever amount ((x) or (y)), after taking into account all applicable federal, state, foreign and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of

(b) the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for you.

(c) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the event described in Section 280G(b)(2)(A)(i) of the Code shall perform the foregoing calculations. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting such Change in Control or similar transaction, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

(d) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and you within thirty (30) calendar days after the date on which your right to a Payment is triggered (if requested at that time by the Company or you) or such other time as reasonably requested by the Company or you. Any good faith determinations of the independent registered public accounting firm made hereunder shall be final, binding and conclusive upon the Company and you.

13. Unsecured Obligation. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue Ordinary Shares pursuant to this Agreement. You shall not have voting or any other rights as a shareholder of the Company with respect to the Ordinary Shares to be issued pursuant to this Agreement until such Ordinary Shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a shareholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. Other Documents. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting officers and directors to sell Ordinary Shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

15. Nature of Grant. In accepting the grant, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the Award grant is voluntary and occasional and does not create any contractual or other right to receive future grants of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past;

(c) all decisions with respect to future grants of RSUs or other grants, if any, will be at the sole discretion of the Company;

(d) you are voluntarily participating in the Plan;

(e) the RSUs and the Ordinary Shares subject to the RSUs, and the income and value of same, are not intended to replace any pension rights or compensation;

(f) the RSUs and the Ordinary Shares subject to the RSUs, and the income and value of same, are not part of normal or expected compensation for any purpose, including, without limitation, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) the future value of the underlying Ordinary Shares is unknown, indeterminable and cannot be predicted with certainty;

(h) no claim or entitlement to compensation or damages shall arise from forfeiture of the Award resulting from the termination of your Continuous Service (for any reason whatsoever, whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any), and in consideration of the Award, you agree not to institute any claim against the Company, any Affiliate or the Employer;

(i) for purposes of the Award, your Continuous Service will be considered terminated as of the date you are no longer actively providing services to the Company or any Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any) and unless otherwise expressly provided in this Agreement or determined by the Company, your right to vest in the Award under the Plan, if any, will terminate as of such date and will not be extended by any notice period (*e.g.*, your period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any); the Board or the chief executive officer of the Company or an Affiliate, as applicable, shall have the exclusive discretion to determine when you are no longer actively providing services for purposes of your RSU grant (including whether you may still be considered to be providing services while on a leave of absence);

(j) unless otherwise agreed with the Company, the RSUs and the Ordinary Shares subject to the RSUs, and the income and value of same, are not granted as consideration for, or in connection with, the service you may provide as a director of the Company or any Affiliate;

(k) unless otherwise provided in the Plan or by the Company in its discretion, the Award and the benefits evidenced by this Agreement do not create any entitlement to have the Award or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the Ordinary Shares; and

(l) neither the Company, the Employer nor any Affiliate shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the Award or of any amounts due to you pursuant to the settlement of the Award or the subsequent sale of any Ordinary Shares acquired upon settlement.

16. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Ordinary Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

17. **Data Privacy.** ***You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Agreement and any other Award grant materials by and among, as applicable, the Employer, the Company and any Affiliate for the exclusive purpose of implementing, administering and managing your participation in the Plan.***

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, email address, date of birth, social insurance number, passport or other identification number, salary, nationality, job title, any Ordinary Shares or directorships held in the Company, details of all Awards or any other entitlement to Ordinary Shares awarded, canceled, exercised, vested, unvested or outstanding in your favor ("Data"), for the exclusive purpose of implementing, administering and managing the Plan.

You understand that Data will be transferred to a third party stock plan service provider as may be selected by the Company in the future, which is assisting the Company with the implementation, administration and management of the Plan. You understand that the recipients of the Data may be located in the United States or elsewhere, and that the recipients' country (e.g., the United States) may have different data privacy laws with a lower level of protection than your country. You understand that you may request a list with the names and addresses of any potential recipients of the Data by contacting your local human resources representative. You authorize the Company, and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer the Data, in electronic or other form, for the sole purpose of implementing, administering and managing your participation in the Plan. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. Further, you understand that you are providing the consents herein on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your Continuous Service and career with the Employer will not be affected; the only consequence of refusing or withdrawing your consent is that the Company would not be able to grant you RSUs or other equity awards or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

18. **Governing Law and Venue.** The Award and the provisions of this Agreement are governed by, and subject to, the laws of the State of Delaware, without regard to the conflict of law provisions.

For purposes of any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, the parties hereby submit to and consent to the sole and exclusive jurisdiction of the courts of Santa Clara County, California, or the federal courts for the United States for the Northern District of California, and no other courts, where this grant is made and/or to be performed.

19. **Language.** If you have received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

20. **Appendix.** Notwithstanding any provisions in this Agreement, the Award shall be subject to any special terms and conditions set forth in any Appendix to this Agreement for your country. Moreover, if you relocate to one of the countries included in the Appendix, the special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

21. **Notices; Electronic Delivery.** Any notices provided for in your Award or the Plan shall be given in writing (including electronically) and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, fourteen (14) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

22. **Miscellaneous.**

(a) All covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company's successors and assigns, if any. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.

(d) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

23. **Insider Trading / Market Abuse Laws.** Depending on your country, you may be subject to insider trading restrictions and/or market abuse laws, which may affect your ability to acquire or sell Ordinary Shares or rights to Ordinary Shares (*e.g.*, RSUs) under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under the Company's insider trading policy as may be in effect from time to time. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you should speak to your personal advisor on this matter.

24. **Foreign Asset/Account, Exchange Control and Tax Reporting.** You may be subject to foreign asset/account, exchange control and/or tax reporting requirements as a result of the acquisition, holding and/or transfer of Ordinary Shares or cash (including dividends and the proceeds arising from the sale of Ordinary Shares) derived from your participation in the Plan, to and/or from a brokerage/bank account or legal entity located outside your country. The applicable laws of your country may require that you report such accounts, assets, the balances therein, the value thereof and/or the transactions related thereto to the applicable authorities in such country. You acknowledge that you are responsible for ensuring compliance

with any applicable foreign asset/account, exchange control and tax reporting requirements and should consult your personal legal advisor on this matter.

25. Governing Plan Document. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as expressly provided in this Agreement, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control. In addition, your Award (and any compensation paid or Ordinary Shares issued under your Award) is subject to recoupment in accordance with the Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

26. Severability. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

27. Amendment. Notwithstanding anything in the Plan to the contrary, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

28. Headings. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

29. Waiver. You acknowledge that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by you or any other Participant.

* * * * *

By signing the Non-U.S. Restricted Stock Unit Award Grant Notice to which this Non-U.S. Restricted Stock Unit Award Agreement is attached, you shall be deemed to have signed and agreed to the terms and conditions of this Non-U.S. Restricted Stock Unit Award Agreement.

* * * * *

Based on the form of Non-U.S. Restricted Stock Unit Award Agreement for the 2011 Equity Incentive Plan as approved by the Compensation Committee of the Board of Directors of Jazz Pharmaceuticals plc on July 31, 2013. Last revision February 25, 2016.

APPENDIX

TO THE

NON-U.S. RESTRICTED STOCK UNIT AWARD AGREEMENT

Terms and Conditions

This Appendix contains additional terms and conditions that govern the Award granted under the Plan to you if you reside and/or work in one of the countries listed below. Certain capitalized terms used but not defined in this Appendix have the meanings set forth in the Plan and/or the Agreement.

If you are a citizen or resident of a country other than the one in which you are currently working, transfer employment and/or residency after the RSUs are granted, or are considered a resident of another country for local law purposes, the information contained herein may not be applicable to you, and the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to you.

Notifications

This Appendix contains information regarding exchange controls and certain other issues of which you should be aware with respect to participation in the Plan. The information is based on the securities, exchange control, and other laws in effect in the respective countries as of February 2016. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information in this Appendix as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time you vest in the RSUs or sell Ordinary Shares acquired pursuant thereto.

The information contained herein is general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of a particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation.

AUSTRIA

Notifications

Consumer Protection Notification. You may be entitled to revoke acceptance of the Agreement on the basis of the Austrian Consumer Protection Act (the "Act") under the conditions listed below, if the Act is considered to be applicable to the Agreement and the Plan:

(i) The revocation must be made within fourteen (14) days after acceptance of the Agreement.

(ii) The revocation must be in written form to be valid. It is sufficient if you return the Agreement to the Company or the Company's representative with language which can be understood as a refusal to conclude or honor the Agreement, provided the revocation is sent within the period discussed above.

Exchange Control Notification. If you hold Ordinary Shares acquired under the Plan outside of Austria, you must submit a report to the Austrian National Bank. An exemption applies if the value of the Ordinary Shares as of any given quarter does not meet or exceed €30,000,000 or if the value of the Ordinary Shares in any given year as of December 31 does not meet or exceed €5,000,000.

If the former threshold is exceeded, quarterly obligations are imposed, whereas if the latter threshold is exceeded, annual reports must be given. The annual reporting date is December 31 and the deadline for filing the annual report is March 31 of the following year.

A separate reporting requirement applies when you sell Ordinary Shares acquired under the Plan or receive a dividend. In that case, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all accounts abroad meets or exceeds €10,000,000, the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed form (*Meldungen SI-Forderungen und/oder SI-Verpflichtungen*).

BELGIUM

Notifications

Foreign Asset / Account Reporting. Belgian residents are required to report any securities held (*e.g.*, Ordinary Shares) or bank accounts opened and maintained outside of Belgium on your annual tax return. In a separate report, Belgian residents are required to provide the National Bank of Belgium with the account details of any such foreign accounts.

CANADA

Terms and Conditions

Settlement of RSUs. Notwithstanding any discretion contained in the Plan, the grant of RSUs does not provide any right for you to receive a cash payment; the RSUs are payable in Ordinary Shares only.

Involuntary Termination Terms. In the event of involuntary termination of your Continuous Service (regardless of the reason for such termination and whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any), vesting will terminate as of the date that is the earlier of: (1) the date you receive notice of termination of employment from the Employer, or (2) the date you are no longer actively rendering services, regardless of any notice period or period of pay in lieu of such notice required under local law (including, but not limited to, statutory law, regulatory law, and/or common law); the Board or the chief executive officer of the Company or an Affiliate, as applicable, shall have the exclusive discretion to determine when you are no longer actively employed or rendering services for purposes of the RSUs.

The following provisions apply if Participant resides in Quebec:

Consent to Receive Information in English. The parties acknowledge that it is their express wish that the Agreement, as well as all documents, notices and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Consentement Pour Recevoir Des Informations en Anglais. *Les parties reconnaissent avoir exigé la rédaction en anglais de la convention, ainsi que de tous documents, avis et procédures judiciaires, exécutés, donnés ou intentés en vertu de, ou liés directement ou indirectement à, la présente convention.*

Data Privacy. The following provision supplements Section 17 of the Agreement:

You hereby authorize the Company and the Company's representatives to discuss and obtain all relevant information from all personnel, professional or non-professional, involved in the administration of the Plan. You further authorize the Company, the Employer and any Affiliate to disclose and discuss such information with their advisors. You also authorize the Company, the Employer and any Affiliate to record such information and to keep such information in your employment file.

Notifications

Foreign Asset / Account Reporting. Canadian residents are required to report any foreign property (including unvested RSUs and Ordinary Shares) annually on Form T1135 (Foreign Income Verification Statement) if the total cost of the foreign property exceeds C$100,000 at any time during the year. The form must be filed by April 30th of the following year. RSUs must be reported - generally at a nil cost - if the C$100,000 cost threshold is exceeded because of other foreign specified property. When Ordinary Shares are acquired, their cost generally is the adjusted cost base ("***ACB***") of the Ordinary Shares. The ACB would ordinarily equal the fair market value of the Ordinary Shares at the time of acquisition, but if other shares are also owned, this ACB may have to be averaged with the ACB of the other shares. You should consult your personal tax advisor to ensure compliance with applicable reporting obligations.

FRANCE

Terms and Conditions

Language Consent. By accepting the grant, you confirm that you have read and understood the documents relating to the grant (the Plan and the Agreement, including this Appendix) which were provided in the English language. You accept the terms of these documents accordingly.

Consentement Relatif à la Langue Utilisée. *En acceptant l'attribution, vous confirmez avoir lu et compris les documents relatifs à l'attribution (le Plan et le Contrat, y compris cette Annexe) qui ont été communiqués en langue anglaise. Vous acceptez les termes de ces documents en connaissance de cause.*

Notifications

Foreign Asset / Account Reporting. If you hold Ordinary Shares outside of France or maintain a foreign bank account, you are required to report such to the French tax authorities when filing your annual tax return.

GERMANY

Notifications

Exchange Control Notification. Cross-border payments in excess of €12,500 must be reported monthly to the German Federal Bank (*Bundesbank*). Effective from September 2013, the report must be filed electronically. The form of report (*Allgemeines Meldeportal Statistik*) can be accessed via the *Bundesbank's* website (www.bundesbank.de) and is available in both German and English. You are responsible for satisfying the reporting obligation..

IRELAND

Terms and Conditions

Vesting. The following supplements Section 2 of the Agreement:

Notwithstanding the vesting schedule provided in the Grant Notice, if any vesting date set forth in the Grant Notice ("***Vesting Date***") falls on a date when the Company determines that you are not permitted to sell Ordinary Shares in the open market for any reason, including under the Company's Policy Regarding Stock Trading by Executive Officers, Directors and Other Designated Employees (or any successor policy) or the Company's Policy Against Trading on the Basis of Inside Information (or any successor policy), then such Vesting Date shall instead be the later of the next U.S. business day of the next occurring open "window period" applicable to you or the next U.S. business day when the Company determines that you are not prohibited from selling Ordinary Shares in the open market (such later date, the "***Actual Vesting Date***").

Notwithstanding the foregoing and Section 2 of the Agreement, if your Continuous Service terminates between the Vesting Date and the Actual Vesting Date, then the vesting of the Ordinary Shares subject to the Award originally scheduled to vest on the Vesting Date will cease and not vest upon termination of your Continuous Service, unless your Continuous Service terminates for a reason other than Cause, in which case they will instead vest in full on the first U.S. business day following the termination of your Continuous Service.

Tax Withholding Obligations. The following replaces Section 10(a) of the Agreement:

On or before the time you receive a distribution of the Ordinary Shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize the Company or, if different, your employer (the "***Employer***") to withhold an amount sufficient to satisfy any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items which arise in connection with your Award ("***Tax-Related Items***"). The Company or the Employer may, in its sole discretion, satisfy all or any portion of the Tax-Related Items obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or your Employer; (ii) causing you to tender a cash payment; or (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the Ordinary Shares to be delivered in connection with your Award to satisfy the Tax-Related Items and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax-Related Items directly to the Company and/or its Affiliates. Furthermore, you acknowledge that the Company and/or your Employer make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award grant, including, but not limited to, the grant or vesting of the RSUs, the subsequent sale of Ordinary Shares acquired pursuant to such vesting and the receipt of any dividends, and do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Award to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You further acknowledge that if you become subject to tax in more than one jurisdiction between the Date of Grant and the date of any relevant taxable event, the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Data Privacy. The following provision replaces Section 17 of the Agreement:

You acknowledge, understand and agree that, in signing or electronically accepting the Grant Notice and/or this Agreement, you consent to the Company and any Affiliate sharing and exchanging your information

held in order to administer and operate the Plan (including personal details, data relating to participation, salary, taxation and employment and sensitive personal data, e.g., data relating to physical or mental health, criminal conviction or the alleged commission of offences) (the "Information") and you further consent to the Company and any Affiliate providing the Company's or Affiliates' agents and/or third parties with the Information for the administration and operation of the Plan. You accept that this may involve the Information being sent to a country outside the European Economic Area which may not have the same level of data protection laws as Ireland. You acknowledge that you have the right to request a list of the names and addresses of any potential recipients of the Information and to review and correct the Information by contacting the local human resources representative. You further acknowledge that the collection, processing and transfer of the Information is important to Plan administration and that failure to consent to same may prohibit participation in the Plan.

Notifications

Director Notification Obligation. If you are a director, shadow director or secretary of the Company or an Irish Affiliate, you must notify the Company or the Irish Affiliate in writing if you receive or dispose of an interest exceeding 1% of the Company (*e.g.*, RSUs, Ordinary Shares), or become aware of the event giving rise to the notification requirement, or if you become a director or secretary if such an interest exceeding 1% of the Company exists at the time. This notification requirement also applies with respect to the interests of a spouse or minor children (whose interests will be attributed to the director, shadow director or secretary, as applicable).

ITALY

Terms and Conditions

Data Privacy Notification. The following provision replaces Section 17 of the Agreement:

You understand that the Employer, the Company and any Affiliate may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, email address, date of birth, social insurance (to the extent permitted under Italian law), passport or other identification number, salary, nationality, job title, Ordinary Shares or directorships held in the Company or any Affiliate, details of all Awards granted, or any other entitlement to Ordinary Shares awarded, canceled, exercised, vested, unvested or outstanding in your favor ("Data"), for the exclusive purpose of implementing, managing and administering the Plan.

You also understand that providing the Company with Data is necessary for the performance of the Plan and that your refusal to provide such Data would make it impossible for the Company to perform its contractual obligations and may affect your ability to participate in the Plan. The Controller of personal data processing is Jazz Pharmaceuticals plc, with registered offices at Fourth Floor, Connaught House, 1 Burlington Road, Dublin 4, Ireland, and, pursuant to Legislative Decree no. 196/2003, its Representative in France for privacy purposes is EUSA Pharma SAS, Les Jardins d'Eole, 3 allér de Séquoias, F-69760, Limonest, France, or, if you are an employee of Gentium S.r.l., is Gentium S.r.l., Piazza XX Settembre 2, 22079 Villa Guardia (Como) Italy. You understand that Data will not be publicized, but it may be transferred to banks, other financial institutions, or brokers involved in the management and administration of the Plan. You understand that Data may also be transferred to the independent registered public accounting firm engaged by the Company. You further understand that the Employer, the Company and/ any Affiliate will transfer Data among themselves as necessary for the purpose of implementing, administering and managing your participation in the Plan, and that the Company and any Affiliate may each further transfer Data to third parties assisting the Company in the implementation, administration, and management of

the Plan, including any requisite transfer of Data to a broker or other third party with whom you may elect to deposit any Ordinary Shares acquired under the Plan. Such recipients may receive, possess, use, retain, and transfer Data in electronic or other form, for the purposes of implementing, administering, and managing your participation in the Plan. You understand that these recipients may be located in the European Economic Area or elsewhere, such as the United States. Should the Company exercise its discretion in suspending all necessary legal obligations connected with the management and administration of the Plan, it will delete Data as soon as it has completed all the necessary legal obligations connected with the management and administration of the Plan.

You understand that Data processing related to the purposes specified above shall take place under automated or non-automated conditions, anonymously when possible, that comply with the purposes for which Data is collected and with confidentiality and security provisions, as set forth by applicable laws and regulations, with specific reference to Legislative Decree no. 196/2003.

The processing activity, including communication, the transfer of Data abroad, including outside of the European Economic Area, as herein specified and pursuant to applicable laws and regulations, does not require your consent thereto, as the processing is necessary to performance of contractual obligations related to implementation, administration, and management of the Plan. You understand that, pursuant to Section 7 of the Legislative Decree no. 196/2003, you have the right to, including but not limited to, access, delete, update, correct, or terminate, for legitimate reason, the Data processing.

Furthermore, you are aware that Data will not be used for direct-marketing purposes. In addition, Data provided can be reviewed and questions or complaints can be addressed by contacting your local human resources representative.

Acknowledgement. You acknowledge that you have read and specifically and expressly approve the following sections of the Agreement: Section 10 - Tax Withholding Obligations; Section 15 - Nature of Grant; Section 18 - Governing Law and Venue; Section 19 - Language; Section 21- Notices; Electronic Delivery; and Section 26 - Severability. In addition, you acknowledge that you have read and specifically and expressly approve the Data Privacy Notification above.

Notifications

Foreign Asset / Account Reporting. Italian residents who, at any time during the fiscal year, hold foreign financial assets (including Ordinary Shares) which may generate income taxable in Italy are required to report these assets on their annual tax returns (UNICO Form, RW Schedule) for the year during which the assets are held, or on a special form if no tax return is due. These reporting obligations will also apply to Italian residents who are the beneficial owners of foreign financial assets under Italian money laundering provisions. You are responsible for complying with this reporting obligation and should speak with your personal legal advisor in this regard.

NETHERLANDS

Notifications

Insider Trading Notification. You should be aware of Dutch insider trading rules, which may impact the sale of Ordinary Shares acquired under the Plan. In particular, you may be prohibited from effecting certain transactions if you have insider information regarding the Company.

By accepting the RSUs and participating in the Plan, you acknowledge having read and understood this Insider Trading Notification and further acknowledge that it is your responsibility to comply with the following Dutch insider trading rules.

Under Article 5:56 of the Dutch Financial Supervision Act, anyone who has "insider information" related to an issuing company is prohibited from effectuating a transaction in securities in or from the Netherlands. "Insider information" is defined as knowledge of details concerning the issuing company to which the securities relate that is not public and which, if published, would reasonably be expected to affect the stock price, regardless of the development of the price. The insider could be any person in Continuous Service in the Netherlands who has insider information as described herein.

Given the broad scope of the definition of insider information, certain persons in Continuous Service in the Netherlands may have insider information and, thus, would be prohibited from effectuating a transaction in securities in the Netherlands at a time when in possession of such inside information. If you are uncertain whether the insider trading rules apply to you, you should consult with your personal legal advisor.

POLAND

Notifications

Exchange Control Notification. Polish residents are required to file quarterly reports to the National Bank of Poland with information on transactions and balances regarding their rights to Ordinary Shares (such as RSUs) and Ordinary Shares if the total value (calculated individually or together with other assets and liabilities possessed abroad) exceeds PLN 7 million.

Polish residents also are required to transfer funds through a bank account in Poland if the transferred amount in any single transaction exceeds a specified threshold (currently €15,000). Polish residents are required to retain documents connected with foreign exchange transactions for a period of five years from the date the exchange transaction was made.

PORTUGAL

Notifications

Exchange Control Notification. If you acquire Ordinary Shares under the Plan and hold the Ordinary Shares with a U.S. broker that is not a Portuguese financial intermediary, you may need to file a report with the Portuguese Central Bank. If the Ordinary Shares are held by a Portuguese financial intermediary, it will file the report for you.

SPAIN

Terms and Conditions

Nature of Grant. This provision supplements Section 15 of the Agreement:

In accepting the RSUs, you consent to participate in the Plan and acknowledge having received and read a copy of the Plan.

You understand that the Company has unilaterally, gratuitously and discretionally decided to grant the RSUs under the Plan to individuals who may be employees of the Employer, the Company or any Affiliate throughout the world. The decision is a limited decision that is entered into upon the express assumption and condition that any grant will not bind the Company or any Affiliate except as set forth in the Plan or Agreement.

Consequently, you understand that the RSUs are granted on the assumption and condition that such RSUs and any Ordinary Shares acquired upon vesting of the RSUs shall not become a part of any employment contract (either with the Employer or the Company or any Affiliate) and shall not be considered a mandatory benefit, salary for any purpose (including severance compensation) or any other right whatsoever. In addition, you understand that the RSUs would not be granted but for the assumptions and conditions referred to above; thus, you acknowledge and freely accept that should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then the grant of the RSUs shall be null and void.

Further, the vesting of the RSUs is expressly conditioned on your Continuous Service, such that if your service or employment terminates for any reason whatsoever, the RSUs will cease to vest immediately effective on the date of termination of your service or employment. This will be the case, for example, even if you (1) are considered to be unfairly dismissed without good cause; (2) are dismissed for disciplinary or objective reasons or due to a collective dismissal; (3) terminate service or employment due to a change of work location, duties or any other employment or contractual condition; (4) terminate service or employment due to the Company's or any Affiliate's unilateral breach of contract; or (5) are terminated from service or employment for any other reason whatsoever. Consequently, upon your termination of service or employment for any of the above reasons, you will automatically lose any rights to the RSUs that were unvested on the date of termination.

Notifications

Securities Law Notification. The RSUs described in the Plan and the Agreement, including this Appendix, do not qualify under Spanish regulations as securities. No "offer of securities to the public," as defined under Spanish law, has taken place or will take place in the Spanish territory. The Plan and the Agreement, including this Appendix, have not been nor will they be registered with the Comisión Nacional del Mercado de Valores (Spanish Securities Exchange Commission), and they do not constitute a public offering prospectus.

Exchange Control Notification. The acquisition, ownership and sale of Ordinary Shares under the Plan must be declared for statistical purposes to the Spanish Dirección General de Comercio e Inversiones (the "***DGCI***"), the Bureau for Commerce and Investments, which is a department of the Ministry of Economy and Competitiveness. Generally, the declaration must be made each January for Ordinary Shares owned as of December 31 of the prior year; however, if the amount of Ordinary Shares acquired or sold exceeds a specific threshold or if you hold 10% or more of the share capital of the Company or such other amount that would entitle you to join the Company's board of directors, the declaration must be filed also within one month of the acquisition or sale, as applicable.

Foreign Asset / Account Reporting. Spanish residents are required to declare electronically to the Bank of Spain any securities accounts (including brokerage accounts held abroad), as well as the Ordinary Shares held in such accounts if the value of the transactions during the prior tax year or the balances in such accounts as of December 31 of the prior tax year exceed €1,000,000. More frequent reporting is required if such transaction value or account balance exceeds €100,000,000.

In addition, you may be subject to certain tax reporting requirements with respect to assets or rights that you hold outside of Spain, including bank accounts, securities and real estate if the aggregate value for particular category of assets exceeds €50,000 as of December 31 each year. Ordinary Shares acquired under the Plan or other equity programs offered by the Company constitute securities for purposes of this requirement, but unvested awards (*e.g.*, RSUs, etc.) are not considered assets or rights for purposes of this reporting requirement. If applicable, you must report the assets on Form 720 by no later than March 31 following the end of the relevant year. After the rights and/or assets are initially reported, the reporting obligation will apply only if the value of previously-reported rights or assets increases by more than €20,000 as of each

subsequent December 31 or if you sell or otherwise dispose of previously-reported rights or assets. You should consult with your personal advisor to determine your obligations in this respect.

SWITZERLAND

Notifications

Securities Law Notification. The grant of the RSUs and the issuance of any Ordinary Shares is not intended to be a public offering in Switzerland. Neither this document nor any other materials relating to the RSUs constitute a prospectus as such term is understood pursuant to article 652a of the Swiss Code of Obligations, and neither this document nor any other materials relating to the RSUs may be publicly distributed nor otherwise made publicly available in Switzerland. Finally, neither this document nor any other offering or marketing material relating to the RSUs have been or will be filed with, or approved or supervised by, any Swiss regulatory authority (in particular, the Swiss Financial Market Supervisory Authority (FINMA)).

UNITED KINGDOM

Terms and Conditions

Tax Withholding Obligations. This provision supplements Section 10 of the Agreement:

If payment or withholding of the income tax due is not made within 90 days of the end of the U.K. tax year in which the event giving rise to the liability or such other period specified in Section 222(1)(c) of the U.K. Income Tax (Earnings and Pensions) Act 2003 (the "***Due Date***"), the amount of any uncollected tax will constitute a loan owed by you to the Employer, effective on the Due Date. You agree that the loan will bear interest at the then-current Her Majesty's Revenue and Custom ("***HMRC***") Official Rate, it will be immediately due and repayable, and the Company or the Employer may recover it at any time thereafter by any of the means referred to in Section 10 of the Agreement. Notwithstanding the foregoing, if you are a director or executive officer of the Company (within the meaning of Section 13(k) of the Exchange Act), you will not be eligible for such a loan to cover the tax liability. In the event that you are a director or executive officer and the income tax due is not collected from or paid by you by the Due Date, the amount of any uncollected income tax may constitute a benefit to you on which additional income tax and national insurance contributions ("***NICs***") may be payable. You will be responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for reimbursing your Employer for the value of any employee NICs due on this additional benefit, which the Company or the Employer may recover from you at any time thereafter by any of the means referred to in Section 10 of the Agreement.

Joint Election for Transfer of Liability for Employer National Insurance Contributions. As a condition of participation in the Plan and the vesting of the RSUs, you agree to accept any liability for secondary Class 1 NICs that may be payable by the Company, the Employer or any Affiliate in connection with the RSUs and any event giving rise to Tax-Related Items (the "***Employer NICs***"). Without prejudice to the foregoing, you agree to execute a joint election with the Company, the form of such joint election (the "Joint Election") having been approved formally by HMRC, and any other required consent or election prior to vesting of the RSUs. You further agree to execute such other joint elections as may be required between you and any successor to the Company, the Employer or any Affiliate. You further agree that the Company, the Employer or any Affiliate may collect the Employer NICs from you by any of the means set forth in Section 10 of the Agreement.

If you do not enter into a Joint Election prior to the vesting of the RSUs, you will not be entitled to vest in the RSUs without any liability to the Company, the Employer or any Affiliate.

Settlement in Ordinary Shares. Notwithstanding anything in the Plan or the Agreement to the contrary, the Award may only be settled by the delivery of Ordinary Shares.

JAZZ PHARMACEUTICALS PLC

2011 EQUITY INCENTIVE PLAN

ELECTION TO TRANSFER THE EMPLOYER'S SECONDARY CLASS 1 NATIONAL INSURANCE LIABILITY TO THE EMPLOYEE

This Election is between:

A. The individual who has received this Election (the "**Employee**"), who is employed by one of the employing companies listed in the attached schedule (the "**Employer**") and who is eligible to receive stock options and/or restricted stock units (together, the "**Awards**") pursuant to the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (the "**Plan**"), and

B. Jazz Pharmaceuticals plc, Fourth Floor, Connaught House, 1 Burlington Road, Dublin 4, Ireland (the "**Company**"), which may grant Awards under the Plan and is entering into this Election on behalf of the Employer.

1. Introduction

1.1 This Election relates to all Awards granted to the Employee under the Plan on or after January 18, 2012 up to the termination date of the Plan.

1.2 In this Election the following words and phrases have the following meanings:

(a) "**Chargeable Event**" means, in relation to the Awards:

(i) the acquisition of securities pursuant to the Awards (within section 477(3)(a) of ITEPA);

(ii) the assignment (if applicable) or release of the Awards in return for consideration (within section 477(3)(b) of ITEPA);

(iii) the receipt of a benefit in connection with the Awards, other than a benefit within (i) or (ii) above (within section 477(3)(c) of ITEPA);

(iv) post-acquisition charges relating to the Awards and/or ordinary shares of the Company acquired pursuant to the Awards (within section 427 of ITEPA); and/or

(v) post-acquisition charges relating to the Awards and/or ordinary shares of the Company acquired pursuant to the Awards (within section 439 of ITEPA).

(b) "**ITEPA**" means the Income Tax (Earnings and Pensions) Act 2003.

(c) "**SSCBA**" means the Social Security Contributions and Benefits Act 1992.

1.3 This Election relates to the Employer's secondary Class 1 National Insurance Contributions (the "**Employer's Liability**") which may arise on the occurrence of a Chargeable Event in respect of the Awards pursuant to section 4(4)(a) and/or paragraph 3B(1A) of Schedule 1 of the SSCBA.

1.4 This Election does not apply in relation to any liability, or any part of any liability, arising as a result of regulations being given retrospective effect by virtue of section 4B(2) of either the SSCBA, or the Social Security Contributions and Benefits (Northern Ireland) Act 1992.

1.5 This Election does not apply to the extent that it relates to relevant employment income which is employment income of the earner by virtue of Chapter 3A of Part VII of ITEPA (employment income: securities with artificially depressed market value).

2. The Election

The Employee and the Company jointly elect that the entire liability of the Employer to pay the Employer's Liability on the Chargeable Event is hereby transferred to the Employee. The Employee understands that, by signing the award grant notice, he or she will become personally liable for the Employer's Liability covered by this Election. This Election is made in accordance with paragraph 3B(1) of Schedule 1 of the SSCBA.

3. Payment of the Employer's Liability

3.1 The Employee hereby authorises the Company and/or the Employer to collect the Employer's Liability from the Employee at any time after the Chargeable Event:

(i) by deduction from salary or any other payment payable to the Employee at any time on or after the date of the Chargeable Event; and/or

(ii) directly from the Employee by payment in cash or cleared funds; and/or

(iii) by arranging, on behalf of the Employee, for the sale of some of the securities which the Employee is entitled to receive in respect of the Awards, the proceeds from which must be delivered to the Employer in sufficient time for payment to be made to Her Majesty's Revenue & Customs ("**HMRC**") by the due date; and/or

(iv) where the proceeds of the gain are to be made through a third party, the Employee will authorize that party to withhold an amount from the payment or to sell some of the securities which the Employee is entitled to receive in respect of the Award, such amount to be paid in sufficient time to enable the Company and/or the Employer to make payment to HMRC by the due date; and/or

(v) by any other means specified in the applicable Award agreement entered into between the Employee and the Company.

3.2 The Company hereby reserves for itself and the Employer the right to withhold the transfer of any securities to the Employee in respect of the Awards until full payment of the Employer's Liability is received.

3.3 The Company agrees to procure the remittance by the Employer of the Employer's Liability to HMRC on behalf of the Employee within 14 days after the end of the UK tax month during which the Chargeable Event occurs (or within 17 days after the end of the UK tax month during which the Chargeable Event occurs if payments are made electronically).

4. Duration of Election

4.1 The Employee and the Company agree to be bound by the terms of this Election regardless of whether the Employee is transferred abroad or is not employed by the Employer on the date on which the Employer's Liability becomes due.

4.2 Any reference to the Company and/or the Employer shall include that entity's successors in title and assigns as permitted in accordance with the terms of the Plan and relevant award agreement. This Election will continue in effect in respect of any awards which replace the Awards in circumstances where section 483 of ITEPA applies.

4.3 This Election will continue in effect until the earliest of the following:

(i) the date on which the Employee and the Company agree in writing that it should cease to have effect;

(ii) the date on which the Company serves written notice on the Employee terminating its effect;

(iii) the date on which HMRC withdraws approval of this Election; or

(iv) the date on which, after due payment of the Employer's Liability in respect of the entirety of the Awards to which this Election relates or could relate, the Election ceases to have effect in accordance with its own terms.

SCHEDULE OF EMPLOYER COMPANIES

The following are employer companies to which this Election may apply:

For each company, provide the following details:

EUSA Pharma (Europe) Limited

Registered Office:	EUSA Pharma (Europe) Limited Wing B, Building 5700 Spires House John Smith Drive - Oxford Business Park South, Oxford OX4 2RW, United Kingdom
Company Registration Number:	4555273
Corporation Tax Reference:	452/76424 00934
Corporation Tax Address:	HM Revenue & Customs CT Operations (Large & Complex Specialist) 16 North Government Buildings Ty Glas, Llanishen Cardiff, CF14 5 FP
PAYE Reference:	120/WZ72892

ATTACHMENT II

JAZZ PHARMACEUTICALS PLC
2011 EQUITY INCENTIVE PLAN

Exhibit 31.1

CERTIFICATION

I, Bruce C. Cozadd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals public limited company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

By: /s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION

I, Matthew P. Young, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals public limited company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

By: /s/ Matthew P. Young

Matthew P. Young
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION[(1)]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Bruce C. Cozadd, Chief Executive Officer of Jazz Pharmaceuticals public limited company (the "Company"), and Matthew P. Young, Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the year ended March 31, 2016, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2016

/s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

/s/ Matthew P. Young

Matthew P. Young
Executive Vice President and Chief Financial Officer

(1) This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Jazz Pharmaceuticals public limited company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Jazz Pharmaceuticals public limited company and will be retained by Jazz Pharmaceuticals public limited company and furnished to the Securities and Exchange Commission or its staff upon request.