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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, 2019

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.)**

Fifth Floor, Waterloo Exchange,
Waterloo 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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value $0.0001 per share	JAZZ	The Nasdaq Stock Market LLC

As of April 30, 2019, 56,660,701 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, 2019

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We own or have rights to various copyrights, trademarks, and trade names used in our business in the U.S. and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Erwinase®, Defitelio® (defibrotide sodium), Defitelio® (defibrotide), CombiPlex®, Vyxeos® (daunorubicin and cytarabine) liposome for injection, Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion, Sunosi™ (solriamfetol) and FazaClo® (clozapine, USP). 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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 547,466	$ 309,622
Investments	285,000	515,000
Accounts receivable, net of allowances	320,485	263,838
Inventories	60,707	52,956
Prepaid expenses	28,974	25,017
Other current assets	62,985	67,572
Total current assets	1,305,617	1,234,005
Property, plant and equipment, net	113,006	200,358
Operating lease assets	147,365	—
Intangible assets, net	2,679,393	2,731,334
Goodwill	919,972	927,630
Deferred tax assets, net	65,090	57,879
Deferred financing costs	9,056	9,589
Other non-current assets	40,736	42,696
Total assets	$ 5,280,235	$ 5,203,491
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 42,669	$ 40,602
Accrued liabilities	292,390	264,887
Current portion of long-term debt	33,387	33,387
Income taxes payable	40,833	1,197
Deferred revenue	4,720	5,414
Total current liabilities	413,999	345,487
Deferred revenue, non-current	8,401	9,581
Long-term debt, less current portion	1,565,277	1,563,025
Operating lease liabilities, less current portion	154,066	—
Deferred tax liabilities, net	296,148	309,097
Other non-current liabilities	111,897	218,879
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	472	472
Additional paid-in capital	2,130,738	2,113,630
Accumulated other comprehensive loss	(220,674)	(197,791)
Retained earnings	819,850	841,050
Total shareholders' equity	2,730,447	2,757,422
Total liabilities and shareholders' equity	$ 5,280,235	$ 5,203,491

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,	
	2019	2018
Revenues:		
Product sales, net	$ 503,331	$ 440,847
Royalties and contract revenues	4,855	3,766
Total revenues	508,186	444,613
Operating expenses:		
Cost of product sales (excluding amortization of intangible assets)	33,506	33,919
Selling, general and administrative	167,947	207,213
Research and development	60,105	62,667
Intangible asset amortization	56,885	53,007
Acquired in-process research and development	56,000	—
Total operating expenses	374,443	356,806
Income from operations	133,743	87,807
Interest expense, net	(17,922)	(20,605)
Foreign exchange loss	(611)	(1,728)
Income before income tax provision and equity in loss of investees	115,210	65,474
Income tax provision	29,116	19,146
Equity in loss of investees	893	337
Net income	$ 85,201	$ 45,991
Net income per ordinary share:		
Basic	$ 1.49	$ 0.77
Diluted	$ 1.47	$ 0.75
Weighted-average ordinary shares used in per share calculations - basic	57,206	59,928
Weighted-average ordinary shares used in per share calculations - diluted	58,081	61,178

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

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

	Three Months Ended March 31,	
	2019	2018
Net income	$ 85,201	$ 45,991
Other comprehensive income (loss):		
Foreign currency translation adjustments	(21,142)	38,853
Unrealized gain (loss) on hedging activities, net of income tax (benefit) provision of ($249) and $458, respectively	(1,741)	3,204
Other comprehensive income (loss)	(22,883)	42,057
Total comprehensive income	$ 62,318	$ 88,048

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

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2018	57,504	$ 6	4,000	$ 55	$ 472	$ 2,113,630	$ (197,791)	$ 841,050	$ 2,757,422
Cumulative effect adjustment from adoption of new accounting standards	—	—	—	—	—	—	—	4,848	4,848
Issuance of ordinary shares in conjunction with exercise of share options	54	—	—	—	—	3,057	—	—	3,057
Issuance of ordinary shares in conjunction with vesting of restricted stock units	203	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(13,810)	—	—	(13,810)
Share-based compensation	—	—	—	—	—	27,861	—	—	27,861
Shares repurchased	(858)	—	—	—	—	—	—	(111,249)	(111,249)
Other comprehensive loss	—	—	—	—	—	—	(22,883)	—	(22,883)
Net income	—	—	—	—	—	—	—	85,201	85,201
Balance at March 31, 2019	56,903	$ 6	4,000	$ 55	$ 472	$ 2,130,738	$ (220,674)	$ 819,850	$ 2,730,447

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2017	59,898	$ 6	4,000	$ 55	$ 472	$ 1,935,486	$ (140,878)	$ 917,956	$ 2,713,097
Cumulative effect adjustment from adoption of new accounting standards	—	—	—	—	—	—	53	(351)	(298)
Issuance of ordinary shares in conjunction with exercise of share options	133	—	—	—	—	10,588	—	—	10,588
Issuance of ordinary shares in conjunction with vesting of restricted stock units	195	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(14,594)	—	—	(14,594)
Share-based compensation	—	—	—	—	—	24,276	—	—	24,276
Shares repurchased	(237)	—	—	—	—	—	—	(34,546)	(34,546)
Other comprehensive income	—	—	—	—	—	—	42,057	—	42,057
Net income	—	—	—	—	—	—	—	45,991	45,991
Balance at March 31, 2018	59,989	$ 6	4,000	$ 55	$ 472	$ 1,955,756	$ (98,768)	$ 929,050	$ 2,786,571

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,	
	2019	**2018**
Operating activities		
Net income	$ 85,201	$ 45,991
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	56,885	53,007
Share-based compensation	27,552	24,303
Depreciation	3,539	3,722
Acquired in-process research and development	56,000	—
Loss on disposal of assets	3	256
Deferred tax benefit	(17,053)	(15,307)
Provision for losses on accounts receivable and inventory	528	590
Amortization of debt discount and deferred financing costs	11,133	10,617
Other non-cash transactions	1,181	16,026
Changes in assets and liabilities:		
Accounts receivable	(56,960)	(56,591)
Inventories	(8,688)	(3,312)
Prepaid expenses and other current assets	(988)	(3,534)
Other non-current assets	426	1,012
Accounts payable	1,554	23,136
Accrued liabilities	(2,685)	47,484
Income taxes payable	39,726	14,183
Deferred revenue	(1,874)	(1,875)
Other non-current liabilities	6,773	7,651
Net cash provided by operating activities	202,253	167,359
Investing activities		
Proceeds from maturity of investments	345,000	195,000
Acquired in-process research and development	(56,000)	—
Purchases of property, plant and equipment	(7,948)	(7,149)
Acquisition of investments	(115,000)	(240,000)
Net cash provided by (used in) investing activities	166,052	(52,149)
Financing activities		
Proceeds from employee equity incentive and purchase plans	3,057	10,588
Payment of employee withholding taxes related to share-based awards	(13,810)	(14,594)
Repayments of long-term debt	(8,347)	(9,023)
Share repurchases	(111,249)	(34,546)
Net cash used in financing activities	(130,349)	(47,575)
Effect of exchange rates on cash and cash equivalents	(112)	(501)
Net increase in cash and cash equivalents	237,844	67,134
Cash and cash equivalents, at beginning of period	309,622	386,035
Cash and cash equivalents, at end of period	$ 547,466	$ 453,169

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 a global biopharmaceutical company dedicated to developing life-changing medicines for people with limited or no options. As a leader in sleep medicine and with a growing hematology/oncology portfolio, we have a diverse portfolio of products and product candidates in development.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in adult and pediatric 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 who have developed hypersensitivity to *E. coli*-derived asparaginase;
- **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, 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; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes.

In March 2019, the FDA approved our new drug application, or NDA, for Sunosi™ (solriamfetol) as a treatment to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea and recommended that Sunosi be scheduled by the U.S. Drug Enforcement Administration, or DEA. We expect to launch the product in the U.S. after the DEA completes its scheduling review. We are also seeking approval for solriamfetol in Europe and submitted a marketing authorization application to the European Medicines Agency in the fourth quarter of 2018.

In March 2019, we announced positive top-line results from our Phase 3 study evaluating the efficacy and safety of JZP-258, an oxybate product candidate that contains 92% less sodium than Xyrem, for the treatment of cataplexy and EDS in adult patients with narcolepsy, and we expect to submit an NDA for this product by as early as the end of 2019.

Our strategy to create shareholder value is focused on:

- Strong financial execution through growth in sales of our current lead marketed products;
- Building a diversified product portfolio and development pipeline through a combination of our internal research and development efforts and obtaining rights to clinically meaningful and differentiated on- or near-market products and early- to late-stage product candidates through acquisitions, collaborations, licensing arrangements, partnerships and venture investments; and
- Maximizing the value of our products and product candidates by continuing to implement our comprehensive global development plans, including through generating additional clinical data and seeking regulatory approval for new indications.

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 U.S. Securities and Exchange Commission 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, 2018.

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, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019, for any other interim period or for any future period.

Our significant accounting policies have not changed substantially from those previously described in our Annual Report on Form 10-K for the year ended December 31, 2018 with the exception of the accounting policy relating to operating leases and financing obligations which was updated as a result of adopting Accounting Standards Update No. 2016-02, "Leases", or ASU No. 2016-02.

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

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.

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.

Leases

We determine if an arrangement is a lease at inception. Operating leases are included in operating lease assets, other current liabilities, and operating lease liabilities on our condensed consolidated balance sheets. Operating lease assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. In determining the net present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date. The operating lease asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We have lease agreements with lease and non-lease components, which are generally accounted for separately. For vehicle leases we account for the lease and non-lease components as a single lease component.

We have elected the short-term lease exemption and, therefore, do not recognize a right-of-use asset or corresponding liability for lease arrangements with an original term of 12 months or less.

Adoption of New Accounting Standards

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02. Under the new guidance, lessees are 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. We adopted ASU No. 2016-02 on a modified retrospective basis applied to leases existing as of, or entered into after, January 1, 2019. We elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification of those leases in place as of January 1, 2019.

The adoption of ASU No. 2016-02 resulted in the recognition of right-of-use assets and lease liabilities of $149.4 million and $162.9 million, respectively, on the consolidated balance sheet as of January 1, 2019, and the de-recognition of the build-to-suit assets and related financing obligations on the consolidated balance sheet as of December 31, 2018 of $95.4 million and $109.8 million, respectively, with the balance impacting retained earnings, deferred rent and deferred tax liabilities. The right-of-use assets and lease liabilities primarily relate to real estate leases. Refer to Note 10 for lease-related disclosures.

The cumulative effect of the changes made to our consolidated balance sheet as of January 1, 2019 for the adoption of the ASU No. 2016-02 was as follows (in thousands):

	Balance at December 31, 2018	Transition Adjustments	Balance at January 1, 2019
Assets:			
Property, plant and equipment, net	$ 200,358	$ (95,397)	$ 104,961
Operating lease assets	—	149,442	149,442
Liabilities:			
Accrued liabilities	264,887	8,165	273,052
Operating lease liabilities, less current portion	—	153,158	153,158
Deferred tax liabilities, net	309,097	1,489	310,586
Other non-current liabilities	218,879	(113,615)	105,264
Shareholders' Equity:			
Retained earnings	841,050	4,848	845,898

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem. Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, including, without limitation, the introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, Xyrem in the treatment of cataplexy and/or EDS in narcolepsy, including our recently-approved product, Sunosi; the introduction of a generic version of Xyrem in the U.S. market before the entry dates specified in our settlements with the abbreviated new drug application, or ANDA, filers or on terms that are different from those contemplated by the settlement agreements; increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, including pressure to agree to discounts, rebates or other restrictive pricing terms for Xyrem; changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and risk evaluation and mitigation strategy, or REMS, programs by government entities; changes to or uncertainties around our Xyrem REMS, or any failure to comply with our REMS obligations to the satisfaction of the FDA; challenges to our intellectual property around Xyrem, including the possibility of new ANDA or NDA filers or new post-grant patent review proceedings; operational disruptions at the Xyrem central pharmacy; any supply or manufacturing problems, including any problems with our sole source Xyrem active pharmaceutical ingredient, or API, provider; continued acceptance of Xyrem by physicians and patients, including as a result of negative publicity that surfaces from time to time; and changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem.

In addition to risks related specifically to Xyrem, 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, including, without limitation, risks and uncertainties associated with: effectively commercializing our other products; competition; obtaining and maintaining adequate coverage and reimbursement for our products; increasing scrutiny of pharmaceutical product pricing and resulting changes in healthcare laws and policy; market acceptance; delays or problems in the supply of our products, loss of single source suppliers or failure to comply with manufacturing regulations; regulatory approval and successful launch of our late-stage product candidates; identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; the regulatory approval process; the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements; and possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, cash equivalents, investments and derivative contracts. 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 investments to the extent recorded on the balance sheet.

We manage our foreign currency transaction risk and interest rate risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of March 31, 2019, we had foreign exchange forward contracts with notional amounts totaling $217.2 million. As of March 31, 2019, the outstanding foreign exchange forward contracts had a net liability fair value of $1.5 million. As of March 31, 2019, we had interest rate swap contracts with notional amounts totaling $300.0 million. These outstanding interest rate swap contracts had a net asset fair value of $2.1 million as of March 31, 2019. The counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not significant.

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 U.S., 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 as of March 31, 2019 and December 31, 2018, allowances on receivables were not material. As of March 31, 2019, two customers accounted for 91% of gross accounts receivable, Express Scripts Specialty Distribution Services, Inc. and its affiliates, or Express Scripts, which accounted for 74% of gross accounts receivable, and McKesson Corporation and affiliates, or McKesson, which accounted for 17% of gross accounts receivable. As of December 31, 2018, two customers accounted for 89% of gross accounts receivable, Express Scripts, which accounted for 74% of gross accounts receivable, and McKesson, which accounted for 15% of gross accounts receivable.

We depend on single source suppliers for most of our products, product candidates and their APIs. With respect to Xyrem, the API is manufactured for us by a single source supplier and the finished product is manufactured both by us in our facility in Athlone, Ireland and by our U.S.-based Xyrem supplier.

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-15, “Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract”, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The standard is effective for us beginning January 1, 2020 and early adoption is permitted. The new guidance is not expected to have a material impact on our results of operations and financial position.

In January 2017, the FASB issued ASU No. 2017-04, “Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment” which simplifies the accounting for goodwill impairment by eliminating Step 2 of the current goodwill impairment test. Goodwill impairment will now be the amount by which the reporting unit’s carrying value exceeds its fair value, limited to the carrying value of the goodwill. The standard is effective for us beginning January 1, 2020. Early adoption is permitted for any impairment tests performed after January 1, 2017. The new guidance is not expected to have a material impact on our results of operations and financial position.

2. Collaboration and License Agreement

On January 2, 2019, we entered into a strategic collaboration agreement with Codiak BioSciences, Inc., or Codiak, focused on the research, development and commercialization of exosome therapeutics to treat cancer. Codiak granted us an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize therapeutic candidates directed at five targets to be developed using Codiak's engEx™ precision engineering platform for exosome therapeutics.

Under the terms of the agreement, Codiak is responsible for the execution of preclinical and early clinical development of therapeutic candidates directed at all five targets through Phase 1/2 proof of concept studies. Following the conclusion of the applicable Phase 1/2 study, we will be responsible for future development, potential regulatory submissions and

commercialization for each product. Codiak has the option to participate in co-commercialization and cost/profit-sharing in the U.S. and Canada on up to two products.

As part of the agreement, we paid Codiak an upfront payment of $56.0 million in January 2019, which was recorded as acquired IPR&D expense in our condensed consolidated statements of income for the three months ended March 31, 2019. Codiak is eligible to receive up to $20 million in preclinical development milestone payments across all five programs. Codiak is also eligible to receive milestone payments totaling up to $200 million per target based on investigational new drug application acceptance, clinical and regulatory milestones, including approvals in the U.S., the European Union, or EU, and Japan, and certain sales milestones. Codiak is also eligible to receive tiered royalties on net sales of each approved product.

3. Cash and Available-for-Sale Securities

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

	March 31, 2019					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 192,328	$ —	$ —	$ 192,328	$ 192,328	$ —
Time deposits	415,000	—	—	415,000	130,000	285,000
Money market funds	225,138	—	—	225,138	225,138	—
Totals	$ 832,466	$ —	$ —	$ 832,466	$ 547,466	$ 285,000

	December 31, 2018					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 215,606	$ —	$ —	$ 215,606	$ 215,606	$ —
Time deposits	515,000	—	—	515,000	—	515,000
Money market funds	94,016	—	—	94,016	94,016	—
Totals	$ 824,622	$ —	$ —	$ 824,622	$ 309,622	$ 515,000

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 balances represent time deposits with original maturities of greater than three months and less than one year.

4. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of March 31, 2019 and December 31, 2018 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	March 31, 2019			December 31, 2018		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:						
Available-for-sale securities:						
Time deposits	$ —	$ 415,000	$ 415,000	$ —	$ 515,000	$ 515,000
Money market funds	225,138	—	225,138	94,016	—	94,016
Interest rate contracts	—	2,090	2,090	—	4,070	4,070
Foreign exchange forward contracts	—	212	212	—	1,194	1,194
Totals	$ 225,138	$ 417,302	$ 642,440	$ 94,016	$ 520,264	$ 614,280
Liabilities:						
Foreign exchange forward contracts	$ —	$ 1,713	$ 1,713	$ —	$ 1,460	$ 1,460
Totals	$ —	$ 1,713	$ 1,713	$ —	$ 1,460	$ 1,460

As of March 31, 2019, our available-for-sale securities included time deposits and money market funds, and their carrying values were approximately equal to their fair values. Time deposits were measured at fair value using Level 2 inputs and money market funds were measured using quoted prices in active markets, which represent Level 1 inputs. 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.

Our derivative assets and liabilities include interest rate and foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates and our own credit risk, as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the fair value hierarchy.

There were no transfers between the different levels of the fair value hierarchy in 2019 or in 2018.

As of March 31, 2019, the carrying amount of investments measured using the measurement alternative for equity investments without a readily determinable fair value was $4.5 million. The carrying amount, which is recorded within other non-current assets, represents the purchase price paid in December 2018.

As of March 31, 2019, the estimated fair values of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, and our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, were approximately $585 million and $563 million, respectively. The fair values of the 2021 Notes and the 2024 Notes, which we refer to together as the Exchangeable Senior Notes, were estimated using quoted market prices obtained from brokers (Level 2). The estimated fair value of our borrowing under our term loan was approximately equal to its book value based on the borrowing rates currently available for variable rate loans (Level 2).

5. Derivative Instruments and Hedging Activities

We are exposed to certain risks arising from operating internationally, including fluctuations in interest rates on our outstanding term loan borrowings and fluctuations in foreign exchange rates primarily related to the translation of euro-denominated net monetary liabilities, including intercompany balances, held by subsidiaries with a U.S. dollar functional currency. We manage these exposures within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes.

To achieve a desired mix of floating and fixed interest rates on our variable rate debt, we entered into interest rate swap agreements in March 2017 which are effective until July 2021. These agreements hedge contractual term loan interest rates. As of March 31, 2019 and December 31, 2018, the interest rate swap agreements had a notional amount of $300.0 million. As

a result of these agreements, the interest rate on a portion of our term loan borrowings was fixed at 1.895%, plus the borrowing spread, until July 12, 2021.

The effective portion of changes in the fair value of derivatives designated as and that qualify as cash flow hedges is recorded in accumulated other comprehensive loss and is subsequently reclassified into earnings in the period that the hedged forecasted transaction affects earnings. The impact on accumulated other comprehensive loss and earnings from derivative instruments that qualified as cash flow hedges for the three months ended March 31, 2019 and 2018 was as follows (in thousands):

	Three Months Ended March 31,	
Interest Rate Contracts:	**2019**	**2018**
Gain (loss) recognized in accumulated other comprehensive loss, net of tax	$ (1,341)	$ 3,037
Loss (gain) reclassified from accumulated other comprehensive loss to interest expense, net of tax	(400)	167

Assuming no change in LIBOR-based interest rates from market rates as of March 31, 2019, $1.3 million of gains, net of tax, recognized in accumulated other comprehensive loss will be reclassified to earnings over the next 12 months.

We enter into foreign exchange forward contracts, with durations of up to 12 months, designed to limit the exposure to fluctuations in foreign exchange rates related to the translation of certain non-U.S. dollar denominated liabilities, including intercompany balances. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of March 31, 2019 and December 31, 2018, the notional amount of foreign exchange contracts where hedge accounting is not applied was $217.2 million and $271.5 million, respectively.

The foreign exchange loss in our condensed consolidated statements of income included the following gains and losses associated with foreign exchange contracts not designated as hedging instruments (in thousands):

	Three Months Ended March 31,	
Foreign Exchange Forward Contracts:	**2019**	**2018**
Gain (loss) recognized in foreign exchange loss	$ (3,409)	$ 3,751

The cash flow effects of our derivative contracts for the three months ended March 31, 2019 and 2018 are included within net cash provided by operating activities in the condensed consolidated statements of cash flows.

The following tables summarize the fair value of outstanding derivatives (in thousands):

	March 31, 2019			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	**Fair Value**	**Balance Sheet Location**	**Fair Value**
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets	$ 1,481	Accrued liabilities	$ —
	Other non-current assets	609		
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	212	Accrued liabilities	1,713
Total fair value of derivative instruments		$ 2,302		$ 1,713

	December 31, 2018			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets	$ 1,929	Accrued liabilities	$ —
	Other non-current assets	2,141		
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	1,194	Accrued liabilities	1,460
Total fair value of derivative instruments		$ 5,264		$ 1,460

Although we do not offset derivative assets and liabilities within our condensed consolidated balance sheets, our International Swap and Derivatives Association agreements provide for net settlement of transactions that are due to or from the same counterparty upon early termination of the agreement due to an event of default or other termination event. The following tables summarize the potential effect on our condensed consolidated balance sheets of offsetting our interest rate contracts and foreign exchange forward contracts subject to such provisions (in thousands):

	March 31, 2019					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 2,302	$ —	$ 2,302	$ (599)	$ —	$ 1,703
Derivative liabilities	(1,713)	—	(1,713)	599	—	(1,114)

	December 31, 2018					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 5,264	$ —	$ 5,264	$ (935)	$ —	$ 4,329
Derivative liabilities	(1,460)	—	(1,460)	935	—	(525)

6. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	$ 7,138	$ 5,604
Work in process	31,254	26,034
Finished goods	22,315	21,318
Total inventories	$ 60,707	$ 52,956

7. Goodwill and Intangible Assets

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

Balance at December 31, 2018	$ 927,630
Foreign exchange	(7,658)
Balance at March 31, 2019	$ 919,972

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

		March 31, 2019			December 31, 2018		
	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	13.8	$ 3,109,876	$ (680,923)	$ 2,428,953	$ 3,110,641	$ (632,413)	$ 2,478,228
Priority review voucher		111,101	—	111,101	111,101	—	111,101
Manufacturing contracts	—	12,026	(12,026)	—	12,256	(12,256)	—
Trademarks	—	2,890	(2,890)	—	2,896	(2,896)	—
Total finite-lived intangible assets		3,235,893	(695,839)	2,540,054	3,236,894	(647,565)	2,589,329
Acquired IPR&D assets		139,339	—	139,339	142,005	—	142,005
Total intangible assets		$ 3,375,232	$ (695,839)	$ 2,679,393	$ 3,378,899	$ (647,565)	$ 2,731,334

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. We reduced the estimated remaining useful life of the Erwinaze intangible asset due to the receipt of a contract termination notice from Porton Biopharma Limited in February 2019. The reduction in the estimated remaining useful life increased intangible asset amortization expense by $10.2 million, reduced net income by $6.9 million and reduced basic and diluted net income per ordinary share by $0.12 during the three months ended March 31, 2019.

Based on acquired developed technology intangible assets recorded as of March 31, 2019, 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
2019 (remainder)	$ 184,982
2020	245,995
2021	198,981
2022	153,990
2023	153,990
Thereafter	1,491,015
Total	$ 2,428,953

8. Certain Balance Sheet Items

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

	March 31, 2019	December 31, 2018
Land and buildings	$ 46,607	$ 46,650
Leasehold improvements	33,328	33,273
Manufacturing equipment and machinery	25,999	25,837
Computer software	18,337	19,062
Construction-in-progress	16,973	51,243
Computer equipment	14,219	13,679
Furniture and fixtures	8,101	8,155
Build-to-suit facility	—	52,067
Subtotal	163,564	249,966
Less accumulated depreciation and amortization	(50,558)	(49,608)
Property, plant and equipment, net	$ 113,006	$ 200,358

The decrease in the carrying amount of construction-in-progress and build-to-suit facility assets as of March 31, 2019 compared to December 31, 2018 reflects the de-recognition of assets related to build-to-suit facility leases on adoption of ASU No. 2016-02.

Accrued liabilities consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Rebates and other sales deductions	$ 87,980	$ 86,495
Accrued loss contingency	58,546	58,154
Employee compensation and benefits	45,547	58,543
Accrued milestones	20,000	—
Clinical trial accruals	8,904	5,904
Current portion of operating lease liabilities	8,669	—
Royalties	7,676	2,679
Inventory-related accruals	7,656	8,753
Selling and marketing accruals	5,986	6,780
Accrued construction-in-progress	4,953	1,065
Professional fees	3,271	2,333
Accrued interest	2,579	7,407
Sales returns reserve	2,336	2,510
Derivative instrument liabilities	1,713	1,460
Other	26,574	22,804
Total accrued liabilities	$ 292,390	$ 264,887

9. Debt

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

	March 31, 2019	December 31, 2018
2021 Notes	$ 575,000	$ 575,000
Unamortized discount and debt issuance costs on 2021 Notes	(55,631)	(60,910)
2021 Notes, net	519,369	514,090
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(133,875)	(138,914)
2024 Notes, net	441,125	436,086
Term loan	638,170	646,236
Total debt	1,598,664	1,596,412
Less current portion	33,387	33,387
Total long-term debt	$ 1,565,277	$ 1,563,025

Exchangeable Senior Notes

The Exchangeable Senior Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of Jazz Pharmaceuticals plc. The Exchangeable Senior Notes are senior unsecured obligations of the Issuer and are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. No subsidiary of Jazz Pharmaceuticals plc guaranteed the Exchangeable Senior 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, 2019, the carrying values of the equity component of the 2021 Notes and the 2024 Notes, net of equity issuance costs, were $126.9 million and $149.8 million, respectively.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of March 31, 2019 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2019 (remainder)	$ 25,040
2020	33,387
2021	608,387
2022	33,387
2023	517,493
Thereafter	575,000
Total	$ 1,792,694

10. Leases

The components of the lease expense for the three months ended March 31, 2019 were as follows (in thousands):

Lease Cost	Three Months Ended March 31, 2019
Operating lease cost	$ 5,870
Short-term lease cost	601
Variable lease cost	3
Sublease income	(162)
Net lease cost	$ 6,312

Supplemental balance sheet information related to operating leases was as follows (in thousands):

Leases	Classification	March 31, 2019
Assets		
Operating lease assets	Operating lease assets	$ 147,365
Liabilities		
Current		
Operating lease liabilities	Accrued liabilities	8,669
Non-current		
Operating lease liabilities	Operating lease liabilities, less current portion	154,066
Total operating lease liabilities		$ 162,735

Lease Term and Discount Rate	March 31, 2019
Weighted-average remaining lease term - operating leases (years)	10.3
Weighted-average discount rate - operating leases	5.3%

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Three Months Ended March 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash outflows from operating leases	$ 4,576
Non-cash operating activities:	
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	151,029

(1) Includes the balances recognized on January 1, 2019 on adoption of ASU No. 2016-02.

Maturities of operating lease liabilities were as follows (in thousands):

Year Ending December 31,	Operating leases
2019 (remainder)	$ 7,658
2020	20,664
2021	20,591
2022	20,674
2023	20,961
Thereafter	128,164
Total lease payments	$ 218,712
Less imputed interest	(55,977)
Present value of lease liabilities	$ 162,735

11. 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, 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, 2019 and December 31, 2018. 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

Operating Leases. 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. Refer to Note 10 for details of the maturity of our operating lease liabilities.

Other Commitments. As of March 31, 2019, we had $70.3 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

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

Other Contingencies

In May and October 2016 and in February 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of charitable organizations that provide financial assistance to Medicare patients. In April 2018, we reached an agreement in principle with the U.S. Department of Justice, or DOJ, on terms for a civil settlement of potential claims by the DOJ in the amount of $57.0 million plus interest to accrue at the statutory rate of 2.75%, subject to negotiation of a definitive settlement agreement and other contingencies. On April 4, 2019, we finalized the settlement agreement with the DOJ and the Office of Inspector General of the U.S. Department of Health and Human Services,

or OIG, and we entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the corporate integrity agreement. During 2018, we recorded $58.2 million related to this matter, including related interest, within accrued liabilities on our consolidated balance sheet with the related expense included in selling, general and administrative expenses on our consolidated statement of income. During the three months ended March 31, 2019, we recorded an additional $0.4 million of interest related to this matter. Under the settlement agreement, we are released from any civil or administrative monetary claim arising from allegations relating to our conduct between 2011 and May 2014 in supporting a charitable foundation that provided financial assistance to Medicare patients. The settlement agreement is not an admission of any wrongdoing or liability by us but a settlement of claims. In the event of a breach of the corporate integrity agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health programs.

12. Shareholders' Equity

Share Repurchase Program

In November 2016, 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 $300.0 million, exclusive of any brokerage commissions. In November and December 2018, our board of directors increased the existing share repurchase program authorization by $320.0 million and $400.0 million, respectively, thereby increasing the total amount authorized to $1.02 billion. Under this program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. 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 the amended credit agreement, corporate and regulatory requirements and market conditions. The share repurchase program may be modified, suspended or discontinued at any time without prior notice. In the three months ended March 31, 2019, we spent a total of $111.2 million to purchase 0.9 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $129.66 per share. All ordinary shares repurchased were canceled. As of March 31, 2019, the remaining amount authorized under the share repurchase program was $267.9 million.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of March 31, 2019 and December 31, 2018 were as follows (in thousands):

	Net Unrealized Gain (Loss) From Hedging Activities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2018	$ 3,557	$ (201,348)	$ (197,791)
Other comprehensive loss before reclassifications	(1,341)	(21,142)	(22,483)
Amounts reclassified from accumulated other comprehensive loss	(400)	—	(400)
Other comprehensive loss, net	(1,741)	(21,142)	(22,883)
Balance at March 31, 2019	$ 1,816	$ (222,490)	$ (220,674)

During the three months ended March 31, 2019, other comprehensive loss reflects foreign currency translation adjustments, primarily due to the weakening of the euro against the U.S. dollar, and the net unrealized loss on derivatives that qualify as cash flow hedges.

13. 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,	
	2019	2018
Numerator:		
Net income	$ 85,201	$ 45,991
Denominator:		
Weighted-average ordinary shares used in per share calculations - basic	57,206	59,928
Dilutive effect of employee equity incentive and purchase plans	875	1,250
Weighted-average ordinary shares used in per share calculations - diluted	58,081	61,178
Net income per ordinary share:		
Basic	$ 1.49	$ 0.77
Diluted	$ 1.47	$ 0.75

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans and the Exchangeable Senior 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 Exchangeable Senior Notes. The potential issue of ordinary shares issuable upon exchange of the Exchangeable Senior 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, 2019 and 2018 did not exceed the effective exchange prices per ordinary share of the Exchangeable Senior Notes.

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,	
	2019	2018
Exchangeable Senior Notes	5,504	5,504
Options, RSUs and ESPP	4,988	3,305

14. Revenues

The following table presents a summary of total revenues (in thousands):

	Three Months Ended March 31,	
	2019	2018
Xyrem	$ 368,317	$ 316,777
Erwinaze/Erwinase	60,899	50,627
Defitelio/defibrotide	41,500	35,061
Vyxeos	28,943	26,228
Other	3,672	12,154
Product sales, net	503,331	440,847
Royalties and contract revenues	4,855	3,766
Total revenues	$ 508,186	$ 444,613

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

	Three Months Ended March 31,	
	2019	2018
United States	$ 462,862	$ 405,687
Europe	35,401	28,331
All other	9,923	10,595
Total revenues	$ 508,186	$ 444,613

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,	
	2019	2018
Express Scripts	72%	71%
McKesson	18%	20%

Financing and payment

Our payment terms vary by the type and location of our customer but payment is generally required in a term ranging from 30 to 45 days.

Contract Liabilities - Deferred Revenue

The deferred revenue balance as of March 31, 2019 primarily related to deferred upfront fees received from Nippon Shinyaku Co., Ltd., or Nippon Shinyaku, in connection with two license, development and commercialization agreements granting Nippon Shinyaku exclusive rights to develop and commercialize each of Defitelio and Vyxeos in Japan. We recognized contract revenues of $1.9 million during the three months ended March 31, 2019, relating to these upfront payments. The deferred revenue balances are being recognized over an average of four years representing the period we expect to perform our research and developments obligations under each agreement.

The following table presents a reconciliation of our beginning and ending balances in contract liabilities from contracts with customers for the three months ended March 31, 2019 (in thousands):

	Contract Liabilities
Balance as of December 31, 2018	$ 14,995
Amount recognized within royalties and contract revenues	(1,874)
Balance as of March 31, 2019	$ 13,121

15. 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,	
	2019	2018
Selling, general and administrative	$ 20,370	$ 18,234
Research and development	5,523	4,375
Cost of product sales	1,659	1,694
Total share-based compensation expense, pre-tax	27,552	24,303
Income tax benefit from share-based compensation expense	(3,667)	(3,668)
Total share-based compensation expense, net of tax	$ 23,885	$ 20,635

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,	
	2019	2018
Shares underlying options granted (in thousands)	1,297	1,152
Grant date fair value	$ 42.84	$ 46.08
Black-Scholes option pricing model assumption information:		
Volatility	32%	35%
Expected term (years)	4.5	4.5
Range of risk-free rates	2.4-2.5%	2.2-2.5%
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,	
	2019	2018
RSUs granted (in thousands)	519	461
Grant date fair value	$ 139.38	$ 140.60

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, generally over four years.

As of March 31, 2019, compensation cost not yet recognized related to unvested share options and RSUs was $109.1 million and $136.5 million, respectively, which is expected to be recognized over a weighted-average period of 3.0 years.

16. Income Taxes

Our income tax provision was $29.1 million in the three months ended March 31, 2019 compared to $19.1 million for the same period in 2018. The effective tax rate was 25.3% in the three months ended March 31, 2019 compared to 29.2% for the same period in 2018. The decrease in the effective tax rate for the three months ended March 31, 2019 compared to the same period in 2018 was primarily due to the impact of the loss contingency expense in 2018. The effective tax rate for the three months ended March 31, 2019 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a higher rate than the Irish statutory rate and unrecognized tax benefits, partially offset by originating tax credits. 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 net deferred tax liability primarily arose due to the acquisition of Celator Pharmaceuticals, Inc. The balance is net of deferred tax assets which are comprised primarily of U.S. federal and state tax credits, U.S. federal and state and foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain foreign and U.S. federal and state 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 recorded an unrecognized tax benefit for certain tax benefits which we judge may not be sustained upon examination. Our most significant tax jurisdictions are Ireland and the U.S. (both at the federal level and in various state jurisdictions). In Ireland, we are no longer subject to income tax audits by taxing authorities for the years prior to 2013. The U.S. jurisdictions generally have statutes of limitations three to four years from the later of the return due date or the date when the return was filed. However, in the U.S. (at the federal level and in most states), carryforward tax attributes that were generated in 2014 and earlier may still be adjusted upon examination by the tax authorities. Certain of our subsidiaries are currently under examination by the French tax authorities for the years ended December 31, 2012, 2013, 2015, 2016 and 2017. These examinations may lead to ordinary course adjustments or proposed adjustments to our taxes. In December 2015, we received proposed tax assessment notices, and, in October 2018, we received revised tax assessment notices from the French tax authorities for 2012 and 2013, and in December 2018, we received a proposed tax assessment notice for 2015, relating to certain transfer pricing adjustments. The notices provide for additional French tax of approximately $42 million for 2012 and 2013 and approximately $4 million for 2015, including interest and penalties through the respective dates of the proposed assessments, translated at the foreign exchange rate at March 31, 2019. We disagree with the assessments and are contesting them vigorously.

17. Subsequent Event

In April 2019, we finalized a settlement agreement with the DOJ and the OIG and entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the corporate integrity agreement. For more information, see Note 11, Commitments and Contingencies—Other Contingencies.

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 "Risk Factors" in Part II, Item 1A 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 a global biopharmaceutical company dedicated to developing life-changing medicines for people with limited or no options. As a leader in sleep medicine and with a growing hematology/oncology portfolio, we have a diverse portfolio of products and product candidates in development.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in adult and pediatric 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;
- **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, 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; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or t-AML, or acute myeloid leukemia, or AML, with myelodysplasia-related changes, or AML-MRC.

Our strategy to create shareholder value is focused on:

- Strong financial execution through growth in sales of our current lead marketed products;
- Building a diversified product portfolio and development pipeline through a combination of our internal research and development efforts and obtaining rights to clinically meaningful and differentiated on- or near-market products and early- to late-stage product candidates through acquisitions, collaborations, licensing arrangements, partnerships and venture investments; and
- Maximizing the value of our products and product candidates by continuing to implement our comprehensive global development plans, including through generating additional clinical data and seeking regulatory approval for new indications.

In the three months ended March 31, 2019, our total net product sales increased by 14%, compared to the same period in 2018, primarily due to an increase in Xyrem net product sales. We expect total net product sales to increase in 2019 over 2018, primarily due to expected growth in sales of Xyrem, Vyxeos and Defitelio. Our ability to increase net product sales is subject to a number of risks and uncertainties as set forth below and under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. For additional information regarding our net product sales, see "—Results of Operations."

Significant Developments Affecting Our Business

In January 2019, we entered into a strategic collaboration agreement with Codiak BioSciences, Inc., or Codiak, focused on the research, development and commercialization of exosome therapeutics to treat cancer.

In February 2019, we received a contract termination notice from Porton Biopharma Limited, or PBL. As a result of our receipt of the contract termination notice, our license and supply agreement with PBL, which includes our license for Erwinaze, will expire on December 31, 2020. Unless we and PBL enter into a new agreement, we will lose our rights to Erwinaze effective December 31, 2020, other than our right to sell certain Erwinaze inventory for a post-termination sales period of 12 months.

In March 2019, we commenced the commercial launch of Xyrem for pediatric patients with narcolepsy, after completing the implementation of the related approved REMS modification. In May 2019, the FDA confirmed that as the first sponsor to obtain marketing approval for use of Xyrem to treat cataplexy and EDS in pediatric narcolepsy patients aged seven years and older, we are entitled to seven years of orphan drug exclusivity for the indication.

In March 2019, the FDA approved our new drug application, or NDA, for Sunosi™ (solriamfetol) as a treatment to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, or OSA, and recommended that Sunosi be scheduled by the U.S. Drug Enforcement Administration, or DEA. We expect to launch the product in the U.S. after the DEA completes its scheduling review. We are also seeking approval for solriamfetol in Europe and submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, in the fourth quarter of 2018.

In March 2019, we announced positive top-line results from our Phase 3 study evaluating the efficacy and safety of JZP-258, an oxybate product candidate that contains 92% less sodium than Xyrem, for the treatment of cataplexy and EDS in adult patients with narcolepsy, and we expect to submit an NDA for this product by as early as the end of 2019.

In April 2019, we finalized a settlement agreement with the U.S. Department of Justice, or DOJ, and the Office of Inspector General of the Department of Health and Human Services, or OIG, and we entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the corporate integrity agreement. For more information, see Note 11, Commitments and Contingencies—Other Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Continued Emphasis on Research and Development

During the three months ended March 31, 2019, we continued our focus on research and development activities, all in our sleep and hematology/oncology therapeutic areas.

Below is a summary of ongoing and planned development projects related to our products and pipeline and their corresponding current stages of development:

Sleep

Product Candidates	**Description**
Submitted for Regulatory Approval	
Solriamfetol in the European Union, or EU	EDS in OSA and EDS in narcolepsy
Phase 3	
JZP-258 (oxybate; 92% sodium reduction)	Cataplexy and EDS in narcolepsy
JZP-258 (oxybate; 92% sodium reduction)	Idiopathic hypersomnia
Preclinical	
Oxybate once-nightly formulation	Narcolepsy

Hematology/Oncology

Product Candidates	**Description**
Phase 3	
Defitelio	Prevention of VOD in high-risk patients following HSCT
Vyxeos	AML or high-risk myelodysplastic syndrome, or MDS (AML19) (cooperative group study)
Vyxeos	AML or high-risk MDS (AML18) (cooperative group study)
Phase 2	
Defitelio	Prevention of acute Graft versus Host Disease following allogeneic HSCT

Product Candidates	Description
Defitelio	Treatment of transplant-associated thrombotic microangiopathy (planned pivotal study)
Defitelio	Prevention of chimeric antigen receptor T-cell therapy-associated neurotoxicity (planned study)
Vyxeos + venetoclax	De novo or relapsed/refractory, or R/R, AML (MD Anderson Cancer Center, or MD Anderson, collaboration study)
Vyxeos	MDS (planned cooperative group study)
Vyxeos	R/R AML (cooperative group study)
Phase 1	
Vyxeos + gemtuzumab	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study)
Vyxeos + venetoclax	Low intensity dosing for unfit AML (planned phase 1/2 study)
Vyxeos	Low intensity dosing for higher risk MDS (planned MD Anderson collaboration study)
IMGN779	CD33+ AML (Jazz opt-in opportunity with ImmunoGen, Inc., or ImmunoGen)
IMGN632	CD123+ hematological malignancies (Jazz opt-in opportunity with ImmunoGen)
Preclinical	
CombiPlex	Solid tumors candidate
CombiPlex	Hematology/oncology exploratory activities
Asparaginase	ALL and other hematological malignancies
Recombinant Pegaspargase	Hematological malignancies (Jazz opt-in opportunity with Pfenex, Inc.)
Defitelio	Exploratory activities
Exosome NRAS candidate	Hematological malignancies (collaboration with Codiak)
Exosome STAT3 candidate	Hematological malignancies (collaboration with Codiak)
Exosome-based candidates	Solid tumors/hematological malignancies (collaboration with Codiak)

In 2019 and beyond, we expect that our research and development expenses will continue to increase from historical levels, particularly as we prepare for anticipated regulatory submissions and trial data read-outs, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates. Our ability to continue to undertake our planned development activities, as well as the success of these activities, are subject to a number of risks and uncertainties, including the risk factors under the headings “Risks Related to Our Business” and “Risks Related to Our Industry” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Challenges, Risks and Trends Related to Our Business

Xyrem. Xyrem is our largest selling product, and our financial results are significantly influenced by sales of Xyrem, which were 73% of our net product sales for the three months ended March 31, 2019 and 75% of our net product sales for the year ended December 31, 2018. Our future plans assume that sales of Xyrem will increase, but there is no guarantee 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 January 2019, and there is no guarantee that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes and revenues from Xyrem.

Although Xyrem is protected by patents covering its manufacture, formulation, distribution system and method of use, nine companies have sent us notices that they had filed abbreviated new drug applications, or ANDAs, seeking approval to market a generic version of Xyrem, and we have filed and settled patent lawsuits with all nine companies. To date, the FDA has approved or tentatively approved three of these ANDAs, and we believe that it is likely that the FDA will approve or tentatively approve additional ANDAs. In connection with the ANDA settlement agreements, we granted four of the filers the right to sell an authorized generic version of Xyrem, or an AG Product, and we granted each of the nine filers a license to launch its own generic sodium oxybate product. The actual timing of the launch of an AG Product or generic sodium oxybate product is uncertain because the launch dates of the AG Products and generic sodium oxybate products under our settlement agreements are subject to acceleration under certain circumstances. In the absence of any circumstances triggering acceleration, the earliest launch of an AG Product would be January 1, 2023. For a further description of the settlement

agreements, including a more complete description of potential dates of market entry for an AG Product(s) and generic sodium oxybate product(s) and circumstances that might trigger acceleration of such dates, see the risk factor under the heading "*The introduction of a new product in the U.S. market that competes with, or otherwise disrupts the market for, Xyrem would adversely affect sales of Xyrem"* in Part II, Item 1A of this Quarterly Report on Form 10-Q.

In addition to generic and authorized generic versions of Xyrem, we and others may launch products as treatment options in cataplexy and/or EDS in patients with narcolepsy, including other branded sodium oxybate products and other new and existing branded market entrants. For example, Avadel Pharmaceuticals plc is conducting a Phase 3 clinical trial of a once-nightly formula of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy, and has indicated that it intends to seek approval of its product candidate in the U.S. under a Section 505(b)(2) NDA approval pathway. Other companies may also develop a sodium oxybate or similar product using, for example, an alternative formulation or a different delivery technology and pursue a similar regulatory approval strategy in the future.

Non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy, even if not directly competitive with Xyrem, could have the effect of changing treatment regimens and payor coverage of Xyrem, and indirectly materially and adversely affect sales of Xyrem. Prescribers often prescribe stimulants or wake-promoting agents for treatment of EDS, and anti-depressants for cataplexy, before prescribing or instead of prescribing Xyrem, and payors often require patients to try such medications before they will cover Xyrem. It is possible that additional branded or generic products that treat symptoms of narcolepsy will also be prescribed before or instead of Xyrem, or that payors will require patients to try such products before they will cover Xyrem. Our product, Sunosi (solriamfetol), is an example of a new market entrant recently approved by the FDA to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA. Another example is pitolisant, a drug that has already been approved in Europe to treat adult patients with narcolepsy with or without cataplexy. Harmony Biosciences LLC, which has exclusive U.S. rights to seek approval of and commercialize pitolisant, announced in February 2019 that the FDA had accepted its pitolisant NDA for filing with priority review.

The receipt of marketing approval and commercialization of an alternative product approved in the U.S. for the treatment of narcolepsy patients could negatively impact our ability to maintain and grow sales of Xyrem, largely due to payor actions taken in response to the disruption of the narcolepsy market. This could have the additional impact of potentially triggering acceleration of market entry of the AG Products or other generic sodium oxybate products under our ANDA litigation settlement agreements. We expect that the approval and launch of any other sodium oxybate or alternative product that treats narcolepsy, or the launch of an AG Product or other generic version of Xyrem, could have a material adverse effect on our sales of and revenues from Xyrem and on our business, financial condition, results of operations and growth prospects.

Future Xyrem sales may also be impacted by changes to, or uncertainties around, regulatory restrictions, including changes to our current Xyrem risk evaluation and mitigation strategy, or REMS, which requires, among other things, that Xyrem be distributed through a single pharmacy. We cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xyrem REMS, including in connection with the submission of applications for new oxybate products, new oxybate indications or the introduction of authorized generics, or whether the FDA will approve modifications to the Xyrem REMS that we consider warranted in connection with the submission of applications for new oxybate products. We may face pressure to further modify the Xyrem REMS or to license or share intellectual property pertinent to the Xyrem REMS, including proprietary data required for the safe distribution of sodium oxybate, in connection with the FDA's approval of the generic sodium oxybate REMS or otherwise. Any such modifications to the Xyrem REMS approved, required or rejected by the FDA could make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, disrupt continuity of care for Xyrem patients and/or negatively affect sales of Xyrem. We also cannot predict the impact of future implementation of a generic sodium oxybate REMS on the Xyrem REMS.

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), were 12% of our net product sales for the three months ended March 31, 2019 and 9% for the year ended December 31, 2018. Erwinaze is licensed from and manufactured by a single source, PBL, a company that is wholly owned by the UK Department of Health and Social Care. Our license and supply agreement with PBL, which includes our license for Erwinaze, expires on December 31, 2020. We and PBL had been engaged in discussions related to entry into a replacement agreement to extend the term of our commercial relationship past 2020, but we did not reach agreement. Unless we and PBL enter into a new agreement, we will lose our rights to Erwinaze effective December 31, 2020, other than our right to sell certain Erwinaze inventory for a post-termination sales period of 12 months. In such event, we may not be able to replace the product sales we would lose from Erwinaze, which in 2018 totaled $174.7 million, and our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, we cannot predict whether and to what extent uncertainty related to our rights to, and availability of, Erwinaze after 2020 will negatively impact sales of and revenues from this product.

A continuing and significant challenge to maintaining sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product adequate to meet market demand. All Erwinaze that PBL has been able to supply is

currently completely absorbed by demand for the product. In addition, PBL is subject to a January 2017 warning letter issued by the FDA citing significant violations of the FDA's current Good Manufacturing Practices, or cGMP, as well as an inspection report from the UK Medicines and Healthcare Products Regulatory Agency listing several major findings, including major deficiencies and failures by PBL to comply with cGMP. PBL's product quality and manufacturing issues have resulted, and continue to result, in disruptions in our ability to supply markets from time to time and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. We have been experiencing, and continue to experience, supply disruptions globally and expect further supply disruptions during 2019. These supply disruptions will continue to adversely impact our ability to generate sales of and revenues from Erwinaze and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Defitelio/defibrotide. Sales of Defitelio/defibrotide were 8% of our net product sales for the three months ended March 31, 2019 and for the year ended December 31, 2018. Our ability to maintain and grow sales and to realize the anticipated benefits from our investment in Defitelio is subject to a number of risks and uncertainties, including continued acceptance by hospital pharmacy and therapeutics committees in the U.S., the continued availability of favorable pricing and adequate coverage and reimbursement, the limited experience of, and need to educate, physicians in recognizing, diagnosing and treating VOD, and the limited size of the population of VOD patients who are indicated for treatment with Defitelio. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product will be negatively affected and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Vyxeos. Sales of Vyxeos were 6% of our net product sales for the three months ended March 31, 2019 and 5% of our net product sales for the year ended December 31, 2018. We began selling Vyxeos in the U.S. in August 2017 following NDA approval. In August 2018, the European Commission, or EC, granted marketing authorization for Vyxeos. We have commenced our rolling launch of Vyxeos in the EU, and we are in the process of making pricing and reimbursement submissions in EU member states.

Our ability to realize the anticipated benefits from our investment in Vyxeos is subject to a number of risks and uncertainties, including acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries, the availability of adequate coverage, pricing and reimbursement approvals, competition from new and existing products and potential competition from products in development, and delays or problems in the supply or manufacture of Vyxeos. If sales of Vyxeos 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.

Sunosi (solriamfetol). As described above, the FDA approved Sunosi in March 2019. In the fourth quarter of 2018, we submitted an MAA to the EMA for solriamfetol. We cannot predict whether our MAA will be approved in a timely manner, or at all. Our ability to realize the anticipated benefits from our investment in Sunosi is subject to a number of risks and uncertainties, including, among other things, any delays in U.S. launch timing due to longer than expected DEA scheduling review which needs to be completed in the U.S. before commercial launch; the availability of adequate formulary positions and pricing and adequate coverage and reimbursement by government programs and other third party payors, including the impact of any delays in coverage decisions by payors; restrictions on permitted promotional activities based on limitations on the approved labeling for the product required by the FDA or the EC; market acceptance of Sunosi; delays or problems in the supply or manufacture of Sunosi; and our ability to satisfy the FDA's post-marketing requirements and other post-marketing requirements or commitments, if any, imposed by the EC in connection with its marketing authorization. If we are unable to successfully launch and commercialize Sunosi in the U.S., if we are unable to obtain approval of our solriamfetol MAA in a timely manner, or at all, if the EC requires product labeling that negatively impacts patient, physician or payor acceptance of the product, or if sales of Sunosi in the U.S. and in the EU (if approved) 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.

JZP-258. As described above, in March 2019, we announced positive top-line results from our Phase 3 study evaluating the efficacy and safety of JZP-258 for the treatment of cataplexy and EDS in adult patients with narcolepsy, and we expect to submit an NDA for this product by as early as the end of 2019. We cannot predict whether we will be able to submit our planned NDA in a timely manner or at all. Any failure or delay in successfully completing necessary clinical trials and conducting other activities, including CMC activities, that are required to complete our planned NDA submission and obtain regulatory approval, could materially and adversely affect our growth prospects. If we submit an NDA to the FDA for approval and the FDA determines that our safety or efficacy data do not warrant marketing approval, we may be required to conduct additional clinical trials, which could be costly and time-consuming, or we may not be able to commercialize JZP-258, in which event we would not receive any return on our investment.

Other Challenges and Risks. We anticipate that we will continue to face a number of other challenges and risks to our business and our ability to execute our strategy in 2019 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. In this regard, a key aspect of our growth strategy is our continued and growing investment in research and development

activities. Our ability to successfully develop product candidates for one or more indications as well as our ability to identify new indications for existing products are subject to a number of risks and uncertainties, such as 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. In addition, obtaining regulatory approval for product candidates is subject to the inherent uncertainty associated with the regulatory approval process, especially as we continue to increase investment in our product pipeline development projects and undertake planned regulatory submissions for our product candidates.

We also seek to expand our business through corporate development activities. Our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business are subject to a number of risks and uncertainties, including 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 historical 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.

We are increasingly experiencing pressure from third party payors to agree to discounts, rebates or other restrictive pricing terms for Xyrem. As our business becomes more complex, we may decide to enter into rebate agreements in order to ensure that patients continue to have access to Xyrem, and to support the long-term success of our sleep franchise, which might result in lower net revenues for Xyrem. In addition to increasing pricing pressure from, and restrictions on reimbursement imposed by, governmental and private third party payors, due to the attention being paid globally to healthcare cost containment, drug pricing by pharmaceutical companies is currently, and is expected to continue to be, under close scrutiny by both federal and state governments, including with respect to companies that have increased the price of products after acquiring those products from other companies. In addition, REMS programs have increasingly drawn public scrutiny from the U.S. Congress, the Federal Trade Commission and the FDA, with allegations that such programs are used as a means of improperly blocking or delaying competition. If we become the subject of any future government investigation with respect to drug pricing or other business practices, including as they relate to the Xyrem REMS or otherwise, we could incur significant expense and could be distracted from operation of our business and execution of our strategy.

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 are discussed in greater detail, along with other risks, in “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Results of Operations

The following table presents our revenues and expenses (in thousands, except percentages):

	Three Months Ended March 31,		Increase/
	2019	2018	(Decrease)
Product sales, net	$ 503,331	$ 440,847	14 %
Royalties and contract revenues	4,855	3,766	29 %
Cost of product sales (excluding amortization of intangible assets)	33,506	33,919	(1)%
Selling, general and administrative	167,947	207,213	(19)%
Research and development	60,105	62,667	(4)%
Intangible asset amortization	56,885	53,007	7 %
Acquired in-process research and development	56,000	—	N/A(1)
Interest expense, net	17,922	20,605	(13)%
Foreign exchange loss	611	1,728	(65)%
Income tax provision	29,116	19,146	52 %
Equity in loss of investees	893	337	165 %

(1) Comparison to prior period not meaningful.

Revenues

The following table presents our product sales, royalties and contract revenues, and total revenues (in thousands, except percentages):

	Three Months Ended March 31,		Increase/
	2019	2018	(Decrease)
Xyrem	$ 368,317	$ 316,777	16 %
Erwinaze/Erwinase	60,899	50,627	20 %
Defitelio/defibrotide	41,500	35,061	18 %
Vyxeos	28,943	26,228	10 %
Other	3,672	12,154	(70)%
Product sales, net	503,331	440,847	14 %
Royalties and contract revenues	4,855	3,766	29 %
Total revenues	$ 508,186	$ 444,613	14 %

Product Sales, Net

Xyrem product sales increased in the three months ended March 31, 2019 compared to the same period in 2018 due to a higher average net selling price and, to a lesser extent, an increase in sales volume. Price increases were instituted in January 2019 and January 2018. Xyrem product sales volume increased by 5% in the three months ended March 31, 2019 compared to the same period in 2018 primarily driven by an increase in the average number of patients on Xyrem. Erwinaze/Erwinase product sales increased in the three months ended March 31, 2019 compared to the same period in 2018 primarily due to an increase in product availability. Ongoing supply challenges at PBL continue to negatively impact our ability to supply the market. We are experiencing supply disruptions globally and expect further supply disruptions during 2019. Defitelio/defibrotide product sales increased in the three months ended March 31, 2019 compared to the same period in 2018 primarily due to higher volumes as a result of increased use by transplant centers that treat adult and pediatric patients. Vyxeos product sales increased in the three months ended March 31, 2019 compared to the same period in 2018 following the commercial launch in the EU in September 2018. Other product sales decreased in the three months ended March 31, 2019 compared to the same period in 2018 primarily due to the sale of our rights to Prialt to TerSera Therapeutics LLC, or TerSera, in September 2018. We expect total product sales will increase in 2019 over 2018, primarily due to expected growth in sales of Xyrem, Vyxeos and Defitelio.

Royalties and Contract Revenues

Royalties and contract revenues increased in the three months ended March 31, 2019 compared to the same period in 2018 primarily due to higher contract revenues from out-licensing agreements. We expect royalties and contract revenues to decrease in 2019 compared to 2018, primarily due to lower milestone revenues from out-licensing arrangements.

Cost of Product Sales

Cost of product sales decreased in the three months ended March 31, 2019 compared to the same period in 2018 primarily due to product mix. Gross margin as a percentage of net product sales was 93.3% in the three months ended March 31, 2019 compared to 92.3% for the same period in 2018. The increase in the gross margin percentage in the three months ended March 31, 2019 was primarily due to a change in product mix. We do not expect our gross margin as a percentage of net product sales to change materially in 2019 compared to 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased in the three months ended March 31, 2019 compared to the same period in 2018 primarily due to the loss contingency of $57.0 million incurred in the three months ended March 31, 2018. In April 2018, we reached an agreement in principle with the DOJ on a proposal for a civil settlement of potential claims by the DOJ in the amount of $57.0 million, subject to accrual of interest on the settlement amount from the date of the agreement in principle, negotiation of a definitive settlement agreement and other contingencies. In April 2019, we finalized a settlement agreement with the DOJ and the OIG. For a further description of this matter, see Note 11, Commitments and Contingencies—Other Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. Selling, general and administrative expenses for the three months ended March 31, 2019, compared to the same period in 2018, included higher expenses related to the planned launch of Sunosi in the U.S., an increase in other

compensation-related expenses driven by higher headcount, and an increase in other expenses related to the expansion and support of our business. We expect selling, general and administrative expenses in 2019 to increase compared to 2018, primarily due to an increase in compensation-related expenses driven by higher headcount and other expenses related to the expansion and support of our business and an increase in expenses related to the preparation for the planned commercial launch of Sunosi in the U.S. and the continuation of the commercial launch of Vyxeos in the EU.

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,	
	2019	2018
Clinical studies and outside services	$ 30,231	$ 28,189
Personnel expenses	21,310	17,204
Milestone expense	—	11,000
Other	8,564	6,274
Total	$ 60,105	$ 62,667

Research and development expenses decreased by $2.6 million in the three months ended March 31, 2019 compared to the same period in 2018. Clinical studies and outside services costs increased by $2.0 million for the three months ended March 31, 2019 compared to the same period in 2018 primarily due to an increase in expenses related to our ongoing pre-clinical and clinical development programs and regulatory activities. Personnel expenses increased by $4.1 million in the three months ended March 31, 2019 compared to the same period in 2018, primarily due to increased headcount in support of our development programs. Milestone expense of $11.0 million in the three months ended March 31, 2018 related to milestone payments following FDA acceptance of our NDA for solriamfetol in March 2018.

For 2019 and beyond, we expect that our research and development expenses will continue to increase from historical levels, particularly as we prepare for anticipated regulatory submissions and data read-outs from clinical trials, initiate and undertake 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 and regulatory submissions for 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.

Intangible Asset Amortization

Intangible asset amortization increased by $3.9 million in the three months ended March 31, 2019 compared to the same period in 2018, primarily due to the reduction in the estimated remaining useful life of the Erwinaze intangible asset resulting from the receipt of the contract termination notice from PBL in February 2019, partially offset by the cessation of amortization of the Prialt intangible asset following our entry into an Asset Purchase Agreement with TerSera in 2018. Intangible asset amortization is expected to increase in 2019 compared to 2018 as a result of the reduction in the estimated remaining useful life of the Erwinaze intangible asset.

Acquired In-Process Research and Development

Acquired in-process research and development, or IPR&D, expense in the three months ended March 31, 2019 related to an upfront payment of $56.0 million to Codiak in connection with our strategic collaboration agreement.

Interest Expense, Net

Interest expense, net for the three months ended March 31, 2019 decreased by $2.7 million compared to the same period in 2018, primarily due to higher interest income. We expect interest expense, net will be lower in 2019 compared to 2018, primarily due to higher interest income.

Foreign Exchange Loss

The foreign exchange loss is primarily related to the translation of euro-denominated net monetary liabilities, primarily intercompany balances, held by subsidiaries with a U.S. dollar functional currency and related foreign exchange forward contracts not designated as hedging instruments.

Income Tax Provision

Our income tax provision was $29.1 million in the three months ended March 31, 2019 compared to $19.1 million for the same period in 2018. The effective tax rate was 25.3% in the three months ended March 31, 2019 compared to 29.2% for the same period in 2018. The decrease in the effective tax rate for the three months ended March 31, 2019 compared to the same period in 2018 was primarily due to the impact of the loss contingency expense in 2018. The effective tax rate for the three months ended March 31, 2019 was higher than the Irish statutory rate of 12.5%, primarily due to income taxable at a rate higher than the Irish statutory rate and unrecognized tax benefits, partially offset by originating tax credits.

Equity in Loss of Investees

Equity in loss of investees relates to our share in the loss of companies in which we have made investments accounted for under the equity method of accounting.

Liquidity and Capital Resources

As of March 31, 2019, we had cash, cash equivalents and investments of $0.8 billion, borrowing availability under our revolving credit facility of $1.6 billion and long-term debt principal balance of $1.8 billion. Our long-term debt included $642.7 million aggregate principal amount term loan, $575.0 million principal amount of our 1.875% exchangeable senior notes due 2021 and $575.0 million principal amount of our 1.50% exchangeable senior notes due 2024. We generated cash flows from operations of $202.3 million during the three months ended March 31, 2019, and we expect to continue to generate positive cash flows from operations during 2019.

We believe that our existing cash, cash equivalents and investments 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. 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 “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q under the headings “Risks Related to Xyrem and Our Other Marketed Products” 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, development, 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 amended credit agreement could be required for certain financings.

In November 2016, our board of directors authorized a new share repurchase program pursuant to which we were authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300 million, exclusive of any brokerage commissions. In November and December 2018, our board of directors increased the existing share repurchase program authorization by $320.0 million and $400.0 million, respectively, thereby increasing the total amount authorized to $1.02 billion. Under this program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. 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 the amended credit agreement, corporate and regulatory requirements and market conditions. The repurchase program may be modified, suspended or discontinued at any time without prior notice. In the three months ended March 31, 2019, we spent a total of $111.2 million to purchase 0.9 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $129.66 per share. All ordinary shares repurchased were canceled. As of March 31, 2019, the remaining amount authorized under the share repurchase program was $267.9 million.

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

	Three Months Ended March 31,	
	2019	2018
Net cash provided by operating activities	$ 202,253	$ 167,359
Net cash provided by (used in) investing activities	166,052	(52,149)
Net cash used in financing activities	(130,349)	(47,575)
Effect of exchange rates on cash and cash equivalents	(112)	(501)
Net increase in cash and cash equivalents	$ 237,844	$ 67,134

Net cash provided by operating activities of $202.3 million for the three months ended March 31, 2019 related to net income of $85.2 million, adjusted for acquired IPR&D expense of $56.0 million and non-cash items of $83.8 million primarily related to intangible asset amortization and share-based compensation expense, partially offset by a net cash outflow of $22.7 million related to changes in operating assets and liabilities. Net cash provided by operating activities of $167.4 million for the three months ended March 31, 2018 related to net income of $46.0 million, adjusted for non-cash items of $93.2 million primarily related to intangible asset amortization and share-based compensation expense and a net cash inflow of $28.2 million related to changes in operating assets and liabilities.

Net cash provided by investing activities for the three months ended March 31, 2019 primarily related to the net proceeds on maturity of investments of $230.0 million, offset by an upfront payment for acquired IPR&D of $56.0 million related to our strategic collaboration agreement with Codiak and purchases of property and equipment of $7.9 million. Net cash used in investing activities for the three months ended March 31, 2018 primarily related to the net acquisition of investments of $45.0 million and purchases of property and equipment of $7.1 million.

Net cash used in financing activities for the three months ended March 31, 2019 primarily related to repurchase of ordinary shares under our share repurchase program of $111.2 million, payment of employee withholding taxes of $13.8 million related to share-based awards and repayment of our term loan principal of $8.3 million, partially offset by proceeds from employee equity incentive and purchase plans of $3.1 million. Net cash used in financing activities for the three months ended March 31, 2018 primarily related to repurchase of ordinary shares under our share repurchase program of $34.5 million, payment of employee withholding taxes of $14.6 million related to share-based awards and repayment of our term loan principal of $9.0 million, partially offset by proceeds from employee equity incentive and purchase plans of $10.6 million.

Debt

The summary of our outstanding indebtedness under our financing arrangements is included in Note 9, Debt, of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. As of March 31, 2019, no amounts were outstanding under our revolving credit facility. During the three months ended March 31, 2019, there were no material changes to our credit agreement and the Exchangeable Senior Notes, as set forth in Note 11, Debt, of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2018.

Contractual Obligations

During the three months ended March 31, 2019, there were no material changes to our contractual obligations as set forth in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2018.

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. generally accepted accounting principles 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, 2018. Except for the operating leases and financing obligations policy that was updated as a result of adopting Accounting Standards Update No. 2016-02, "Leases", 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, 2018.

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 risk factors in greater detail under Part II, Item 1A of this Quarterly Report on Form 10-Q. 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, 2019, 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, 2018.

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, 2019.

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, 2019, 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

The information required to be set forth under this Item 1 is incorporated by reference to Note 11, Commitments and Contingencies—Other Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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.

Risks Related to Xyrem and Our Other Marketed Products

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® (sodium oxybate) oral solution is the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in adult and pediatric patients with narcolepsy. Xyrem is our largest selling product, and our financial results are significantly influenced by sales of Xyrem, which accounted for 73% of our net product sales for the three months ended March 31, 2019 and 75% of our net product sales for the year ended December 31, 2018. Our future plans assume that sales of Xyrem will increase, but there is no guarantee 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 January 2019, and there is no guarantee that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes and revenues from Xyrem.

Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties. The most important of these risks and uncertainties, any of which could have a material adverse effect on our sales of and revenue from Xyrem, are discussed in more detail in this Part II, Item 1A and include those related to:

- the introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, Xyrem in the treatment of cataplexy and/or EDS in narcolepsy, including our recently-approved product, Sunosi™ (solriamfetol);
- the introduction of a generic version of Xyrem in the U.S. market before the entry dates specified in our settlements with the abbreviated new drug application, or ANDA, filers or on terms that are different from those contemplated by the settlement agreements;
- increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, including pressure to agree to discounts, rebates or other restrictive pricing terms for Xyrem;
- changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and risk evaluation and mitigation strategy, or REMS, programs by government entities;
- changes to or uncertainties around our Xyrem REMS, or any failure to comply with our REMS obligations to the satisfaction of the FDA;
- challenges to our intellectual property around Xyrem, including the possibility of new ANDA or new drug application, or NDA, filers or new post-grant patent review proceedings;
- operational disruptions at the Xyrem central pharmacy;
- any supply or manufacturing problems, including any problems with our sole source Xyrem active pharmaceutical ingredient, or API, provider;
- continued acceptance of Xyrem by physicians and patients, including as a result of negative publicity that surfaces from time to time; and
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell 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, including on our ability to acquire, in-license or develop new products to grow our business.

The introduction of a new product in the U.S. market that competes with, or otherwise disrupts the market for, Xyrem would adversely affect sales of Xyrem.

While Xyrem is currently the only product approved by the FDA and marketed in the U.S. for the treatment of both cataplexy and EDS in patients with narcolepsy, we and others may launch products as treatment options in cataplexy and/or EDS in narcolepsy, including other branded sodium oxybate products and other new and existing branded market entrants. In addition, Xyrem will face competition from generics and authorized generics. We expect that the approval and launch of any other sodium oxybate or alternative product that treats narcolepsy, or the launch of an authorized generic product, or AG Product, or other generic version of Xyrem, could have a material adverse effect on our sales of and revenues from Xyrem and on our business, financial condition, results of operations and growth prospects.

With respect to generic and authorized generic competition, nine companies sent us notices that they filed ANDAs with the FDA seeking approval to market a generic version of Xyrem, and we filed patent lawsuits against each of them, asserting that such generic products would violate our patents covering Xyrem. As of October 2018, we have settled patent litigation with all nine companies. In our settlement with the first filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), or West-Ward, we granted West-Ward the right to sell an AG Product in the U.S. beginning on January 1, 2023, or earlier under certain circumstances. These include circumstances related to the licensing or market entry of another generic sodium oxybate product, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time. West-Ward has a right to elect to continue to sell the West-Ward AG Product for a total of up to five years. We also granted West-Ward a license to launch its own generic sodium oxybate product as early as six months after it has the right to sell the West-Ward AG Product, but if it elects to begin selling its own generic product, it cannot continue to sell the West-Ward AG Product. In our settlements with Amneal Pharmaceuticals LLC, or Amneal, Lupin Inc., or Lupin, and Par Pharmaceutical, Inc., or Par, we granted each party the right to sell a limited volume of an AG Product in the U.S. beginning on July 1, 2023, or earlier under certain circumstances, including events related to the acceleration of West-Ward's AG Product launch date, the earlier launch of another party's AG Product, the launch of another generic sodium oxybate product or a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable. We also granted each of Amneal, Lupin and Par a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including events related to the launch of another generic sodium oxybate product or a final decision that all unexpired claims of the Xyrem patents are not infringed, or are invalid and/or unenforceable. If an acceleration event occurs, then each of Amneal, Par and Lupin will have the option to elect to market its AG Product until December 31, 2025, but will not be entitled to market its AG Product and its own generic sodium oxybate product simultaneously. Under the terms of our settlement agreements, we are entitled to receive royalty and other revenue based on sales of AG Products. In our settlements with each of the other five ANDA filers, we granted each a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including the launch of another generic sodium oxybate product.

In order to launch a generic sodium oxybate product, an ANDA filer must obtain and maintain FDA approval of its ANDA. In January 2017, the FDA approved West-Ward's ANDA and tentatively approved two additional ANDAs for generic sodium oxybate products, and we believe that it is likely that the FDA will approve or tentatively approve the additional ANDAs that have been filed.

Any ANDA holder launching an AG Product or another generic sodium oxybate product will establish the price of the AG Product and/or its own generic sodium oxybate product. Generic competition often results in decreases in the prices at which branded products can be sold. After any introduction of a generic product, whether or not it is an AG Product, a significant percentage of the prescriptions written for Xyrem may be filled with the generic product. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. This would result in reduction in sales of, and revenue from, Xyrem, although we would continue to receive royalty and other revenue based on sales of an AG Product in accordance with the terms of our settlement agreements. For more information on the impact of generic competition, see the risk factors under the heading "*Adequate coverage and reimbursement from third party payors may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably*" and "*The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition"* in this Part II, Item 1A.

It is possible that additional companies may file ANDAs seeking to market a generic version of Xyrem which could lead to additional patent litigation or challenges with respect to Xyrem. Such patent litigation or challenges could potentially trigger acceleration of the launch dates in our settlement agreements. For example, the launch dates in our settlement agreements would be accelerated if a new ANDA filer were to obtain a final decision prior to January 1, 2023 that all unexpired claims of the Xyrem patents are invalid and/or unenforceable. Alternatively, the launch dates in our settlement agreements could be accelerated if a new ANDA filer were to obtain FDA approval for its sodium oxybate product, and launch its generic product

through a generic sodium oxybate REMS before the entry dates specified in our settlement agreements, if, for example, we are unable to obtain an injunction or because that party launches "at risk" of being held liable for damages for patent infringement. It is also possible that we could enter into a settlement agreement with a future ANDA filer that would permit such filer to enter the market on or prior to the launch date(s) in our settlement agreements. If a company launches a generic or authorized generic sodium oxybate product in any of these scenarios, except in limited circumstances related to an "at risk" launch, the launch date for West-Ward's AG Product would be accelerated to a date on or prior to the date of such entry, which could lead to acceleration of the other settling ANDA filers' AG Product and generic sodium oxybate product launch dates as described above. For further discussion of Xyrem-related patent matters, see the risk factors under the heading "Risks Related to Our Intellectual Property" in this Part II, Item 1A.

Another circumstance that could trigger acceleration of West-Ward's launch date for an AG Product, which would also accelerate Amneal, Lupin and Par's launch dates for their AG Products and ultimately could lead to acceleration of the other settling ANDA filers' launch dates for their generic sodium oxybate products, is a substantial reduction in Xyrem net sales. Such a reduction could occur under various circumstances, including if we introduce, or a third party introduces, a product to treat EDS or cataplexy in narcolepsy that leads to a substantial decline in Xyrem net sales prior to January 1, 2023. For example, we are developing JZP-258, an oxybate product candidate that contains 92% less sodium than Xyrem, for the treatment of cataplexy and EDS in adult patients with narcolepsy. In March 2019, we announced positive top-line results from a Phase 3 study of JZP-258, and we expect to submit an NDA for this product by as early as the end of 2019. Given the well-accepted relationship between dietary sodium and blood pressure as well as published hypertension guidelines underscoring that excessive consumption of sodium is independently associated with an increased risk of stroke, cardiovascular disease and other adverse outcomes, we believe that lower sodium intake would be beneficial for patients. Other companies may similarly develop a sodium oxybate product for treatment of narcolepsy, using an alternative formulation or a different delivery technology, and seek approval in the U.S. using an NDA approval pathway under Section 505(b)(2) and referencing the safety and efficacy data for Xyrem, which could lead to additional patent litigation or challenges. We are aware that a company called Avadel Pharmaceuticals plc, or Avadel, is conducting a Phase 3 clinical trial of a once-nightly formula of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy, and has indicated that it intends to seek approval using the Section 505(b)(2) approval pathway. Approval and successful commercialization of JZP-258, or Avadel's sodium oxybate formulation, or any other new non-generic sodium oxybate or other product for treatment of narcolepsy patients could negatively impact our ability to maintain and grow sales of Xyrem.

Although, as noted above, Xyrem is currently the only product approved by the FDA and marketed in the U.S. for the treatment of cataplexy associated with narcolepsy, we are aware that prescribers often prescribe branded or generic medications for cataplexy before prescribing or instead of prescribing Xyrem, and that payors often require patients to try such medications before they will cover Xyrem, even if they are not labeled for this use. For example, prescribers often treat mild cataplexy with drugs that have not been approved by the FDA for this indication, including tricyclic antidepressants and selective serotonin reuptake inhibitors or selective norepinephrine reuptake inhibitors. These drugs have known side effects, including for example, somnolence or insomnia, that can be problematic for patients with narcolepsy. We are also aware that branded or generic stimulants may be prescribed off label for treatment of EDS in narcolepsy. Wake-promoting agents Provigil® (modafinil) and Nuvigil® (armodafinil), and their generic equivalents are labeled for treatment of EDS in narcolepsy and other conditions, and may be used in conjunction with or instead of Xyrem. Prescribers often prescribe these medications before prescribing or instead of prescribing Xyrem, and payors often require patients to try such medications before they will cover Xyrem.

It is possible that additional branded or generic products may be introduced to treat symptoms of narcolepsy that will also be prescribed before or instead of Xyrem, or that payors will require patients to try before they will cover Xyrem. Our product, Sunosi, is an example of a new market entrant recently approved by the FDA to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, or OSA. Another example is pitolisant, a drug that has already been approved in Europe to treat adult patients with narcolepsy with or without cataplexy. Published data and prescribing patterns in the EU suggest that pitolisant would likely be appropriately used in patients with less severe cataplexy than those treated with Xyrem. While pitolisant is not currently approved in the U.S., Harmony Biosciences LLC, which has exclusive U.S. rights to seek approval of and commercialize pitolisant, has established an expanded access program for pitolisant, received Breakthrough Therapy and Fast Track designations from the FDA and, in February 2019, announced that the FDA had accepted its pitolisant NDA for filing with priority review.

Non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy, even if not directly competitive with Xyrem, could have the effect of changing treatment regimens and payor coverage of Xyrem, which could materially and adversely affect sales of Xyrem.

The distribution and sale of Xyrem are subject to significant regulatory restrictions, including the requirements of a REMS, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xyrem.

The active ingredient of Xyrem, sodium oxybate, is the sodium salt of gamma-hydroxybutyric acid, or GHB, a central nervous system depressant known to be associated with facilitated sexual assault as well as with respiratory depression and other serious side effects. As a result, the FDA requires that we maintain a REMS with elements to assure safe use, or ETASU, for Xyrem to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the serious risks of the drug. The REMS imposes extensive controls and restrictions on the sales and marketing of Xyrem that we are responsible for implementing. For example, under the Xyrem REMS, all of the Xyrem sold in the U.S. must be dispensed and shipped directly to patients or caregivers through a central pharmacy, and may not be stocked in retail pharmacies. Physicians and patients must complete an enrollment process prior to fulfillment of Xyrem prescriptions, and each physician and patient must receive materials concerning the serious risks associated with Xyrem before the physician can prescribe, or a patient can receive, the product. The central certified pharmacy must monitor and report instances of patient or prescriber behavior giving rise to a reasonable suspicion of abuse, misuse or diversion of Xyrem, and maintains enrollment and prescription monitoring information in a central database. Any failure to comply with our REMS obligations, or a determination by the FDA that the Xyrem REMS is not meeting its goals, 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 require us to invest a significant amount of resources, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

While we believe that the Xyrem REMS has met its goal of mitigating the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse and diversion of Xyrem, we cannot guarantee that the FDA will agree or that the Xyrem REMS will continue to do so in the future. We are required to prepare and submit regular assessments of the Xyrem REMS, and the FDA has stated that it will evaluate the REMS on an ongoing basis and will require modifications as may be appropriate. We cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xyrem REMS, including in connection with the submission of applications for new oxybate products, new oxybate indications, or the introduction of authorized generics, or whether the FDA will approve modifications to the Xyrem REMS that we consider warranted in connection with the submission of applications for new oxybate products. Any modifications approved, required or rejected by the FDA could change the safety profile of Xyrem, and have a significant negative impact in terms of product liability, public acceptance of Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, any of which could have a material adverse effect on our Xyrem business. Modifications approved, required or rejected by the FDA could also make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, disrupt continuity of care for Xyrem patients and/or negatively affect sales of Xyrem.

In October 2018, the FDA approved a modification to the Xyrem REMS in connection with our submission of our pediatric supplemental NDA to include information for pediatric patients and their caregivers and, in March 2019, we completed the implementation of the approved REMS modification. We have also submitted and expect to continue to submit ongoing assessments as required by the FDA. However, we cannot guarantee that the ongoing assessments will be completed on our expected timing or 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.

We depend on outside vendors, including the central certified pharmacy, to implement the requirements of the Xyrem REMS. We have an exclusive agreement with Express Scripts Specialty Distribution Services, Inc., the central pharmacy for Xyrem, which expires on July 1, 2020. The agreement may be terminated by either party at any time without cause on 180 days' prior written notice to the other party. If the central pharmacy fails to meet the requirements of the Xyrem REMS applicable to the central pharmacy or otherwise does not fulfill its contractual obligations to us, 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 or challenges in implementing REMS modifications, 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 payors 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 U.S. Drug Enforcement Administration, or DEA, and certified 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.

A generic version of a drug subject to a REMS with ETASU is required to have the same REMS as the brand drug, and generics and brands are mandated to use a single shared system REMS. 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 under certain circumstances. In its approval of West-Ward's ANDA, the FDA waived the shared REMS requirement, approving West-Ward's ANDA with a generic sodium oxybate REMS, on the condition that the generic sodium oxybate REMS be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. In connection with the waiver, FDA issued a statement that it considers the generic sodium oxybate REMS to have the same ETASU as the Xyrem REMS and operationalizes those elements in a comparable manner to achieve the same level of safety as the Xyrem REMS. However, the generic sodium oxybate REMS, unlike the Xyrem REMS, permits multiple certified pharmacies and multiple databases that are connected via an electronic "switch" system. The generic sodium oxybate REMS also requires the certified pharmacies in its system to contact the Xyrem REMS program to verify that the patient has no other active prescriptions for Xyrem that overlap with the generic prescription to be filled and to identify any patient and prescriber disenrollments from the Xyrem system for suspected abuse, misuse and diversion.

We were not involved in development of the generic sodium oxybate REMS and were not consulted regarding any features of this REMS. A sodium oxybate distribution system that is less restrictive than the Xyrem REMS, such as the generic sodium oxybate REMS, which provides that generic sodium oxybate products and potentially sodium oxybate products approved under a Section 505(b)(2) NDA approval pathway could be distributed through multiple pharmacies, could increase the risks associated with sodium oxybate distribution. Because patients, consumers and others may not differentiate generic sodium oxybate from Xyrem or differentiate between the different REMS programs, any negative outcomes, including risks to the public, caused by or otherwise related to a separate sodium oxybate REMS, could have a significant negative impact in terms of product liability, our reputation and good will, public acceptance of Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, any of which could have a material adverse effect on our Xyrem business.

We may face pressure to further modify the Xyrem REMS or to license or share intellectual property pertinent to the Xyrem REMS, including proprietary data required for the safe distribution of sodium oxybate, in connection with the FDA's approval of the generic sodium oxybate REMS or otherwise. Our settlement agreements with ANDA filers do not directly impact the FDA's waiver of the single shared system REMS requirement, any other ANDA filer's ability to develop and implement the generic sodium oxybate REMS for its generic sodium oxybate product or our ability to take any action with respect to the generic sodium oxybate REMS. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the FDA's waiver of the single shared system REMS requirement, its approval and tentative approval of generic versions of Xyrem or the consequences of distribution of sodium oxybate through the generic sodium oxybate REMS approved by the FDA or another separate REMS.

REMS programs have increasingly drawn public scrutiny from the U.S. Congress, the Federal Trade Commission, or FTC, and the FDA, with allegations that such programs are used as a means of improperly blocking or delaying competition. The U.S. Congress, for example, has introduced proposed legislation aimed at preventing companies from using REMS and other restricted distribution programs as a means to deny potential competitors access to product samples needed for bioequivalence testing. The FDA has stated that it will seek to coordinate with the FTC in identifying and publicizing practices the FTC finds to be anticompetitive and has further stated that the FDA has concerns related to the role of REMS programs in delaying approval of generic products. For example, in May 2018, FDA published a list of companies that it said had potentially been blocking access to the samples of their branded products, including one of our subsidiaries that sells FazaClo® (clozapine, USP) through a REMS program. It is possible that the FTC, the FDA, other governmental authorities or other third parties could claim that, or launch an investigation into whether, we are using our REMS programs in an anticompetitive manner or have engaged in other anticompetitive practices. The Federal Food, Drug and Cosmetic Act further states that a REMS ETASU shall not be used by an NDA holder to block or delay generic drugs or drugs covered by an application under Section 505(b)(2) from entering the market. In its 2015 letter approving the Xyrem REMS, the FDA expressed concern that we were aware that the Xyrem REMS could have the effect of blocking or delaying generic competition. We cannot predict whether we would face a government investigation or a complaint by a third party premised on a claim that the Xyrem REMS is blocking competition, or the outcome or impact of any such claim.

Pharmaceutical companies, including their agents and employees, are required to monitor adverse events occurring during the use of their products and report them to the FDA. The patient counseling and monitoring requirements of the Xyrem REMS provide more extensive information about adverse events, including deaths, than is generally available for other products that are not subject to similar REMS requirements. 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, including additional warnings or additional boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of Xyrem. As required by the FDA, Xyrem's current labeling includes a boxed warning regarding the risk of central nervous system depression and misuse and abuse.

Any failure to demonstrate our substantial compliance with the REMS or any other applicable regulatory requirements to the satisfaction of the FDA or another 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 "*In addition to those specifically described in other risk factors, 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 this Part II, Item 1A.

While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products.

In addition to Xyrem, we are commercializing a portfolio of products, including our other lead marketed products, Erwinaze, Defitelio and Vyxeos, and we are making significant investments in maximizing the value and therapeutic reach of Defitelio and Vyxeos by conducting additional research and development activities, which include generating additional supportive clinical data and seeking regulatory approval for new indications, as appropriate. Our inability to effectively commercialize our lead marketed products and to maximize their potential where possible through successful research and development activities could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Erwinaze

Erwinaze® (asparaginase *Erwinia chrysanthemi*) is 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. Erwinaze is licensed from, and manufactured by, a single source, Porton Biopharma Limited, or PBL, a company that is wholly owned by the UK Department of Health and Social Care. In February 2019, we received a contract termination notice from PBL. As a result of our receipt of the contract termination notice, our license and supply agreement with PBL, which includes our license for Erwinaze, will expire on December 31, 2020. We and PBL had been engaged in discussions related to entry into a replacement agreement to extend the term of our commercial relationship past 2020, but we did not reach agreement. Unless we and PBL enter into a new agreement, we will lose our rights to Erwinaze effective December 31, 2020, other than our right to sell certain Erwinaze inventory for a post-termination sales period of 12 months. In such event, we may not be able to replace the product sales we would lose from Erwinaze, which in 2018 totaled $174.7 million, and our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, we cannot predict whether and to what extent uncertainty related to our rights to, and availability of, Erwinaze after 2020 will negatively impact sales of and revenues from this product.

A continuing and significant challenge to our ability to maintain sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product adequate to meet market demand. PBL's product quality and manufacturing issues have resulted, and continue to result, in supply disruptions, and our need for PBL to minimize or avoid additional supply disruptions due to capacity constraints, production delays, quality or regulatory challenges and other manufacturing difficulties. In addition, we have incurred and continue to incur significant internal and external costs and expenses as a result of these issues, including due to managing the increased need for regulatory and customer interaction. See the discussion regarding Erwinaze supply issues in the risk factor under the heading "*Delays or problems in the supply of our products for sale or our for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations could materially and adversely affect our business, financial condition, results of operations and growth prospects*" in this Part II, Item 1A.

Our ability to maintain sales of Erwinaze is also subject to a number of additional challenges, including the following as well as other risks and uncertainties described elsewhere in this Part II, Item 1A:

- the limited population of patients with ALL, and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population;
- the development and/or approval of new asparaginase treatments or treatment protocols for ALL that may not include asparaginase-containing regimens and prescribers' use of alternate methods to address hypersensitivity reactions;
- the failure to obtain regulatory approval from the FDA or UK Medicines and Healthcare Products Regulatory Agency, or MHRA, to release batches of Erwinaze requiring batch-specific approval due to quality and manufacturing issues;
- difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements;
- potential competition from future biosimilar products;
- PBL's ability to meet the manufacturing post-marketing commitments imposed by the FDA in connection with its approval of our biologics license application, or BLA;
- our failure to comply with obligations under our agreement with PBL resulting in PBL claiming an uncured material breach; 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 if we decide to launch promotional efforts in those countries.

If we fail to maintain revenue from sales of Erwinaze, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

To expand our asparaginase franchise beyond Erwinaze, we are pursuing activities related to the development of improved asparaginase products for patients with ALL or other hematological malignancies. Several of our external research and development collaborations are focused on these efforts, including our agreement with Pfenex, Inc. which includes worldwide rights to develop and commercialize multiple early-stage hematology product candidates and an option to negotiate a license for a recombinant pegaspargase product candidate, and our agreement with XL-protein GmbH, or XLp, for rights to use XLp's PASylation® technology to extend the plasma half-life of selected asparaginase product candidates. If these activities are unsuccessful, our growth prospects could be materially adversely affected.

Defitelio

Defitelio® (defibrotide sodium) is a product approved in the U.S. in 2016 for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe in 2013 (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy.

Our ability to maintain and successfully and sustainably grow sales of Defitelio is subject to a number of risks and uncertainties, including the following as well as other risks and uncertainties described elsewhere in this Part II, Item 1A:

- the continued acceptance of Defitelio in the U.S., the EU and other countries by hospital pharmacy and therapeutics committees and the continued availability of favorable pricing and adequate coverage and reimbursement by government programs and third party payors;
- the limited experience of, and need to educate, physicians in recognizing, diagnosing and treating VOD, particularly in adults;
- the possibility that physicians recognizing VOD symptoms may not initiate or may delay initiation of treatment while waiting for those symptoms to improve, or may terminate treatment before the end of the recommended dosing schedule;
- our ability to successfully maintain or grow sales of Defitelio in Europe and other non-U.S. countries, including our ability to obtain marketing approval in new countries;
- 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 diagnosis);
- our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA and by the European Commission, or EC, in connection with its marketing authorization granted "under exceptional circumstances"; and
- our ability to maintain favorable pricing and reimbursement approvals across Europe, particularly in countries that represent significant markets.

To expand the potential of Defitelio, our clinical development strategy generally focuses on the prevention and treatment of serious diseases associated with endothelial cell damage, including an ongoing Phase 3 clinical trial in prevention of VOD in high-risk patients following HSCT, ongoing Phase 2 trials in prevention of acute Graft versus Host Disease following allogeneic HSCT, and planned Phase 2 trials in the treatment of transplant-associated thrombotic microangiopathy and the prevention of chimeric antigen receptor T-cell therapy-, or CAR-T-, associated neurotoxicity. In addition to clinical trials we are sponsoring, there are more than 20 investigator-sponsored trials ongoing in the U.S. and EU to evaluate defibrotide in multiple conditions. If these development activities are unsuccessful, our growth prospects could be materially adversely affected.

Because VOD is an ultra-rare disease, we have experienced inter-quarter variability in our Defitelio sales, which makes Defitelio sales difficult to predict from period to period. As a result, Defitelio sales results or trends in any period may not necessarily be indicative of future performance. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Vyxeos

Vyxeos® (daunorubicin and cytarabine) liposome for injection is a product approved in the U.S. in 2017 and in Europe in August 2018 (where it is marketed as Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or t-AML, or acute myeloid leukemia, or AML, with myelodysplasia-related changes, or AML-MRC. We made a significant investment in Vyxeos through the acquisition of Celator Pharmaceuticals, Inc. in 2017. Our ability to realize the anticipated benefits from our investment in

Vyxeos by successfully and sustainably growing sales is subject to a number of risks and uncertainties, including the following as well as other risks and uncertainties described elsewhere in this Part II, Item 1A:

- our ability to differentiate Vyxeos from other liposomal chemotherapies and generically available chemotherapy combinations with which physicians and treatment centers are more familiar;
- the acceptance of Vyxeos in the U.S., the EU and other countries by hospital pharmacy and therapeutics committees and the availability of favorable pricing and adequate coverage and reimbursement by government programs and third party payors;
- delays or problems in the supply or manufacture of the product, including the ability of the third parties upon which we rely to manufacture Vyxeos and its APIs to manufacture sufficient quantities in accordance with applicable specifications;
- the increasing complexity of the AML landscape requiring changes in patient identification and treatment selection, including diagnostic tests and monitoring that clinicians may find challenging to incorporate;
- the use of new and novel compounds in AML that are either used off-label or are only approved for use in combination with other agents and that have not been tested in combination with Vyxeos;
- the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos, particularly given the ongoing clinical trials by other companies with the same patient population; and
- our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA and by the EC in connection with its marketing authorization.

The lack of prescriber usage data from U.S. commercialization of Vyxeos makes Vyxeos sales difficult to predict from period to period, and sales results or trends in any period may not necessarily be indicative of future performance. Following receipt of marketing authorization from the EC in late 2018, as part of our rolling launch of Vyxeos in the EU, we are in the process of making pricing and reimbursement submissions. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement, planned launches in the affected EU member states would be delayed, which could negatively impact anticipated revenue.

To expand the potential of Vyxeos, our clinical development strategy is designed to target potential new patient segments across the AML landscape, to pursue indications related to myelodysplastic syndrome and to generate clinical data on Vyxeos when used in combination with other therapeutic agents. We are pursuing this strategy by sponsoring clinical trials, working with cooperative groups who are conducting clinical trials and partnering with The University of Texas MD Anderson Cancer Center to evaluate potential treatment options for hematologic malignancies, with a near-term focus on Vyxeos. In addition, there are multiple investigator-sponsored trials ongoing. Because combination regimens and the continual generation of new data have become particularly important in AML, if we are unable to initiate multiple combination studies, safely combine Vyxeos with novel agents, or if efficacy results do not meet clinicians' expectations, our growth prospects could be materially adversely affected.

If sales of Vyxeos 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 a discussion of the risks inherent in implementing our research and clinical development strategy with respect to Defitelio and Vyxeos, see the discussion in the risk factor under the heading "*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*" in this Part II, Item 1A.

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

Our products compete, and our product candidates may in the future compete, with currently existing therapies, product candidates currently under development by others and/or future product candidates, including new chemical entities that may turn out to be safer or more effective than our products. Any products that we develop may be commercialized in competitive markets, and our competitors, which include large global pharmaceutical companies and small research-based companies and institutions, may succeed in developing products that render our products obsolete or noncompetitive.

We also face competition, and may in the future face additional competition, from manufacturers of generic drugs. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. Generic competition often results in decreases in the prices at which branded products can be sold.

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.

For a discussion of specific risks relating to the launch of new products that treat cataplexy and/or EDS in narcolepsy, including generic versions of Xyrem or other sodium oxybate products, see the risk factor under the heading "*The introduction of a new product in the U.S. market that competes with, or otherwise disrupts the market for, Xyrem would adversely affect sales of Xyrem*" in this Part II, Item 1A. We expect that the approval and launch of any other sodium oxybate or alternative product that treats narcolepsy, or the launch of an AG Product or other generic version of Xyrem, could have a material adverse effect on our sales of and revenues from Xyrem and on our business, financial condition, results of operations and growth prospects.

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. Some new asparaginase treatments could reduce the rate of hypersensitivity in patients with ALL, and new treatment protocols are being developed and approved for ALL that may not include asparaginase-containing regimens, including some for the treatment of relapsed or refractory ALL patients. We have experienced frequent intermittent shortages of the product that have impacted prescribing habits for Erwinaze, including prescribers' use of alternate methods to address hypersensitivity reactions. The development of these new treatments could negatively impact our ability to maintain, and potentially in the future grow, sales of Erwinaze in patient populations where the benefit of an asparaginase-containing regimen is not well established. As a biologic product, Erwinaze also faces potential competition from biosimilar products.

While there is currently no direct competition to Defitelio to treat severe VOD, changes in the types of conditioning regimens used as part of HSCT may affect the incidence rate of VOD and demand for Defitelio.

With respect to Vyxeos, there are a number of alternative established therapies in AML. A key consideration in the treatment of AML patients is the patient's suitability for chemotherapy. The AML patient population studied in the Vyxeos Phase 3 clinical trial supporting our NDA included fit patients, or those deemed able to tolerate intensive induction chemotherapy. The existing options for the treatment of newly-diagnosed t-AML and AML-MRC in fit patients include cytarabine in combination with an anthracycline (i.e., daunorubicin), known as 7+3. In addition, we are aware of several other products that have been recently approved by the FDA or are in development as treatment options for newly diagnosed AML patients eligible for intensive chemotherapy, such as targeted agents (e.g. midostaurin, enasidenib and ivosidenib), immunotherapies (e.g., gemtuzumab ozogamicin and CAR-T-cell therapy), and agents disrupting leukemia cell survival (e.g., glasdegib). We are also aware of the increasing use of venetoclax, an AML treatment recently approved by the FDA. Some of the patient populations being studied for, or treated by, these products overlap with the patient population studied in the Vyxeos Phase 3 clinical trial supporting our NDA. The existence of established treatment options and the development of competing products for the treatment of newly-diagnosed t-AML or AML-MRC could negatively impact our ability to successfully commercialize Vyxeos and achieve the level of sales we expect.

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 and marketing activities. As a result, our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we can 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.

We have a relatively small number of sales representatives compared with most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. Many of our competitors deploy more personnel to market and sell their products than we do. In particular, we compete with companies with extensive sales, marketing and promotional experience in hematology/oncology markets, and our failure to compete effectively in this area could negatively affect sales of our hematology/oncology products. If our sales force and sales support organization are not appropriately resourced and sized to adequately promote our products, the commercial potential of our current and any future products may be diminished.

The 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 such growth. We may not be able to expand in a timely or cost-effective manner, or we may not have the financial resources to achieve the necessary growth. We also compete with other companies to recruit, hire, train and retain pharmaceutical sales and marketing personnel, and excessive turnover in such personnel could negatively affect sales of our products.

Adequate coverage and reimbursement from third party payors 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 successfully commercialize and achieve market acceptance of our products depends in significant part on adequate financial coverage and reimbursement from third party payors. Third party payors include governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health insurers. Without third party payor support, patients may not be able to obtain prescribed medications due to barriers to access, including the inability to afford the medication.

Third party payors' reimbursement practices are complex, vary widely from payor to payor and can impose time-consuming burdens for patients and prescribing physicians. As part of the overall trend toward cost containment, third party payors often require prior authorization for, and require reauthorization for continuation of, prescription products or impose step edits, which require prior use of another medication, usually a generic or preferred brand, prior to approving coverage for a new or more expensive product. Such restrictive conditions for reimbursement and an increase in reimbursement-related activities can extend the time required to fill prescriptions and may discourage patients from seeking treatment. For example, we are experiencing increasingly restrictive conditions for reimbursement required by some third party payors for Xyrem, which have extended the time required to fill some prescriptions and could continue to do so in the future and which may have a material effect on the overall level of reimbursement coverage for Xyrem. We cannot predict actions that third party payors may take, or whether they will limit the access and level of reimbursement for our products or refuse to provide any approvals or coverage. From time to time, third party payors have refused to provide reimbursement for our products, and others may do so in the future.

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 inpatient hospital services provided under Medicare, which some states also use for Medicaid. The MS-DRG system entitles a hospital 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 hematology/oncology products, all of which are used primarily or exclusively in the inpatient hospital setting, there may not be sufficient reimbursement under the relevant MS-DRG to fully cover the cost of our products. In addition, in 2017 CMS approved, and reauthorized for 2018 and 2019, a New Technology Add-on Payment, or NTAP, for Defitelio. For 2019, CMS approved an NTAP for Vyxeos. An NTAP is in addition to the MS-DRG-based reimbursement that hospitals receive. NTAP designations are reviewed by CMS on a yearly basis, and we cannot guarantee that CMS will continue the NTAP designation. If the NTAPs for Vyxeos or Defitelio are not renewed, the relevant MS-DRG may not fully cover the cost of our products.

In addition, a significant portion of our revenue from our hematology/oncology products, particularly Erwinaze and Vyxeos, is obtained through government payors, including Medicare, Medicaid and similar types of payors in other countries, and any failure to qualify for or receive adequate reimbursement under those programs, including as a result of legislative changes to these programs, would have a material adverse effect on revenues from such products. Significant 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 affected 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.

On February 6, 2019, the U.S. Department of Health and Human Services, or HHS, published a proposed rule in the Federal Register proposing to modify the scope of the discount safe harbor to carve out many discounts or rebates provided to pharmacy benefit managers, known as PBMs, which are tasked with administering prescription drug programs for large employers, health plans and government programs for patients receiving benefits under Medicare Part D or a managed Medicaid plan, as well as discounts or rebates paid to the sponsors of such prescription drug plans. While the potential impact of such a rule is still unclear, the potential disruption to the marketplace could have the practical effect of limiting our ability, in some instances, to effectively negotiate with PBMs or prescription drug plans for access to our products for patients. Medicaid and other governmental programs are described under the heading "Business—Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2018. For a discussion of specific risks relating to our reporting and payment obligations to government payors, see 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 this Part II, Item 1A. Third party payors outside the federal government are also increasingly considering new metrics as the basis for reimbursement rates, including those used by federal government payors

such as average net sales price, average manufacturer price and actual acquisition cost. It is not possible to predict the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

Third party payors increasingly examine the cost effectiveness of pharmaceutical products, in addition to their safety and efficacy, when making coverage and reimbursement decisions. 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 coverage and reimbursement for our products. If our competitors offer their products at prices that provide lower treatment costs than our products, or otherwise suggest that their products are safer, more effective or more cost-effective than our products, this may result in a greater level of access for their products relative to our products, which would reduce our sales and harm our results of operations. 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. Because some of our products compete in a market with both branded and generic products, obtaining and maintaining access and reimbursement coverage for our products may be more challenging than for products that are new chemical entities for which no therapeutic alternatives exist.

A small number of third party payors and PBMs have market power and negotiating leverage to limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, and to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, or place drugs on formulary tiers with higher patient co-pay obligations, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. In many instances, third party payors and PBMs may also exert negotiating leverage by requiring incremental rebates from manufacturers in order to maintain their formulary position. In the past, we have not entered into such arrangements with third party payors for any of our products. The increasing pressure of the pharmaceutical coverage environment may require us, or we may decide, to do so in the future, which could have a negative impact on our revenue from Xyrem.

Specifically, we are experiencing increasing pressure from third party payors to agree to discounts, rebates or other restrictive pricing terms for Xyrem. As our business becomes more complex, we may decide to enter into rebate agreements in order to ensure that patients continue to have access to Xyrem, and to support the long-term success of our sleep franchise, which might result in lower net revenues for Xyrem.

Sunosi (solriamfetol), which was approved by the FDA in March 2019 to improve wakefulness in adults with EDS associated with narcolepsy or OSA and is pending DEA scheduling, will enter a competitive retail pharmacy market of branded and generic products. Any delays or unforeseen difficulties in obtaining access or reimbursement approvals could delay or prevent our commercial launch and our ability to receive a return on our investment in Sunosi. Third party payors could impose steps edits that require patients to try alternative, including generic, treatments before authorizing payment for Sunosi, exclude Sunosi from formulary coverage lists, limit the types of diagnoses for which coverage will be provided or demand rebates, discounts, exclusivity or other concessions for Sunosi and potentially our other products. Additionally, at launch, many payors impose a moratorium on coverage for products while the payor makes a coverage decision. These potential utilization management strategies could limit patient access to Sunosi and depress therapy adherence rates. We cannot predict market acceptance of, and our ability to obtain adequate formulary positions, access to and reimbursement coverage for Sunosi. An inability to obtain adequate formulary positions could increase patient cost-sharing for Sunosi and cause some patients to determine not to use our product. If we are unsuccessful in obtaining broad coverage for Sunosi, our anticipated revenue from and growth prospects for Sunosi could be negatively affected.

In addition, new products indicated for the treatment of symptoms of narcolepsy, like pitolisant (if approved by the FDA) and Sunosi, could impact access to Xyrem, particularly for newly diagnosed narcolepsy patients, if, for example, payors impose a step edit requiring a narcolepsy patient to try Sunosi before authorizing payment for Xyrem. For more information on Sunosi, see the risk factor under the heading "*Our future success depends on our ability to successfully develop and obtain and maintain regulatory approval in the U.S. and Europe for our late-stage product candidates and, if approved, to successfully launch and commercialize those product candidates.*" in this Part II, Item 1A.

The demand for, and the profitability of, our products could be materially harmed if the Medicaid program, Medicare program or other third party payors in the U.S. or elsewhere deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms. We are unable to predict what additional legislation, regulations or policies, if any, relating to third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business.

The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. 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. The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, together, the Healthcare Reform Act, has substantially changed the way healthcare is financed by both governmental and private insurers. These changes have impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment-for-performance initiatives. Some of the provisions of the Healthcare Reform Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges, including pending litigation in which several states and the Trump Administration have taken the position that the Healthcare Reform Act in its entirety is invalid. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Healthcare Reform Act and to alter the implementation of the Healthcare Reform Act and related laws. Additional legislative and regulatory changes and judicial challenges related to the Healthcare Reform Act remain possible. For example, while "repeal and replace" efforts by the Trump Administration and the U.S. Congress have failed, aspects of the Healthcare Reform Act have been changed legislatively, such as the repeal of the requirement that certain individuals who fail to maintain qualifying health coverage for all or part of a year make a tax-based shared responsibility payment commonly referred to as the "individual mandate." In addition, there have been delays in the implementation of key provisions of the Healthcare Reform Act, including the excise tax on generous employer-based health plans. We expect that the Healthcare Reform Act and its implementation, efforts to repeal or replace, or invalidate, the Healthcare Reform Act or portions thereof 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 products.

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 our revenues. For details of the changes to the Medicaid Drug Rebate program and the Public Health Service's 340B program, or the 340B program, see "Business—Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2018 and 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 this Part II, Item 1A. The U.S. 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.

In addition to the Healthcare Reform Act, we anticipate that the U.S. Congress, state legislatures, regulators and the private sector will continue to consider and may adopt healthcare policies and reforms intended to curb healthcare costs. These cost containment measures may include federal and state controls on government-funded reimbursement for drugs, new or increased requirements to pay prescription drug rebates to government health care programs, additional pharmaceutical cost transparency bills that aim to require drug companies to justify their prices through required disclosures, 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, 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, several states have passed laws or are considering legislation aimed at increasing transparency relating to drug pricing, and other states may do so in the future.

There also continue to be legislative proposals to amend U.S. laws to allow the importation into the U.S. of prescription drugs, which have not been subject to U.S. regulatory oversight. The potential importation of such prescription drugs could pose significant safety concerns for patients, increase the risk of counterfeit products becoming available in the market, and have a negative impact on prescription drug prices in the U.S.

There is increasing bipartisan support within the U.S. Congress, and continuing support by the Trump Administration, for drug pricing reform-related policies. Any specific reforms that may be enacted or implemented remain uncertain, both as to their substance and timing, and may affect a broad range of public policy considerations, including the Medicare and Medicaid programs and the FDA regulatory regime. In addition, heightened scrutiny of drug pricing-related issues by the U.S. Congress,

the Trump Administration, the media and other stakeholders is expected. All such considerations may adversely affect our business in ways that we cannot accurately predict.

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 affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. We have periodically increased the price of Xyrem, most recently in January 2019, 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. There is no guarantee that such price adjustments will not negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our products, which could limit the prices that we charge for our products, including Xyrem, limit the commercial opportunities for our products and/or negatively impact revenues from sales of our products.

If we become the subject of any future government investigation or U.S. Congressional hearing with respect to drug pricing or other business practices, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. Any such investigation or hearing could also 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. For more information, see the risk factor under the heading "*In addition to those specifically described in other risk factors, 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 this Part II, Item 1A.

In many countries outside the U.S., procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing approval. The process of maintaining pricing and reimbursement approvals is complex and varies from country to country. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. We cannot predict the outcome of any periodic reviews required to maintain pricing and reimbursement approvals across Europe. In addition, orphan products that have a 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 maintain favorable pricing and reimbursement approvals across Europe. 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 we are unable to maintain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected.

In August 2018, the EC granted marketing authorization for Vyxeos, and, as part of our rolling launch of Vyxeos in the EU, we are in the process of making pricing and reimbursement submissions in EU member states. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected EU member states would be delayed, which could negatively impact anticipated revenue from Vyxeos. If we are unable to obtain favorable pricing and reimbursement approvals in the EU member states that represent significant potential markets, our anticipated revenue from and growth prospects for Vyxeos in the EU could be negatively affected.

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. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including those representing the larger markets. 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. 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 currently varies between EU member states, although a recently proposed EU regulation governing HTA procedures may lead to harmonization.

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.

We expect that legislators, policymakers and healthcare insurance funds in the EU will continue to propose and implement cost-containing measures to keep healthcare costs down. Such measures could include limitations on the prices we

will be able to charge for our products or the amounts of reimbursement available for these products from governmental authorities or third party payors, may increase the tax obligations on pharmaceutical companies, 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. 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. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted, could negatively affect our growth prospects in Europe.

In addition to access, coverage and reimbursement, the commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.

If physicians do not prescribe our products, we cannot generate the revenues we anticipate from product sales. Market acceptance of each of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved and any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and its diagnosis;
- the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand, particularly with respect to Erwinaze;
- physicians' decisions relating to treatment practices based on availability of product, particularly with respect to Erwinaze;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- with respect to Xyrem, 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; and
- the availability of financial or other assistance for patients who are uninsured or underinsured.

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 GHB and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the API 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.

For additional discussion about payor acceptance, see the risk factor under the heading "*Adequate coverage and reimbursement from third party payors may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably*" in this Part II, Item 1A.

Delays or problems in the supply of our products for sale or for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations 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 API and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. We and our suppliers may 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. In addition, we and our suppliers are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and equivalent rules and regulations prescribed by non-U.S. regulatory authorities. We have cGMP responsibilities for the products we manufacture in our facilities and also have oversight responsibilities for the manufacturing conducted by our third party suppliers operating under contract. If we or any of our suppliers encounter manufacturing, quality or compliance difficulties with respect to any of our products, we may be unable to obtain or maintain regulatory approval or meet commercial demand for such products, which could adversely affect our business, financial condition, results of operations and growth prospects. In addition, the failure of any of our suppliers to

comply with cGMP or other rules and regulations while manufacturing products on our behalf could result in regulatory action directed at the adequacy of our oversight of our contract suppliers, which could result in enforcement actions against us by the FDA and other regulatory entities.

We have a manufacturing and development facility in Ireland where we manufacture Xyrem and development-stage oxybate products, including JZP-258, and a manufacturing plant in Italy where we produce the defibrotide drug substance. We currently do not have our own commercial manufacturing or packaging capability for our other products, product candidates or their APIs. As a result, our ability to develop and supply products in a timely and competitive manner depends primarily on third party suppliers being able to meet our ongoing commercial and clinical trial needs for API, other raw materials, packaging materials and finished products. For details of our arrangements with our suppliers, see "Business—Manufacturing" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2018.

In part due to the limited market size for our products and product candidates, we have a single source of supply for most of our marketed products, product candidates and their APIs. We are the sole supplier of the defibrotide compound. We have a single source for sodium oxybate, the API for Xyrem, for Erwinaze, for the finished vial form of Defitelio and for Vyxeos. Single sourcing puts us at risk of interruption in supply in the event of manufacturing, quality or compliance difficulties. There is no guarantee that our suppliers can or will continue to supply on a timely basis, or at all, the quantities of API or finished product that we need. 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 implement and execute the necessary technology transfer to, and 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 API 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 APIs 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 meet FDA's 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, which could negatively impact our anticipated revenues 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.

Erwinaze is licensed from, and manufactured for us by, a single source, PBL. The Erwinaze BLA includes a number of post-marketing commitments related to the manufacture of Erwinaze by PBL.

In January 2017, the FDA issued a warning letter to PBL indicating that it was not satisfied with PBL's response to the FDA Form 483 issued to PBL in March 2016 and citing significant violations of cGMP for finished pharmaceuticals and significant deviations from cGMP for APIs. In March 2017, PBL filed a response to the warning letter with the FDA. In August 2018, the FDA conducted an inspection of the PBL manufacturing facility and issued an FDA Form 483 to PBL citing observations related to items referenced in the warning letter as well as other manufacturing practices, including data and records management. PBL continues to address the issues identified by the FDA in the warning letter and has submitted its response to the August 2018 Form 483.

In the United Kingdom, or UK, where PBL's manufacturing facilities are located, PBL is subject to similar inspections conducted by the MHRA. Following a site inspection of PBL by MHRA in December 2017, MHRA issued an inspection report listing several major findings, including major deficiencies and failures by PBL to comply with cGMP. In January 2018, PBL filed a response to the report with the MHRA.

Inability to comply with regulatory requirements of the FDA, the MHRA or other competent authorities in the EU member states in which Erwinaze is subject to marketing authorization, including any failure by PBL to correct the violations and deviations referenced above to the satisfaction of the FDA and MHRA, could further adversely affect Erwinaze supply, particularly in light of the ongoing limited supply of Erwinaze, and could result in enforcement actions by the FDA, MHRA or other EU member states' competent authorities (including the issuance of the local equivalents of FDA Form 483s or warning letters), the approval of the FDA or other competent authorities being suspended, varied, or revoked, product release being delayed or suspended, including potentially the FDA refusing admission of Erwinaze in the U.S., or product being seized or recalled. Any of these actions could have a material adverse effect on our sales of, and revenues from, Erwinaze and further limit our future maintenance and potential growth of the market for this product. We have incurred and continue to incur significant internal and external costs and expenses as a result of these issues, including due to managing the increased need for regulatory and customer interaction. 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 PBL may increase its price to supply Erwinaze meeting such specifications, which may result in additional costs to us or a delay in supply and may decrease any profit we would otherwise achieve with Erwinaze.

All Erwinaze that PBL has been able to supply is currently completely absorbed by demand for the product. As a consequence, there is no product inventory that can be used to absorb supply disruptions resulting from quality, manufacturing, regulatory or other issues. PBL has experienced and continues to experience product quality and manufacturing issues that have resulted, and continue to result, in disruptions in our ability to supply markets from time to time and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. We cannot predict whether the required remediation activities by PBL in connection with its January 2017 FDA warning letter, the December 2017 MHRA report or the August 2018 FDA Form 483 will further strain PBL's manufacturing capacity or otherwise further adversely affect Erwinaze supply. As capacity constraints and supply disruptions continue, whether as a result of continued quality or manufacturing challenges at PBL, regulatory issues or otherwise, we will be unable to build product inventory, our ability to supply the market will continue to be compromised and physicians' decisions to use Erwinaze will continue to be negatively impacted.

If PBL's quality, manufacturing or regulatory issues persist and supply disruptions continue, our agreement with PBL, which will expire on December 31, 2020, only gives us the right to engage a backup supplier for Erwinaze in very limited circumstances, such as following termination of the agreement by us due to 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 disruption in manufacturing or exacerbate the supply shortage. In addition, if our contract is not extended, there would not be sufficient time for us to engage a backup or alternative supplier before the contract expires at the end of 2020. If we continue to fail to obtain a sufficient supply of Erwinaze from PBL, our sales of and revenues from Erwinaze, our future maintenance and potential growth of the market for this product, our reputation and our business, financial condition, results of operations and growth prospects would continue to be materially adversely affected.

The API 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.

Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location. Given that our Vyxeos launch is still at a relatively early stage, there is limited experience with the complex manufacturing process relating to Vyxeos. Baxter manufactured batches that were used in the Phase 3 clinical trial for Vyxeos; there have since been batch failures due to mechanical, component and other issues, and batches have been produced that have otherwise not been in compliance with applicable specifications. We are continuing to work with Baxter to address manufacturing complexities. Moreover, the proprietary technology that supports the manufacture of Vyxeos is not easily transferable. Consequently, engaging an alternate manufacturer may be difficult, costly and time-consuming. If we fail to obtain a sufficient supply of Vyxeos in accordance with applicable specifications on a timely basis for any reason or due to manufacturing or regulatory challenges, our sales of and revenues from Vyxeos, our future maintenance and potential growth of the market for this product, our ability to conduct ongoing and future clinical trials of Vyxeos, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

In addition, while the APIs in Vyxeos, daunorubicin and cytarabine are available from a number of suppliers, certain suppliers have received warning letters from the FDA. As a result, we have qualified other suppliers for each API, and we provided the qualification data to the FDA. If the FDA restricts importation of API from either supplier, and we are unable to qualify API from additional suppliers in a timely manner, or at all, our ability to successfully commercialize Vyxeos and generate sales of this product at the level we expect and to conduct ongoing and future clinical trials of Vyxeos could be materially and adversely affected.

To conduct our ongoing and any future clinical trials of, complete marketing authorization submissions for, and potentially launch our other product candidates, we need to have sufficient quantities of product manufactured. For example, Siegfried USA, LLC, or Siegfried, is currently our sole supplier of both the API and finished product for our development activities involving Sunosi, and we expect that Siegfried will manufacture and supply Sunosi for commercial sale. If Siegfried does not or is not able to supply us with Sunosi for any reason, it may take time and resources to implement and execute the necessary technology transfer to another provider, and such delay could negatively impact our anticipated revenues from Sunosi.

We or our suppliers may not be able to produce sufficient supplies of our product candidates in a timely manner or in accordance with applicable specifications. If any of our suppliers 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. In addition, to obtain FDA approval of any product candidate, we or our supplier or suppliers for that product must obtain approval by the FDA to manufacture and supply product, in some cases based on qualification data provided to the FDA as part of our NDA submission. Any delay in generating, or failure to generate, data required in connection with submission of the chemistry, manufacturing and controls, or CMC, portions of any NDA could negatively impact our ability to meet our anticipated submission dates, and therefore our anticipated timing for obtaining FDA approval, or our ability to obtain FDA approval at all.

In addition, any failure of us or a supplier to obtain approval by the FDA to manufacture and supply product or any delay in receiving, or failure to receive, adequate supplies of a product on a timely basis or in accordance with applicable specifications could negatively impact our ability to successfully launch and commercialize products and generate sales of products at the levels we expect.

Our manufacturing facilities and manufacturing facilities of our suppliers have been and are subject to periodic unannounced inspection by the FDA, the European Medicines Agency, or 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, recordkeeping 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.

Risks Related to Growth of Our Product Portfolio and Research and Development

Our future success depends on our ability to successfully develop and obtain and maintain regulatory approval in the U.S. and Europe for our late-stage product candidates and, if approved, to successfully launch and commercialize those product candidates.

In furtherance of our growth strategy, we have made and are making significant investments in a number of product candidates, including Sunosi and JZP-258. Our inability to obtain and maintain regulatory approval for our product candidates in the U.S. and Europe, and, if approved, to successfully commercialize new products would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Sunosi (solriamfetol)

In March 2019, we received FDA approval for Sunosi as a treatment to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA. Upon its anticipated launch in the U.S. after DEA scheduling, Sunosi will face competition from existing and future products that treat EDS or improve wakefulness in adult patients with narcolepsy or OSA in a competitive retail pharmacy market of branded and generic products. In particular, we will need to successfully differentiate Sunosi from other branded and generic products that treat EDS in patients with narcolepsy with which physicians are more familiar, including stimulants, wake-promoting agents, such as Provigil and Nuvigil, and generic versions of stimulants and wake-promoting agents. We are also aware that stimulants are prescribed for patients to treat excessive sleepiness in OSA. Sunosi will likely face competition from this genericized market. In addition, we are aware of several other products in development as potential treatments for excessive daytime sleepiness in patients with narcolepsy or OSA, including, for example, pitolisant, mazindol, modafinil combinations and Avadel's once-nightly sodium oxybate formulation.

We submitted a marketing authorization application, or MAA, for solriamfetol to the EMA in the fourth quarter of 2018. We cannot predict whether our MAA will be approved in a timely manner, or at all. If we fail to obtain approval for solriamfetol in the EU, or if the EC requires product labeling that negatively impacts patient, physician or payor acceptance of the product, our growth prospects could be materially adversely affected.

In addition to challenges and uncertainties related to Sunosi competition and obtaining regulatory approval of solriamfetol in the EU, our ability to realize the anticipated benefits from our investment in Sunosi is subject to a number of risks and uncertainties, including the following as well as other risks and uncertainties described elsewhere in this Part II, Item 1A:

- our ability to successfully launch and grow sales of Sunosi in the U.S. and, if approved, in the EU;
- any delay in U.S. launch timing due to longer than expected DEA scheduling review, which needs to be completed before commercial launch in the U.S.;
- the availability of adequate formulary positions and pricing and adequate coverage and reimbursement by third party payors, including government programs, including the impact of any delays in coverage decisions by payors;
- restrictions on permitted promotional activities based on limitations on the approved labeling for the product required by the FDA or the EC;
- market acceptance of Sunosi;
- delays or problems in the supply or manufacture of Sunosi; and

- our ability to satisfy the FDA's post-marketing requirements and other post-marketing requirements or commitments, if any, imposed by the EC in connection with its potential marketing authorization.

If we are unable to successfully launch and commercialize Sunosi in the U.S., if we are unable to obtain approval of our solriamfetol MAA in a timely manner, or at all, if the EC requires product labeling that negatively impacts patient, physician or payor acceptance of the product, or if sales of Sunosi in the U.S. and EU (if approved) do not reach the levels we expect, our anticipated revenue from Sunosi will be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

JZP-258

JZP-258 is an oxybate product candidate that contains 92% less sodium than Xyrem. Given the well-accepted relationship between dietary sodium and blood pressure as well as published hypertension guidelines, we believe that lower sodium intake would be beneficial for patients. On March 26, 2019, we announced positive top-line results from our Phase 3 study evaluating the efficacy and safety of JZP-258 for the treatment of cataplexy and EDS in adult patients with narcolepsy, and we expect to submit an NDA for this product by as early as the end of 2019. Although we received positive results from that Phase 3 study, we cannot guarantee the timing or acceptance of our planned NDA by the FDA. We are also conducting a Phase 3 clinical trial for the treatment of idiopathic hypersomnia, a chronic neurological disorder that is primarily characterized by EDS. Any failure or delay in successfully completing necessary clinical trials and conducting other activities, including CMC activities, that are required to complete our planned NDA submission and obtain regulatory approval could materially and adversely affect our growth prospects. If we submit an NDA to the FDA for approval and the FDA determines that our safety or efficacy data do not warrant marketing approval, we may be required to conduct additional clinical trials, which could be costly and time-consuming, or we may not be able to commercialize JZP-258, in which event we would not receive any return on our investment.

Avadel has announced that it has obtained an orphan drug designation from the FDA for its once-nightly sodium oxybate formulation for the treatment of EDS and cataplexy in patients with narcolepsy. To obtain orphan drug exclusivity upon approval, Avadel will have to show clinical superiority to Xyrem, or, if applicable, clinical superiority to JZP-258. However, if the FDA approves Avadel's product and grants it orphan drug exclusivity before we obtain approval for JZP-258, there is a risk that JZP-258 will not be approvable for seven years unless it can establish clinical superiority to Avadel's product. We cannot predict the timing of the two submissions or how FDA will evaluate any clinical superiority arguments that either company may make, but a delay in our ability to obtain approval for JZP-258, if at all, could be detrimental to our business.

For a discussion of the risks inherent in product development and regulatory approval, see the discussions in the risk factors under the headings "*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*" and "*The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or our partners from obtaining and maintaining approvals for the commercialization of some or all of our product candidates"* in this Part II, Item 1A. If we are not successful in the clinical development of our product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be able to successfully identify and acquire or in-license additional products or product candidates to grow our business, and, even if we are able to do so, we may otherwise fail to realize the anticipated benefits of these acquisitions.

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, additional products and product candidates that we believe are highly differentiated and 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, sales and marketing 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.

Even if we are able to successfully identify and acquire, in-license or develop additional products or product candidates, we may not be able to successfully manage the risks associated with integrating any products or product candidates into our portfolio 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 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 an acquired 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 or for any other reason;
- 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 to identify and manage these risks and uncertainties effectively could 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 or otherwise manage an 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. 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.

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 in animal models, may not predict the results of human clinical trials. Similarly, results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and later clinical trials may fail to show the desired safety and efficacy of our product candidates despite successful initial clinical testing. Even if we believe we have successfully completed testing, 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. If a product candidate fails at any stage of development or the data is otherwise not sufficient for regulatory approval, we will not be able to commercialize it and receive any return on our investment in that product candidate.

If the FDA determines that the safety or efficacy data we submit in our planned NDA for JZP-258 do not warrant marketing approval, we may be required to conduct additional clinical trials, which could be costly and time-consuming, or we may not be able to commercialize JZP-258, in which event we would not receive any return on our investment in this product candidate. The FDA may also require product labeling that negatively impacts patient, physician or payor acceptance of the product. For more information, see the risk factor under the heading "*Our future success depends on our ability to successfully*

develop and obtain and maintain regulatory approval in the U.S. and Europe for our late-stage product candidates and, if approved, to successfully launch and commercialize those product candidates" in this Part I, Item 1A.

Any adverse events or other data generated during the course of clinical trials of our product candidates and/or clinical trials related to additional indications for our commercialized 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 data could otherwise have a material adverse effect on a related commercial product, including with respect to its safety profile. Any failure or delay in completing such clinical trials 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:

- difficulty identifying or enrolling eligible patients, often based on the number of clinical trials, particularly in hematology and oncology, with enrollment criteria targeting the same patient population;
- 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, known as an ethics committee 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' requirements, commonly referred to as good clinical practices;
- unforeseen safety issues;
- 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 contract research organizations and other third parties, such as cooperative groups, to assist us in designing, coordinating, managing, monitoring and otherwise conducting clinical trials with our product candidates. If we, contract research organizations assisting us with clinical trials, other third parties conducting clinical trials with our product candidates, or our trial sites fail to comply with applicable good clinical practices, the clinical data generated in these clinical trials may be deemed unreliable, and the FDA and/or other global regulatory agencies may require us to perform additional clinical trials before approving our marketing applications. In addition, clinical trials must be conducted with product candidates 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 completion of clinical trials and the regulatory approval process.

If third parties do not successfully carry out their contractual 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 generate additional clinical data in support of these products.

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

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. 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.

Although the Prescription Drug User Fee Act, or PDUFA, provides a ten-month deadline for the FDA to review an NDA, or a six-month deadline for priority review, there is no guarantee that the FDA will meet that deadline, and the FDA can extend

a PDUFA action date under certain circumstances. If the FDA fails to meet PDUFA targeted action dates established for any of our product candidates, the commercialization of the affected product candidate could be delayed or impaired.

We submitted an MAA to the EMA in November 2018 for solriamfetol as a treatment to improve wakefulness and reduce EDS in adult patients with narcolepsy (with or without cataplexy) or OSA. We cannot predict whether we will be able to obtain marketing authorization approval in the EU in a timely manner and on what terms, or at all.

Moreover, the redemption of a rare pediatric disease priority review voucher may not result in faster review or approval compared to products considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by FDA. Any delay or failure in obtaining approval of a product candidate, or receipt of approval for narrower indications than sought, can have a negative impact on our ability to recoup or research and development costs and to successfully commercialize that product and on our financial performance.

If the FDA, the EC or the competent authorities of the EU member states determine that our quality, safety or efficacy data do not warrant marketing approval, we could be required to conduct additional clinical trials as a condition to receiving approval, which could be costly and time-consuming and could delay the approval of our application.

Even if we receive approval, it may be subject to significant labeling restrictions, including limitations on the dosing of the product, indicated uses for which we may market the product, the imposition of a boxed warning or other warnings and precautions, and/or the requirement for a REMS to ensure that the benefits of the drug outweigh the risks. 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. The FDA requires a REMS and a boxed warning for Xyrem, and similar restrictions could be imposed on other products in the future.

Regulatory authorities may also impose post-marketing obligations as part of their approval. Post-marketing obligations may lead to additional costs and burdens associated with commercialization of the drug, and may pose a risk to maintaining approval of the drug. We are subject to certain post-marketing requirements and commitments in connection with the approval of certain of our products, including Erwinaze, Defitelio, Vyxeos and Sunosi. For example, for Defitelio, in the U.S. the FDA imposed several post-marketing commitments and requirements in connection with its approval, 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, and in the EU marketing authorization was granted under exceptional circumstances and requires us to comply with a number of post-marketing obligations, including a study to provide further data on long-term safety, health outcomes and patterns of utilization of Defitelio in normal use. Similarly, the FDA imposed post-marketing requirements in connection with its approval of our NDA for Vyxeos, including the requirement that we conduct a safety study to characterize infusion-related reactions in patients treated with Vyxeos and a clinical trial to determine dosing to minimize toxicity in patients with moderate and severe renal impairment, and the marketing authorization in the EU also requires us to comply with certain manufacturing-related post-approval commitments. The FDA also required us to conduct additional post-marketing safety studies related to pregnancy and lactation for Sunosi. In the event that we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the U.S. or EU, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of and revenues from our products could be materially adversely affected.

A significant proportion of the regulatory framework in the UK is derived from EU laws. For that reason, the results of the formal procedure of withdrawal from the EU, initiated by the UK in March 2017, could materially change the regulatory regime applicable to our operations, including with respect to the approval of our product candidates, as there is significant uncertainty concerning the future relationship between the UK and the EU. For a further discussion, see the risks under the heading "*The UK's planned withdrawal from the EU, commonly referred to as Brexit, may have a negative effect on global economic conditions, financial markets and our business*" in this Part II, Item 1A.

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, maintaining and defending intellectual property protection for our products and product candidates, including protection of their use and methods of manufacturing and distribution. 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 adequately protected trade secrets that cover these activities.

The patent position of pharmaceutical companies can be highly uncertain and involve complex and often changing legal, regulatory and factual questions. The degree of 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:

- our patent applications, or those of our licensors or partners, may not result in issued patents;
- others may independently develop similar or therapeutically equivalent products without infringing our patents, or those of our licensors, such as products that are not covered by the claims of our patents, or for which we do not have adequate exclusive rights under our license agreements;
- our issued patents, or those of our licensors or partners, may be held invalid or unenforceable as a result of legal challenges by third parties or may be vulnerable to legal challenges as a result of changes in applicable law;
- 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 those of our licensors or partners;
- competitors may manufacture products in countries where we have not applied for patent protection or that have a different scope of patent protection or that do not respect our patents; or
- others may be issued patents that prevent the sale of our products or require licensing and the payment of significant fees or royalties.

We have patents covering many of our products in Europe and other parts of the world where patent laws operate differently and provide a different scope of protection than in the U.S. For example, in the EU, approval of a generic pharmaceutical product can occur independently of whether the reference brand product is covered by patents, and enforcement of such patents generally must await approval and an indication that the generic product is being offered for sale. Patent enforcement generally must be sought on a country-by-country basis, and issues of patent validity and infringement may be judged differently in different countries.

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, Defitelio, Vyxeos and Sunosi. 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, and potentially invalidated or held unenforceable, including through patent litigation or through patent office procedures that permit challenges to patent validity. Patents can also be circumvented, potentially including by FDA approval of an ANDA or Section 505(b)(2) application that avoids infringement of our intellectual property.

Xyrem is covered by patents covering its manufacture, formulation, distribution system and method of use, and we have U.S. patents that extend to 2033. We have settled patent litigation with nine companies seeking to introduce generic versions of Xyrem in the U.S. by granting those companies licenses to launch their generic products in advance of the expiration of the last of our patents. Notwithstanding our patents and settlement agreements, additional third parties may also attempt to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy that design around our patents or assert that our patents are invalid or otherwise unenforceable. If these efforts are successful, then that third party could launch a generic or 505(b)(2) product referencing Xyrem before the dates provided in our patents or settlement agreements.

For example, we have several method of use patents listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book, that expire in 2033 that cover instructions on the Xyrem package insert and Xyrem REMS related to a drug-drug interaction, or DDI, with divalproex sodium. Although the FDA has stated, in granting a Citizen Petition we submitted in 2016, that it would not approve any sodium oxybate ANDA referencing Xyrem that does not include the portions of the currently approved Xyrem package insert related to the DDI patents, we cannot predict whether a future ANDA filer, or a company that files a Section 505(b)(2) application for a drug referencing Xyrem, may pursue regulatory strategies to avoid infringing our DDI patents notwithstanding the FDA's response to the Citizen Petition, or whether any such strategy would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of these patents or will otherwise obtain a judicial determination that a generic or other sodium oxybate product, its package insert or the generic sodium oxybate REMS or another separate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents a future ANDA filer or other company introducing a different sodium oxybate product from marketing its product, or instead require that party to pay damages in the form of lost profits or a reasonable royalty.

Since Xyrem's regulatory exclusivity has expired in the EU, we are aware that generic or hybrid generic applications have been approved by various EU regulatory authorities, and additional generic or hybrid generic applications may be submitted and approved. We cannot predict whether our licensee in the EU will be able to enforce our existing European patents against generic or hybrid generic filers in the EU.

For a discussion regarding the risks associated with our ANDA litigation settlement agreements, the potential launch of AG Products or other generic versions of Xyrem, or the approval and launch of other sodium oxybate or other products that

compete with Xyrem, as well as other risks and challenges we face with respect to Xyrem, see the risk factors under the headings "Risks Related to Xyrem and the Our Other Marketed Products" and "*We have incurred and may in the future 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 this Part II, Item 1A.

We also rely on trade secrets and other unpatented proprietary information to protect our products and their commercial position, particularly with respect to our products with limited or no patent protection, such as Erwinaze, which has no patent protection. We seek to protect our trade secrets and other unpatented proprietary information in part through confidentiality and invention agreements with our employees, consultants, advisors and partners. Nevertheless, 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. Enforcing a claim that a third party illegally obtained or is using any of our inventions or trade secrets would be 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.

In some instances, we also rely on regulatory exclusivity to protect our commercial position. In addition to relying on trade secret protection, Erwinaze was granted orphan drug exclusivity by the FDA for the treatment of ALL in the U.S. for a seven-year period from its FDA approval, which had precluded approval of another product with the same principal molecular structure for the same indication until November 2018. As a biologic product approved under a BLA, Erwinaze 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. However, interpretation of regulatory exclusivity under the BPCIA may evolve over time based on FDA issuance of guidance documents, proposed regulations or decisions made by the FDA in the course of considering specific applications. In addition, the BPCIA exclusivity period does not prevent another company from independently developing a product that is highly similar to Erwinaze, generating all the data necessary for a full BLA and seeking approval. BPCIA exclusivity only assures that another company cannot rely on the FDA's prior approvals of Erwinaze to support the biosimilar product's approval. As a result, it is possible that a potential competing drug product might obtain FDA approval before the expected BPCIA exclusivity period has expired, which would adversely affect sales of Erwinaze. In the EU, the regulatory data protection that provides an exclusivity period for Erwinase has lapsed. 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 employees, consultants, advisors or partners over the ownership of rights to inventions, including 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 may in the future 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. 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 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. In addition, the inter partes review, or IPR, process under the Leahy-Smith 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, many types of entities, including ANDA filers, have challenged valuable pharmaceutical patents through the IPR process, and six of our Orange Book-listed patents for Xyrem were invalidated through this process.

There is a risk that a court or the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO, could decide that our patents or certain claims in our patents are not valid or infringed, and that we do not have the

right to stop a third party from using the inventions covered by those claims, as happened with the decision of the PTAB that certain of our patent claims covering the Xyrem REMS are invalid. In addition, even if we prevail in establishing that another product infringes a valid claim of one of our patents, a court may determine that we can be compensated for the infringement in damages, and refuse to issue an injunction. As a result, we may not be entitled to stop another party from infringing our patents for their full term. For more information, see the risk factors under the headings "Risks Related to Xyrem and Our Other Marketed Products" and "*It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection"* in this Part II, Item 1A. Lawsuits or proceedings we may file in the future, or our defense against any lawsuits or other proceedings that may be brought against us, may not costly and time-consuming and may not be successful in stopping the infringement of our patents.

Litigation involving patent matters is frequently settled between the parties, rather than continuing to a court ruling, and we have settled patent litigation with all nine Xyrem ANDA filers. The FTC has publicly stated that, in its view, certain types of agreements between branded 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 have entered into or might enter into in the future constitutes a reasonable and lawful patent settlement. Parties to such settlement agreements in the U.S. are required by law to file the agreements with the FTC and the U.S Department of Justice, or DOJ, for review. Accordingly, we have submitted our ANDA litigation settlement agreements to the FTC and the DOJ for review. We may receive formal or informal requests from the FTC regarding our ANDA litigation settlements, and there is a risk that the FTC may commence a formal investigation or action against us, or a third party may initiate civil litigation regarding such settlements, which could divert the attention of management and cause us to incur significant costs, regardless of the outcome. Any claim or finding that we or our business partners have failed to comply with applicable laws and regulations could be costly to us and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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.

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. For further discussion of our Xyrem-related patent matters, see the risk factors under the headings "Risks Related to Xyrem and Our Other Marketed Products" and "Risks Related to Our Intellectual Property."

Other Risks Related to Our Business and Industry

We have substantially expanded our international footprint and operations, and we may expand further in the future, which subjects us to a variety of risks and complexities which, if not effectively managed, could negatively affect our business.

We are headquartered in Dublin, Ireland and have multiple offices in the U.S., Canada, the UK, Italy and other countries in Europe. Our headcount has grown to approximately 1,460 as of May 2019. This includes employees in 16 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. We may further expand our international operations into other countries in the future, either organically or by acquisition. While we have 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. These risks and complexities include:

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

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

The UK's planned withdrawal from the EU, commonly referred to as Brexit, may have a negative effect on global economic conditions, financial markets and our business.

Brexit has created significant uncertainty concerning the future relationship between the UK and the EU, particularly if the UK withdraws from the EU without a ratified withdrawal agreement in place. From a regulatory perspective, there is uncertainty about which laws and regulations will apply. A significant portion of the regulatory framework in the UK is derived from EU laws. However, it is unclear which EU laws the UK will decide to replace or replicate in connection with its withdrawal from the EU. In particular, the regulatory regime applicable to our operations, including with respect to the approval of our product candidates, may change, potentially significantly, and the impact on the process for obtaining or maintaining marketing authorization for pharmaceutical products manufactured or sold in the UK is otherwise unknown.

A basic requirement related to the grant of a marketing authorization for a medicinal product in the EU is the requirement that the applicant be established in the EU. Following withdrawal of the UK from the EU, marketing authorizations previously granted to applicants established in the UK through the centralized, mutual recognition or decentralized procedures may no longer be valid. Moreover, depending upon the exact terms of the UK's withdrawal, there is a risk that the scope of a marketing authorization for a medicinal product granted by the EC pursuant to the centralized procedure, or by the competent authorities of other EU member states through the decentralized or mutual recognition procedures, would not encompass the UK. In these circumstances, a separate authorization granted by the UK competent authorities would be required to place medicinal products on the UK market.

In addition, the laws and regulations that will apply after the UK withdraws from the EU may have implications for manufacturing sites that hold certifications issued by the UK competent authorities. Our capability to rely on these manufacturing sites for products intended for the EU market will depend on the terms of the UK's withdrawal and, potentially, on the ability to obtain relevant exemptions under EU law to supply the EU market with products manufactured at UK-certified sites. There is also the risk that if batch release and quality control testing sites for our products are located only in the UK, manufacturers will need to use sites in other EU member states. All of these changes, if they occur, could increase our costs and otherwise adversely affect our business.

Brexit has also given rise to calls for the governments of other EU member states to consider withdrawal from the EU. These developments, or the perception that they could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, including by significantly reducing global market liquidity or restricting the ability of key market participants to operate in certain financial markets. In addition, currency exchange rates for the British Pound and the euro with respect to each other and to the U.S. dollar have already been negatively affected by Brexit. Should this foreign exchange volatility continue or be exacerbated by UK's withdrawal from the EU, it could cause volatility in our quarterly financial results.

We have an office in Oxford, England which is focused on commercialization of our products outside of the U.S. We do not know to what extent, or when, the UK's withdrawal from the EU or any other future changes to membership in the EU will impact our business, particularly our ability to conduct international business from a base of operations in the UK. The UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, possibly resulting in

increased trade barriers, which could make doing business in Europe more difficult and/or costly. Moreover, in the U.S., tariffs on certain U.S. imports have recently been imposed, and the EU and other countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating global trade and political tensions. However, these tariffs and other trade restrictions, whether resulting from the UK's withdrawal from the EU or otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results.

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. 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 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 to operate our business. In the ordinary course of our business, we collect, store, process 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, integrity and availability of such information. We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third party vendors who may have, or could gain, access to our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

Our information technology systems are large and complex and store large amounts of confidential information. The size and complexity of these systems make them 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. Attacks of this nature are increasing in frequency, persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of important information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our information. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue.

Significant disruptions of our, our third party vendors' and/or business partners' 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 further harm us. 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. In addition, failure to maintain effective internal accounting controls

related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

In addition to those specifically described in other risk factors, 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.

FDA and Equivalent Non-U.S. Regulatory Authorities

Our activities are subject to extensive regulation encompassing the entire life cycle of our products, from research and development activities to marketing approval (including specific post-marketing obligations), manufacturing, labeling, packaging, adverse event and safety reporting, storage, advertising, promotion, sale, pricing and reimbursement, recordkeeping, distribution, importing and exporting. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. The failure by us or any of our third party partners, including clinical trial sites, 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, restrictions on our products, our suppliers, our other partners or us, the 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 result in a significant drop in our revenues from the affected products and harm to our reputation and could have a significant impact on our sales, business and financial condition.

We monitor adverse events resulting from the use of our 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 variation, withdrawal or suspension of the marketing authorization, 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 our 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 may propose to the Committee for Medicinal Products for Human Use that the marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended or revoked. Failure to adequately and promptly correct the observation(s) can result in further regulatory enforcement action, which could include the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures. The failure to adequately address and promptly correct any matters identified by the FDA or other foreign regulatory authorities could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Erwinaze, defibrotide and Vyxeos are available on a named patient basis in many countries where they are not commercially available. If any such country's regulatory authorities determine that we are promoting such products without proper authorization, we could be found to be in violation of pharmaceutical advertising laws or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties. Moreover, any failure to maintain revenues from sales of Erwinaze, defibrotide and/or Vyxeos 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.

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. Regulatory authorities actively investigate allegations of off-label promotion in order to enforce regulations prohibiting these types of activities. If we are found to have promoted an approved product for off-label uses, we may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties, other sanctions and imprisonment. Even if we are not determined to have engaged in off-label promotion, an allegation that we have engaged in such activities could have a significant impact on our 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. 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.

In the EU, the advertising and promotion of our products are also subject to EU member states' laws and industry codes of practice governing promotion of medicinal products, including limitations on our promotional activities with health care professionals, prohibition of the advertising and promotion of our products to the general public, misleading and comparative advertising and unfair commercial practices. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, limitations on promotional activities, fines and imprisonment. These laws may also impose limitations on our promotional activities with health care professionals.

Other Regulatory Authorities

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the DOJ, the FTC, the United States Department of Commerce, the Office of Inspector General, or OIG, of the HHS and other regulatory bodies, as well as similar governmental authorities in those non-U.S. countries in which we commercialize our products.

We are subject to numerous anti-fraud and abuse laws and regulations globally and our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws and regulations. For example, the U.S. federal anti-kickback statute is broad and activities that involve providing anything of value to those who prescribe, purchase, or recommend pharmaceutical products may be subject to scrutiny. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities, the exemptions and safe harbors are drawn narrowly, and practices or arrangements that involve remuneration may be subject to scrutiny if they do not clearly qualify for an exemption or safe harbor. While we maintain a comprehensive compliance program to try to ensure that our practices and the activities of our third-party contractors and employees fall within the scope of such exceptions and safe harbors, regulators and enforcement agencies may disagree with our assessment or find fault with the conduct of our employees or contractors. In addition, existing regulations are subject to regulatory revision or changes in interpretation by the DOJ or OIG. Violations of the federal anti-kickback statute may be punished by civil and criminal fines, imprisonment, and/or exclusion from participation in federal healthcare programs.

The federal civil False Claims Act prohibits, among other things, making a fraudulent claim for payment of federal funds, causing such a fraudulent claim to be made, or making a false statement to get a false claim paid. The government may assert that a claim resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim under the False Claims Act. Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities, including providing free product to customers expecting 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, the government and private whistleblowers have pursued False Claims Act cases against 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. If we become the subject of a government False Claims Act or other investigation or whistleblower suit, we could incur substantial legal costs (including settlement costs) and business disruption responding to such investigation or suit, regardless of the outcome. Violations of the False Claims Act may result in significant financial penalties (on a per claim or statement basis), treble damages and exclusion from participation in federal health care programs.

The majority of individual states also have statutes or regulations similar to the federal anti-kickback law and the False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The Physician Payment Sunshine Act, or Sunshine provisions, currently requires us to track and report to the federal government payments and transfers of value that we make to physicians and teaching hospitals and ownership interests held by physicians and their family, and provides for public disclosures of these data. Public reporting under the Sunshine provisions has resulted in increased scrutiny of the financial relationships between industry, teaching hospitals and physicians. Such scrutiny may negatively impact our ability to engage with physicians on matters of importance to us. In addition, government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports. Moreover, certain states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and gifts and payments to individual physicians, and/or restrict when and to what extent pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities. 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 or similar requirements of state or local regulators, we may be subject to significant civil, criminal and administrative penalties, damages or fines.

Outside the U.S., 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. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products, which is prohibited in the EU, is governed by the national anti-bribery laws of the EU member states, as described below and by industry codes of practice. Violation of these laws could result in substantial fines and imprisonment. The national laws of certain EU member states and industry codes of practice require that payments made to physicians 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.

Xyrem is a controlled substance under the Controlled Substances Act, or CSA. Our suppliers, distributors, clinical sites and the central pharmacy for Xyrem are subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, including limitations on prescription refills, and are required to maintain DEA registration and state licenses, when handling Xyrem and its API. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA, relevant state authorities or any comparable international requirements could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, could result in, among other things, additional operating costs to us or delays in shipments outside or into the U.S. and could have an adverse effect on our business and financial condition. DEA quotas are required for any U.S. supplier to manufacture sodium oxybate or Xyrem. New oxybate market entrants, including generic products, may impact the amount of quota available in the U.S., and if, 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.

The FDA approved Sunosi subject to scheduling of the product under the CSA. The scheduling process under the CSA must be completed before the product can be commercially launched. The CSA requires DEA to issue an interim final rule scheduling the product within 90 days of the date of notification of FDA approval. Sunosi may be marketed only after DEA has published a notice announcing the interim final scheduling in the Federal Register and after we make appropriate revisions to the Prescribing Information, Medication Guide, and carton and container labeling with scheduling information.

We have various programs to help patients access our products, including patient assistance programs, which include co-pay coupons for certain of our products, services that help patients determine their insurance coverage for our products, and a free product program. Co-pay coupon programs for commercially insured patients, including our program for Xyrem, have received negative publicity related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. In the past, payors brought class action lawsuits challenging the legality of manufacturer co-pay programs under a variety of federal and state laws and insurers have taken actions through their network pharmacies and PBMs to restrict manufacturer co-pay programs. In September 2014, the OIG issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and other laws if they do not take appropriate steps to exclude Medicare Part D beneficiaries from using co-pay coupons. 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 have established programs to consider grant applications submitted by independent charitable organizations, including organizations that provide co-pay support to patients who suffer from the diseases treated by our drugs. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are *bona fide* charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. If we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, such facts could be used as the basis for an enforcement action against us by the federal government.

In 2016 and 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of charitable organizations that provide financial assistance to Medicare patients. On April 4, 2019, we finalized our civil settlement agreement with the DOJ and OIG in the amount of $57.0 million plus interest. In connection with the settlement agreement, we entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the corporate integrity agreement. In the event of a breach of the corporate integrity agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs, which would have a material adverse effect on our sales, business and financial condition.

We may also become subject to similar investigations by other state or federal governmental agencies or offices. Any additional investigations of our patient assistance programs or other business practices may result in damages, fines, penalties or other criminal, civil or administrative sanctions or enforcement actions. Such investigations may also result in negative publicity or other negative actions that could harm our reputation, impact our business practices, reduce demand for, or patient access to, our products and/or reduce coverage of our products, including by federal and state health care programs. If any or all of these events occur, our business, financial condition, results of operations and stock price could be materially and adversely affected.

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 UK Bribery Act of 2010, or the UK Bribery Act. Our heavily regulated business involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in certain 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 and the UK Bribery Act. 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 original information to the SEC that leads to successful enforcement actions may be eligible for a monetary award. 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 data protection and privacy laws and regulations governing the processing of personal data. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues which may affect our business. Failure to comply with current and future laws and regulations, such as the EU General Data Protection Regulation that became effective in May 2018 and the California Consumer Privacy Act of 2018 that will become effective beginning January 2020, could result in government enforcement actions (including the imposition of significant penalties), criminal and civil liability for us and our officers and directors, private litigation and/or adverse publicity that negatively affects our business. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon for the transfer of personal data are ever deemed inadequate, 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 European Economic Area or Switzerland is restricted, which could adversely impact our operating results. In addition, although we are not directly subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, other than with respect to providing certain employee benefits, we potentially could be subject to criminal penalties if we, our affiliates or our agents 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.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, agreements between branded pharmaceutical companies and potential generic competitors settling patent litigation must be submitted to the FTC and the DOJ for review. The FTC has publicly stated that, in its view, certain brand-generic settlement agreements violate the antitrust laws and has 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 have entered into or might enter into in the future constitutes a reasonable and lawful patent settlement. We may receive formal or informal requests from the FTC regarding our Xyrem patent settlements, and there is a risk that the FTC may commence a formal investigation or action against us, or a third party may initiate civil litigation regarding such settlements, which could divert the attention of management and cause us to incur significant costs, regardless of the outcome. We cannot predict the outcome of any potential government investigation of any antitrust claims, including those described above, or the impact of any such claims.

In addition to those described in this and other risk factors, numerous federal, state and non-U.S. statutes and regulations govern 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. Any claim or finding that we or our business partners have failed to comply with applicable laws and regulations could be costly to us and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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.

Our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs are described under the heading "Business-Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2018. Our failure to comply with these obligations could negatively impact our financial results.

The Centers for Medicare and Medicaid Services, or CMS, issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. The issuance of the final regulation, as well as any other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program, has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

We also participate in the 340B program, which is described in more detail under the heading "Business-Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018. The Health Resources and Services Administration, or HRSA, issued a final 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, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. HRSA also began to implement a ceiling price reporting requirement related to the 340B program during the first quarter of 2019, under which we are required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. There is no guarantee that our submissions will not be found by HRSA to be incomplete or incorrect. Further, any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act or otherwise could affect our 340B ceiling price calculations and negatively impact our results of operations. 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 an inpatient setting.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS 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 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, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. 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. There is no guarantee that our submissions will not be found by CMS to be incomplete or incorrect.

We participate in the U.S. Department of Veterans Affairs, Federal Supply Schedule, or FSS, pricing program and the Tricare Retail Pharmacy program, as described in more detail under the heading "Business—Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018. Pursuant to applicable law, knowing provision of false information in connection with price reporting under these programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements.

If we overcharge the government in connection with our arrangements with FSS or Tricare, 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.

Our business and operations could be negatively affected if we become subject to shareholder activism, which could cause us to incur significant expense, hinder execution of our business strategy and impact our stock price.

Shareholder activism, which takes many forms and arises in a variety of situations, has been increasingly prevalent. If we become the subject of certain forms of shareholder activism, such as proxy contests, the attention of our management and our board of directors may be diverted from execution of our strategy. Such shareholder activism could give rise to perceived uncertainties as to our future strategy, adversely affect our relationships with business partners and make it more difficult to attract and retain qualified personnel. Also, we may incur substantial costs, including significant legal fees and other expenses, related to activist shareholder matters. Our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

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 impairment or even death. This could result in product liability claims against us and/or recalls of one or more of our products. 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 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 therapeutic 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 Italy and Ireland administer laws 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. Our manufacturing facilities are involved in the controlled storage, use and disposal of chemicals and solvents. Even if our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by EU laws, 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. In certain cases, laws 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.

We may incur significant costs to comply with current or future EU environmental laws.

Risks Related to Our Financial Condition and Results

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

As of March 31, 2019, we had total indebtedness of approximately $1.8 billion, which included $642.7 million in outstanding term loan indebtedness under a secured credit agreement that we entered into in June 2015 and subsequently amended in July 2016 and in June 2018, which we refer to as the amended credit agreement, $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, and $575.0 million of outstanding indebtedness under our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, which were issued in August 2017 and which we refer to, together with the 2021 Notes, as the Exchangeable Senior Notes.

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 the Exchangeable Senior 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 amended 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.

The amended credit agreement provides for a $667.7 million principal amount term loan due in June 2023 and a $1.6 billion revolving credit facility, with any loans under such revolving credit facility due in June 2023, subject to early mandatory repayments under certain circumstances. The amended credit agreement contains various covenants that, among other things, limit our ability and/or our restricted subsidiaries' ability to:

- 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.

The amended 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 the amended 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 amended 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 the amended credit agreement could also lead to a default under other debt agreements or obligations, including the indentures governing the Exchangeable Senior Notes.

In addition, the holders of the Exchangeable Senior 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 Exchangeable

Senior Notes, unless we elect to deliver only our ordinary shares to settle such exchange, we will be required to make cash payments in respect of the Exchangeable Senior Notes. It is our intent and policy to settle the principal amount of the Exchangeable Senior 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 Exchangeable Senior Notes or to pay cash upon exchanges of the Exchangeable Senior Notes. Our failure to repurchase the Exchangeable Senior Notes at a time when the repurchase is required by the indentures governing the Exchangeable Senior Notes or to pay any cash payable on future exchanges of the Exchangeable Senior Notes as required by the indentures governing the Exchangeable Senior Notes would constitute a default under that indenture. A default under those indentures could also lead to a default under other debt agreements or obligations, including the amended 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 the amended credit agreement, the lenders under the amended 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. The amended 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 the amended 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 Public Limited Company, which we refer to as the Azur Merger, and our acquisitions of EUSA Pharma Inc., Gentium S.r.l. and Celator Pharmaceuticals, Inc. To continue to grow our business over the longer term, we will need to commit substantial additional resources to our business and execution of our strategy. Our ongoing capital requirements will depend on many factors, including:

- the revenues from our commercial products, which may be affected by many factors, including the extent of competition for Xyrem or our other products;
- the cost of acquiring and/or in-licensing any new products and product candidates;
- the costs of our commercial operations;
- 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;
- the costs of integration activities related to any future strategic transactions we may engage in; and
- the costs arising from changes in laws and regulations, including, for example, healthcare reform legislation.

Our strategy includes the expansion of our business through acquiring or in-licensing, and developing, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. See the risk factor under the heading "*We may not be able to successfully identify and acquire or in-license additional products or product candidates to grow our business, and, even if we are able to do so, we may otherwise fail to realize the anticipated benefits of these acquisitions*" in this Part II, Item 1A. 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. 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 variability in stock prices, which has caused uncertainty with regard to credit availability for many borrowers. 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, including as a result of the UK's withdrawal from the EU or as a result of tariffs and other trade restrictions potentially contributing to instability in the global financial markets, 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 also adversely affect our cost of financing and have an adverse effect on the market price of our securities.

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, 2019, we had recorded $3.6 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. For example, in connection with entry into an asset purchase agreement in June 2018 to sell substantially all of the assets held by us related to Prialt® (ziconotide) intrathecal infusion, we recognized an impairment charge of $42.9 million in our consolidated statements of income in 2018, primarily related to the carrying balances of intangible assets. 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. Our results of operations and financial position in future periods could be negatively impacted should 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, Erwinase and Vyxeos 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, as well as our expanding operations, there is no guarantee that we will be able to effectively manage currency transaction and/or translation risks. We use foreign exchange forward contracts to manage currency risk primarily related to certain intercompany balances denominated in non-functional currencies. These foreign exchange forward contracts are not designated as hedges. Gains and losses on these derivative instruments are designed to offset gains and losses on the underlying balance sheet exposures. Fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations and financial condition.

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. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various jurisdictions where we operate. Our effective tax rate may fluctuate depending on a number of factors, including, but not limited to, the distribution of our profits or losses between the jurisdictions where we operate and differences in interpretation of tax laws. In addition, the tax laws of any jurisdiction in which we operate may change in the future, which could impact our effective tax rate. We are subject to reviews and audits by the U.S. Internal Revenue Services, or IRS, and other taxing authorities from time to time, and the IRS or other taxing authority may challenge our structure, transfer pricing arrangements and tax positions through an audit or lawsuit. Responding to or defending against challenges from taxing authorities could be expensive and consume time and

other resources. 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. Any of these actions could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In December 2015, we received proposed tax assessment notices, and, in October 2018, we received revised tax assessment notices from the French tax authorities for 2012 and 2013 and in December 2018, we received a proposed tax assessment notice for 2015, relating to certain transfer pricing adjustments. The notices propose additional French tax of approximately $42 million for 2012 and 2013 and approximately $4 million for 2015, including interest and penalties through the respective dates of the proposed assessments, translated at the foreign exchange rate at March 31, 2019.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act, or U.S. Tax Act, was signed into law. The U.S. Tax Act made broad and complex changes to the U.S. tax code. The U.S. Department of Treasury has issued limited regulations and other interpretive guidance under the U.S. Tax Act, and is expected to issue additional guidance, the impact of which is uncertain but could change the financial impacts that were previously recorded or are expected to be recorded in future periods. Furthermore, the impact of this tax reform on certain holders of our ordinary shares could be adverse. Among other things, changes to the rules for determining a foreign corporation's status as a controlled foreign corporation could have an adverse effect on U.S. persons who are treated as owning (directly or indirectly) at least 10% of the value or voting power of our ordinary shares. Investors should consult their own advisers regarding the potential application of these rules to their investments.

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 U.S. Internal Revenue Code, 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. 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. 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 prospective or retroactive application to us, our shareholders, Jazz Pharmaceuticals, Inc. and/or the Azur Merger.

Our U.S. affiliates' ability to use their net operating losses to offset potential taxable income and related income taxes that would otherwise be due is limited under Section 7874 of the Code and 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.

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. Our U.S. affiliates have a significant amount of NOLs. As a result of Section 7874 of the Code, after the Azur Merger, our U.S. affiliates have not been able and will continue to be unable, for a period of time, to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions. While we expect to be able to fully utilize our U.S. affiliates' U.S. NOLs prior to their expiration, as a result of this limitation, it may take our U.S. affiliates longer to use their NOLs.

Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is also dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, our U.S. affiliates will generate sufficient taxable income to use all of the NOLs. In addition, the use 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.

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

The U.S. Congress, the EU, the Organization for Economic Co-operation and Development, or OECD, 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 the OECD's initiative 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. Some countries are beginning to implement legislation and other guidance to align their international tax rules with the OECD's recommendation. As a result of the focus on the taxation of multinational corporations, the tax laws in Ireland, 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.

A substantial portion of our indebtedness bears interest at variable interest rates based on USD LIBOR and certain of our financial contracts are also indexed to USD LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Financial Conduct Authority, the authority that regulates the London Inter-bank Offered Rate, or LIBOR, announced that it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021. The Alternative Reference Rates Committee, or ARRC, in the U.S. has proposed that the Secured Overnight Financing Rate, or SOFR, is the rate that represents best practice as the alternative to the U.S. dollar, or USD, LIBOR for use in derivatives and other financial contracts that are currently indexed to USD LIBOR. ARRC has proposed a paced market transition plan to SOFR from USD LIBOR and organizations are currently working on industry-wide and company-specific transition plans as relating to derivatives and cash markets exposed to USD LIBOR. We have certain financial contracts, including the amended credit agreement and our interest rate swaps, that are indexed to USD LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness. Any transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that rely on LIBOR, reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. We are monitoring this activity and evaluating the related risks, and any such effects of the transition away from LIBOR may result in increased expenses, may impair our ability to refinance our indebtedness or hedge our exposure to floating rate instruments, or may result in difficulties, complications or delays in connection with future financing efforts, any of which could adversely affect our financial condition and results of operations.

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 $184.00 on June 20, 2018 and a low of $113.52 on December 24, 2018 during the period from March 31, 2018 through March 31, 2019. 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 trading volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. In particular, 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 our marketed products. The risks and uncertainties associated with our ability to maintain or increase sales of our products 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 transactions, including the Celator Acquisition and/or potential future acquisitions, on our financial or operating results 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 the Exchangeable Senior Notes who may view the Exchangeable Senior 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 the Exchangeable Senior Notes.

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 U.S. jurisdiction.

Our articles of association, Irish law and the indentures governing the Exchangeable Senior Notes contain provisions that 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 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 to our articles of association, 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 indentures governing the Exchangeable Senior Notes require us to repurchase the Exchangeable Senior Notes for cash if we undergo certain fundamental changes and, in certain circumstances, to increase the exchange rate for a holder of 2021 Notes or 2024 Notes. A takeover of us may trigger the requirement that we purchase the Exchangeable Senior 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, whether alone or together, 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, whether alone or together, could also discourage proxy contests and make it more difficult for our 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, 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 the amended 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 the amended 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. In addition, in the event that we pay a dividend on our ordinary shares, in certain circumstances, as an Irish tax resident company, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

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 in respect of transfers by shareholders who hold our ordinary shares beneficially through brokers which in turn hold those shares through the Depository Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by or to 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 permits, 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.

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, 2019:

	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, 2019	294,978	$ 127.64	294,978	$ 341,493,487
February 1 - February 28, 2019	300,610	$ 126.16	300,610	$ 303,575,534
March 1 - March 31, 2019	262,400	$ 135.96	262,400	$ 267,905,862
Total	857,988	$ 129.66	857,988	

(1) This column includes ordinary shares that we reacquired in satisfaction of the exercise price of employee stock options upon exercise, but does not include ordinary shares that we withheld in order to satisfy minimum tax withholding requirements in connection with the vesting of restricted stock units.

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

(3) The ordinary shares reported in this column above were purchased pursuant to our publicly announced share repurchase program. In November 2016, we announced that our board of directors authorized the use of up to $300 million to repurchase our ordinary shares. In November and December 2018, our board of directors increased the existing share repurchase program authorization by $320.0 million and $400.0 million, respectively, thereby increasing the total amount authorized for repurchase to $1.02 billion. This authorization has no expiration date.

(4) The dollar amount shown represents, as of the end of each fiscal month, 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 5. Other Information

On April 9, 2019, we extended by one year the term of our master services agreement for Xyrem with Express Scripts Specialty Distribution Services, Inc., or Express Scripts, through June 30, 2020. Additional information about our master services agreement for Xyrem with Express Scripts is included in "Business—Our Commercialized Products—Xyrem" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2018. We have no material relationship with Express Scripts other than in respect of the master services agreement.

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) 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 among 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).
2.9	Agreement and Plan of Merger, dated as of May 27, 2016, by and among Jazz Pharmaceuticals plc, Plex Merger Sub, Inc., and Celator Pharmaceuticals, 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 May 31, 2016).
3.1	Amended and Restated Memorandum and Articles of Association of Jazz Pharmaceuticals plc, as amended on August 4, 2016 (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2016, as filed with the SEC on August 9, 2016).
4.1	Reference is made to Exhibit 3.1.
4.2A	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).
4.2B	Form of 1.875% Exchangeable Senior Note due 2021 (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).
4.3A	Indenture, dated as of August 23, 2017, among Jazz Pharmaceuticals Public Limited Company, 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. 001-033500), as filed with the SEC on August 23, 2017).
4.3B	Form of 1.50% Exchangeable Senior Note due 2024 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on August 23, 2017).

10.1+	Transition Employment Letter Agreement, dated as of February 6, 2019, by and between Jazz Pharmaceuticals, Inc. and Suzanne Sawochka Hooper.
10.2+	Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan.
10.3+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan.
10.4+	Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.5+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.6	Corporate Integrity Agreement, dated as of April 3, 2019, by and between Jazz Pharmaceuticals plc and the Office of Inspector General of the United States Department of Health and Human Services.
10.7	Settlement Agreement, dated as of April 4, 2019, by and among United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Ltd.
10.8	Amendment No. 1 to Pharmacy Master Services Agreement, effective as of June 30, 2019, by and between Jazz Pharmaceuticals, Inc. and Express Scripts Specialty Distribution Services, Inc.
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.

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 7, 2019

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(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 10.1

[JAZZ PHARMACEUTICALS LETTERHEAD]

February 6, 2019

Suzanne Sawochka Hooper
Jazz Pharmaceuticals
3170 Porter Drive
Palo Alto, CA 94304

Re: Transition Employment Terms

Dear Suzanne:

We are writing to memorialize your transition employment terms related to your decision to resign from your employment with Jazz Pharmaceuticals, Inc. (the "**Company**").

- **General Counsel Role:** You will continue in your role of EVP and General Counsel on a full-time basis through February 28, 2019. Effective as of March 1, 2019, you will: (i) step down from your General Counsel role and from the Executive Committee; (ii) cease to be a Section 16 officer of Jazz Pharmaceuticals plc; and (iii) cease to be a director or officer of the Company or any of its affiliates. Your employment will continue in a transition period at half-time status (as discussed further below) until your employment ends on June 3, 2019, or a later date upon mutual agreement of you and the Company.

- **Transition Employment Terms:** Effective beginning March 1 and continuing through your employment end date, your job title will be "Special Projects" reporting to Bruce, and you will be reclassified to half-time status (a regular work schedule of approximately 20 hours per week). Your base salary will be reduced to fifty percent (50%) of full-time, and your vacation accrual also will be prorated to fifty percent. You will remain eligible for regular employee benefits, and your equity awards will continue to vest in accordance with their vesting schedules. During the period from March 1 through June 3, we expect that you generally will be using your accrued vacation at a rate of four (4) hours per day, other than for time during which you provide transition services to the Company.

- **2018 Cash Bonus:** Because your employment is expected to continue through the March 4, 2019 scheduled payment date for 2018 bonuses, you will be eligible for receipt of a 2018 cash bonus through the normal annual bonus cycle. You will not be eligible for new equity awards or a salary increase due to your planned departure from the Company.

Your other terms and conditions of employment will remain in effect.

If your understanding of your transition employment terms is consistent with this letter, please sign and date this letter in the space provided below and return it to me at your earliest convenience. Let me know if you have any questions.

Bruce, and the rest of the Executive Committee, are very appreciative of your valuable contributions to the Company's success and we look forward to continuing to work with you through your transition period.

We wish you the very best on the next chapter of your life!

Sincerely,

JAZZ PHARMACEUTICALS, INC.

By: /s/ Heidi Manna
Heidi Manna
Chief Human Resources Officer

REVIEWED, UNDERSTOOD, AND AGREED:

/s/ Suzanne Hooper
Suzanne Sawochka Hooper

06-Feb-2019
Date

Exhibit 10.2

JAZZ PHARMACEUTICALS PLC
AMENDED AND RESTATED
2007 NON-EMPLOYEE DIRECTORS STOCK AWARD PLAN

NON-U.S. OPTION GRANT NOTICE

Jazz Pharmaceuticals plc (the "***Company***"), pursuant to its Amended and Restated 2007 Non-Employee Directors Stock Award 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: Nonstatutory Stock Option

Vesting Schedule: Subject to Section 1 of the Agreement and any country-specific Appendix to the Agreement, this option will vest as follows: [_____]

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

☒ By cash or check
☒ 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

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

By: _____
Signature

Title: _____

Date: _____

OPTIONHOLDER

_____
Signature

Date: _____

ATTACHMENTS: Non-U.S. Option Agreement and Amended and Restated 2007 Non-Employee Directors Stock Award Plan

* * * * *

Based on the form of Non-U.S. Option Grant Notice for the Amended and Restated 2007 Non-Employee Directors Stock Option Plan as approved by the Board of Directors of Jazz Pharmaceuticals plc on August 1, 2013.

ATTACHMENT I

NON-U.S. OPTION AGREEMENT

JAZZ PHARMACEUTICALS PLC
AMENDED AND RESTATED
2007 NON-EMPLOYEE DIRECTORS STOCK AWARD 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 Amended and Restated 2007 Non-Employee Directors Stock Award 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.

Notwithstanding the foregoing, if you do not stand for reelection at an annual general meeting of the Company's shareholders (an "***Annual Meeting***") in the year in which your term expires or you otherwise resign effective at an Annual Meeting, and, in either case, your Continuous Service terminates at such Annual Meeting, then effective as of the date of such Annual Meeting, the unvested portion, if any, of your option shall become vested and exercisable with respect to the portion of your option that would have vested through the anniversary of the Vesting Commencement Date (as set forth in the Grant Notice) in the year of such Annual Meeting.

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 (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.

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 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(i) 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 your Disability or death or upon a Change in Control (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 death;

(d) twelve (12) months after the effective date of a Change in Control if your Continuous Service terminates as of, or within twelve (12) months following the Change in Control (except as otherwise provided in Section 7(c) above);

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

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

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 (defined below) 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. If you are either (i) required to resign your position as a Non-Employee Director as a condition of a Change in Control, or (ii) removed from your position as a Non-Employee Director in connection with a Change in Control, your option shall become fully vested and exercisable immediately prior to the effectiveness of such resignation or removal (and contingent upon the effectiveness of such Change in Control).

10. 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.

11. 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 providing services to the Company or an Affiliate, or of the Company or an Affiliate to continue your services and shall not in any way restrict the Company or an Affiliate to terminate your Continuous Service. 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.

12. TAX WITHHOLDING OBLIGATIONS.

You acknowledge that, regardless of any action taken by the Company or, if different, your employer, if your employer is an Affiliate of the Company (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 from any cash compensation paid to you by the Company and/or the Employer.

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.

Finally, you agree to pay to the Company 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.

13. 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 future value of the Ordinary Shares underlying the option is unknown, indeterminable, and cannot be predicted with certainty;

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

(g) 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;

(h) no claim or entitlement to compensation or damages shall arise from forfeiture of the option resulting from the termination of your Continuous Service; and

(i) neither the Company 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.

14. 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 should consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

15. DATA PRIVACY. The Company and any Affiliate may collect, use, process, transfer or disclose your Personal Information for the purpose of implementing, administering and managing your participation in the Plan, in accordance with the Company's privacy practices. For example, your Personal Information will be transferred to the Company's stock administration team located in the United States and may be directly or indirectly transferred to E*TRADE or any other third party stock plan service provider as may be selected by the Company, and any other third parties assisting the Company with the implementation, administration and management of the Plan. For more information on the Company's privacy practices, log in to your E*TRADE account to view a copy of the Jazz Pharmaceuticals Privacy Notice.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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 Optionholder.

25. INSIDER TRADING / MARKET ABUSE LAWS. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Ordinary Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Ordinary Shares, rights to Ordinary Shares (e.g., options) or rights linked to the value of Ordinary Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (a) disclosing the inside information to any third party and (b) "tipping" third parties or causing them otherwise to buy or sell securities (third parties include fellow directors). 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.

26. 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.

27. REPORTING 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).

* * * * *

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 Amended and Restated 2007 Non-Employee Directors Stock Option Plan as approved by the Board of Directors of Jazz Pharmaceuticals plc on February 14, 2019.

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 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 January 2019. 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.

HONG KONG

TERMS AND CONDITIONS

Restriction on Sale of Ordinary Shares. Ordinary Shares issued upon exercise are accepted as a personal investment. In the event you exercise the options and Ordinary Shares are issued to you (or your heirs) within six months of the Date of Grant, you (or your heirs) agree that the Ordinary Shares will not be offered to the public or otherwise disposed of prior to the six-month anniversary of the Date of Grant.

NOTIFICATIONS

Securities Law Notification. *WARNING: The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice. Neither the grant of the options nor the issuance of Ordinary Shares upon exercise of the options constitutes a public offering of securities under Hong Kong law and the grant is available only to directors of the Company or its Affiliates. The Agreement, the Plan and other incidental*

communication materials distributed in connection with the options (i) have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong, and (ii) are intended only for the personal use of each eligible director of the Company or its Affiliates and may not be distributed to any other person.

IRELAND

There are no country-specific provisions.

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

There are no country-specific provisions.

Attachment II

JAZZ PHARMACEUTICALS PLC
AMENDED AND RESTATED
2007 NON-EMPLOYEE DIRECTORS STOCK AWARD PLAN

Exhibit 10.3

JAZZ PHARMACEUTICALS PLC
AMENDED AND RESTATED
2007 NON-EMPLOYEE DIRECTORS STOCK AWARD PLAN

NON-U.S. RESTRICTED STOCK UNIT AWARD GRANT NOTICE

Jazz Pharmaceuticals plc (the "***Company***"), pursuant to its Amended and Restated 2007 Non-Employee Directors Stock Award 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 Subject to Award:	_____
Consideration:	Participant's Services (payment of par value of newly issued shares)
Vesting Schedule:	Subject to Section 3 of the Agreement and any country-specific Appendix to the Agreement, the Award will vest as follows: [_____]
Issuance Schedule:	One Ordinary Share will be issuable for each RSU which vests at the time set forth in Section 4 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 written agreement between Participant and the Company 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	**PARTICIPANT**
By: _____	_____
Signature	Signature
Title: _____	Date: _____
Date: _____	

ATTACHMENTS: Non-U.S. Restricted Stock Unit Award Agreement, Amended and Restated 2007 Non-Employee Directors Stock Award Plan

* * * * *

Based on the form of Non-U.S. Restricted Stock Unit Award Grant Notice for the Amended and Restated 2007 Non-Employee Directors Stock Award Plan as approved by the Board of Directors of Jazz Pharmaceuticals plc on 3 November 2016.

ATTACHMENT I

NON-U.S. RESTRICTED STOCK UNIT AWARD AGREEMENT

JAZZ PHARMACEUTICALS PLC
AMENDED AND RESTATED
2007 NON-EMPLOYEE DIRECTORS STOCK AWARD 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 Amended and Restated 2007 Non-Employee Directors Stock Award 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. 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) 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. 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 2 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.

(c) Notwithstanding the provisions of this Section 2, no fractional Ordinary Shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 2. 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 2.

3. VESTING. Subject to Section 12 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.

4. 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 2 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 4(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 4(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 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 4(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 4(b) shall supersede anything to the contrary in Section 4(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 4(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.

5. 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.

6. 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.

7. RESTRICTIVE LEGENDS. The Ordinary Shares issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

8. 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 4 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.

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 3 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 service 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 service 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 your service 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 3 is earned only by providing Continuous Service (not through the act of being elected to the Board, 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 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 a Non-Employee Director 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. 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 4 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.

11. 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 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 4. Additionally, the Company 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; (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. If the obligation for Tax-Related Items is satisfied by withholding from Ordinary Shares otherwise issuable to you, (i) the number of such Ordinary Shares so withheld shall not exceed the minimum statutory withholding rates in connection with the taxes composing the Tax Related-Items, and (ii) 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 makes no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award, 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 does not commit to and is 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 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 are satisfied, the Company shall have no obligation to deliver to you any Ordinary Shares.

(c) In the event the Company'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 withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. CHANGE IN CONTROL. If you are either (i) required to resign your position as a Non-Employee Director as a condition of a Change in Control, or (ii) removed from your position as a Non-Employee Director in connection with a Change in Control, your Award shall become fully vested immediately prior to the effectiveness of such resignation or removal (and contingent upon the effectiveness of such Change in Control).

13. 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.

14. 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 future value of the underlying Ordinary Shares is unknown, indeterminable and cannot be predicted with certainty;

(f) no claim or entitlement to compensation or damages shall arise from forfeiture of the Award resulting from the termination of your Continuous Service; and

(g) neither the Company 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.

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 should 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. The Company and any Affiliate may collect, use, process, transfer or disclose your Personal Information for the purpose of implementing, administering and managing your participation in the Plan, in accordance with the Company's privacy practices. For example, your Personal Information will be transferred to the Company's stock administration team located in the United States and may be directly or indirectly transferred to E*TRADE or any other

third party stock plan service provider as may be selected by the Company, and any other third parties assisting the Company with the implementation, administration and management of the Plan. For more information on the Company's privacy practices, log in to your E*TRADE account to view a copy of the Jazz Pharmaceuticals Privacy Notice.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

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.

28. INSIDER TRADING / MARKET ABUSE LAWS. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Ordinary Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Ordinary Shares, rights to Ordinary Shares (e.g., RSUs) or rights linked to the value of Ordinary Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (a) disclosing the inside information to any third party and (b) "tipping" third parties or causing them otherwise to buy or sell securities (third parties include fellow directors). 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.

29. 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.

30. 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).

* * * * *

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 Amended and Restated 2007 Non-Employee Directors Stock Award Plan as approved by the Board of Directors of Jazz Pharmaceuticals plc on February 14, 2019.

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 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 January 2019. 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.

HONG KONG

TERMS AND CONDITIONS

Restriction on Sale of Ordinary Shares. Ordinary Shares issued at vesting are accepted as a personal investment. In the event that the RSUs vest and Ordinary Shares are issued to you (or your heirs) within six months of the Date of Grant, you (or your heirs) agree that the Ordinary Shares will not be offered to the public or otherwise disposed of prior to the six-month anniversary of the Date of Grant.

NOTIFICATIONS

Securities Law Notification. *WARNING: The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice. Neither the grant of the RSUs nor the issuance of Ordinary Shares upon vesting of the RSUs constitutes a public offering of securities under Hong Kong law and the grant is available only to directors of the Company or its Affiliates. The Agreement, the Plan and other incidental communication materials distributed in connection with the RSUs (i) have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong, and (ii) are intended only for the personal use of each eligible director of the Company or its Affiliates and may not be distributed to any other person.*

IRELAND

TERMS AND CONDITIONS

Vesting and Issuance. The following supplements Sections 3 and 4 of the Agreement:

Notwithstanding the vesting schedule provided in the Grant Notice and Section 4 (a) of the Agreement, (i) 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), and (ii) the Company elects not to satisfy any Tax-Related Items (defined in Section 11) by withholding Ordinary Shares, 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 3 of the Agreement: (i) 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; and (ii) if you are a Non-Employee Director and you do not stand for reelection at an annual general meeting of the Company's shareholders (an "***Annual Meeting***") in the year in which your term expires or you otherwise resign effective at an Annual Meeting, and, in either case, your Continuous Service terminates at such Annual Meeting, then effective as of the date of such Annual Meeting, the unvested portion, if any, of the Award shall become vested with respect to the portion of the Award that would have vested on the anniversary of the Vesting Commencement Date in the year of such Annual Meeting.

For purposes of the foregoing, "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.

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

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.

ATTACHMENT II

JAZZ PHARMACEUTICALS PLC
AMENDED AND RESTATED
2007 NON-EMPLOYEE DIRECTORS STOCK AWARD PLAN

Exhibit 10.4

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:	_____

Vesting Schedule: Subject to Section 1 of the Agreement and any country-specific Appendix to the Agreement, this option will vest as follows: one quarter (1/4th) of the Number of Ordinary Shares Subject to the Option will vest on the first anniversary of the Vesting Commencement Date and the remaining three quarters (3/4th) will vest monthly in approximately equal installments over the next 36 months. Please refer to your online records available on E*TRADE or any successor system maintained by the Company for specific vesting dates.

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

[**x**] By cash, check, bank draft or money order payable to the Company
[**x**] 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
[**x**] 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	**PARTICIPANT**
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

JAZZ PHARMACEUTICALS PLC
2011 EQUITY INCENTIVE PLAN

NON-U.S. OPTION AGREEMENT
(NONQUALIFIED 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 Nonqualified 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) 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;

(l) 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

(m) 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. The Employer, the Company and any Affiliate may collect, use, process, transfer or disclose your Personal Information for the purpose of implementing, administering and managing your participation in the Plan, in accordance with the Jazz Pharmaceuticals Employee Data Privacy Notice you have previously received. (Please contact Human Resources if you would like to receive another copy of this notice.) For example, your Personal Information may be directly or indirectly transferred to E*TRADE or any other third party stock plan service provider as may be selected by the Company, and any other third parties assisting the Company with the implementation, administration and management of the Plan.

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. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Ordinary Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Ordinary Shares, rights to Ordinary Shares (e.g., options) or rights linked to the value of Ordinary Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (a) disclosing the inside information to any third party and (b) "tipping" third parties or causing them otherwise to buy or sell securities (third parties include fellow employees). 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, as amended and restated by delegation of the Compensation Committee on May 25, 2018 and on January 31, 2019.

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 January 2019. 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

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 (including brokerage accounts) opened and maintained outside of Belgium on their annual tax returns. Belgian residents are also required to complete a separate report, providing the Central Contact Point of the National Bank of Belgium with details regarding any such account, including the account number, the name of the bank in which such account is held and the country in which such account is located the first time they report the foreign security and/or bank account on their annual tax returns. The forms to complete this report are available on the website of the National Bank of Belgium, www.nbb.be, under *Kredietcentrales / Centrales des crédits* caption. You should consult your personal tax advisor to ensure compliance with applicable reporting obligations.

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.

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.

NOTIFICATIONS

Securities Law Notification. You will not be permitted to sell or otherwise dispose of Ordinary Shares acquired upon exercise of the option within Canada. You will be permitted to sell or dispose of any Ordinary Shares only if such sale or disposal takes place outside of Canada through the facilities of the stock exchange on which the Ordinary Shares are traded (*i.e.,* Nasdaq).

Foreign Asset / Account Reporting. Canadian residents are required to report any foreign specified property (including unvested options and Ordinary Shares) annually on Form T1135 (Foreign Income Verification Statement) if the total cost of the foreign specified 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.

DENMARK

NOTIFICATIONS

Special Notice for Employees in Denmark. A Special Notice for Employees in Denmark, Employer Statement pursuant to the Danish Act on Stock Options, as amended effective January 1, 2019, will be provided to you under separate cover.

FINLAND

There are no country-specific provisions.

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 obligations.

IRELAND

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.

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 16 - Data Privacy; Section 17 - Governing Law and Venue; Section 18 - Language; Section 19 - Severability; Section 21 - Notices; Electronic Delivery; and Section 26 - Imposition of Other Requirements.

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

There are no country-specific provisions.

NORWAY

There are no country-specific provisions.

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, unless the transfer of funds is considered to be connected with the business activity of an entrepreneur, in which case a lower threshold may apply). 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

TERMS AND CONDITIONS

Language Consent. You hereby expressly declare that you have full knowledge of the English language and have read, understood and fully accepted and agreed with the terms and conditions established in the Plan and the Agreement.

Conhecimento da Lingua. Por meio do presente, eu declaro expressamente que tem pleno conhecimento da língua inglesa e que li, compreendi e livremente aceitei e concordei com os
termos e condições estabelecidas no Plano e no Acordo.

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.

SWEDEN

There are no country-specific provisions.

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:

Without limitation to Section 13 of the Agreement, you agree that you are liable for all Tax-Related Items and hereby covenant to pay all such Tax-Related Items as and when requested by the Company or the Employer or by Her Majesty's Revenue and Customs (**"*HMRC*"**) (or any other tax authority or any other relevant authority). You also agree to indemnify and keep indemnified the Company and the Employer against any taxes that they are required to pay or withhold or have paid or will pay on your behalf to HMRC (or any other tax authority or any other relevant authority).

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), the terms of the immediately foregoing provision will not apply. In such case, if the amount of any income tax due is not collected from or paid by you within 90 days of the end of the UK tax year in which an event giving rise to the indemnification described above occurs, 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:

Employer Company:	Jazz Pharmaceuticals UK Limited
Registered Office:	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 10.5

JAZZ PHARMACEUTICALS PLC
2011 EQUITY INCENTIVE PLAN
NON-U.S. RESTRICTED STOCK UNIT AWARD 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 Subject to Award:	
Consideration:	Participant's Services (payment of par value of newly issued shares)

Vesting Schedule:

Issuance Schedule: One Ordinary Share will be issuable 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 Unit Award 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.

ATTACHMENT I

NON-U.S. RESTRICTED STOCK UNIT AWARD 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.

(c) 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 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.

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) 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;

(j) 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

(k) 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. The Employer, the Company and any Affiliate may collect, use, process, transfer or disclose your Personal Information for the purpose of implementing, administering and managing your participation in the Plan, in accordance with the Jazz Pharmaceuticals Employee Data Privacy Notice you have previously received. (Please contact Human Resources if you would like to receive another copy of this notice.) For example, your Personal Information may be directly or indirectly transferred to E*TRADE or any other third party stock plan service provider as may be selected by the Company, and any other third parties assisting the Company with the implementation, administration and management of the Plan.

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. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Ordinary Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Ordinary Shares, rights to Ordinary Shares (e.g., RSUs) or rights linked to the value of Ordinary Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (a) disclosing the inside information to any third party and (b) "tipping" third parties or causing them otherwise to buy or sell securities (third parties include fellow employees). 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 (the "***Committee***") on July 31, 2013, and as amended and restated by the Committee on May 4, 2016 and November 2, 2016, and further amended and restated by delegation of the Compensation Committee on May 25, 2018 and on January 31, 2019.

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 January 2019. 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

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 (including brokerage accounts) opened and maintained outside of Belgium on their annual tax returns. Belgian residents are also required to complete a separate report, providing the Central Contact Point of the National Bank of Belgium with details regarding any such account, including the account number, the name of the bank in which such account is held and the country in which such account is located the first time they report the foreign security and/or bank account on their annual tax returns. The forms to complete this report are available on the website of the National Bank of Belgium, www.nbb.be, under *Kredietcentrales / Centrales des crédits* caption. You should consult your personal tax advisor to ensure compliance with applicable reporting obligations.

CANADA

TERMS AND CONDITIONS

Settlement of RSUs. Notwithstanding any discretion contained in Section 6(b)(iii) of 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.

NOTIFICATIONS

Securities Law Notification. You will not be permitted to sell or otherwise dispose of the Ordinary Shares acquired under the Plan within Canada. You will be permitted to sell or dispose of any Ordinary Shares only if such sale or disposal takes place outside of Canada through the facilities of the stock exchange on which the Ordinary Shares are traded (*i.e.,* Nasdaq).

Foreign Asset / Account Reporting. Canadian residents are required to report any foreign specified property (including unvested RSUs and Ordinary Shares) annually on Form T1135 (Foreign Income Verification Statement) if the total cost of the foreign specified 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.

DENMARK

NOTIFICATIONS

Special Notice for Employees in Denmark. A Special Notice for Employees in Denmark, Employer Statement pursuant to the Danish Act on Stock Options, as amended effective January 1, 2019, will be provided to you under separate cover.

FINLAND

There are no country-specific provisions.

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 obligations.

IRELAND

TERMS AND CONDITIONS

Vesting and Issuance. The following supplements Sections 2 and 6 of the Agreement:

Notwithstanding the vesting schedule provided in the Grant Notice and Section 6 (a) of the Agreement, (i) 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), and (ii) the Company elects not to satisfy any Tax-Related Items (defined in Section 10) by withholding Ordinary Shares, 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.

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

Tax Withholding Obligations. The following provisions replace Section 10 of the Agreement:

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***"). 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.

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 17 - Data Privacy; Section 18 - Governing Law and Venue; Section 19 - Language; Section 21- Notices; Electronic Delivery; and Section 26 - Severability.

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

There are no country-specific provisions.

NORWAY

There are no country-specific provisions.

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, unless the transfer of funds is considered to be connected with the business activity of an entrepreneur, in which case a lower threshold may apply). 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

TERMS AND CONDITIONS

Language Consent. You hereby expressly declare that you have full knowledge of the English language and have read, understood and fully accepted and agreed with the terms and conditions established in the Plan and the Agreement.

Conhecimento da Lingua. Por meio do presente, eu declaro expressamente que tem pleno conhecimento da língua inglesa e que li, compreendi e livremente aceitei e concordei com os termos e condições estabelecidas no Plano e no Acordo.

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

Tax Withholding Obligations. The following provisions replace Section 10 of the Agreement:

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 a cash bonus in the amount of the Ordinary Shares that are held back for the purpose of paying the Tax-Related Items and compensation in kind corresponding to the number of Ordinary Shares issued to you. 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.

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.

SWEDEN

There are no country-specific provisions.

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:

Without limitation to Section 10 of the Agreement, you agree that you are liable for all Tax-Related Items and hereby covenant to pay all such Tax-Related Items as and when requested by the Company or the Employer or by Her Majesty's Revenue and Customs ("***HMRC***") (or any other tax authority or any other relevant authority). You also agree to indemnify and keep indemnified the Company and the Employer against any taxes that they are required to pay or withhold or have paid or will pay on your behalf to HMRC (or any other tax authority or any other relevant authority).

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), the terms of the immediately foregoing provision will not apply. In such case, if the amount of any income tax due is not collected from or paid by you within 90 days of the end of the UK tax year in which an event giving rise to the indemnification described above occurs, 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 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.

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:

Employer Company:	Jazz Pharmaceuticals UK Limited
Registered Office:	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

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JAZZ PHARMACEUTICALS PLC

I. PREAMBLE

Jazz Pharmaceuticals plc (Jazz) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Jazz is entering into a Settlement Agreement with the United States.

Prior to the Effective Date, Jazz established a compliance program that Jazz represents addresses all seven elements of an effective compliance program and that is designed to address compliance with Federal health care program requirements (Compliance Program). Jazz shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Jazz may modify the Compliance Program as appropriate. However, at a minimum, Jazz shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Jazz under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Jazz's final Annual Report; or (2) any additional materials submitted by Jazz pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

    a. all owners of Jazz who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of Jazz;

b. all U.S. employees of Jazz who engage in or supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.5); and

c. all U.S. contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Jazz and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), consumers or independent third-party patient assistance programs; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Jazz employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to perform a Covered Function for Jazz more than 160 hours per year, except that any such individual shall become a "Covered Person" at the point when they work more than 160 hours on a Covered Function for Jazz during the calendar year.

2. "Government Reimbursed Products" refers to all Jazz products that are: (a) marketed or sold by Jazz in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

3. The term "Promotional Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Jazz's review and approval processes for promotional materials and any applicable review committee(s).

4. The term "Contribution and Assistance Related Functions" includes: all activities, systems, processes, and procedures relating to the following: (a) any grants, charitable contributions, or cash or in kind donations to any independent third-party patient assistance program (Independent Charity PAP) by Jazz or any entity acting on behalf of Jazz; and (b) the operation of, or participation in, any patient assistance program by Jazz or any entity acting on behalf of Jazz that provides free drugs to patients, including Federal health care program beneficiaries (i.e., Jazz's internal free drug program) or programs to provide financial assistance to patients in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay cards).

5. The term "Covered Functions" refers to "Promotional Functions," and "Contribution and Assistance Related Functions," collectively.

6. The term "Jazz Affiliate" shall mean any entity, including Jazz Pharmaceuticals Inc., that is owned or controlled directly or indirectly, by Jazz Pharmaceuticals plc and whose employees or contractors perform any Covered Functions. All obligations set forth in Section III below shall apply to the Covered Functions performed by any Jazz Affiliate and all references to "Jazz" in the defined terms set forth in this Section II shall mean Jazz and any Jazz

Affiliate. In addition, the notice requirements in Section IV and the certification obligations set forth in Section V.C. below shall apply to both Jazz and any Jazz Affiliate.

7. The term "Third Party Personnel" refers to personnel who engage in Promotional Functions who are employees of entities with which Jazz has entered or may in the future (during the term of this CIA) enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. Jazz represents that: (1) Third Party Personnel are employed by entities other than and independent of Jazz; (2) Jazz does not control Third Party Personnel; and (3) it would be commercially impractical to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Jazz agrees to promote compliance by Third Party Personnel with Federal health care program requirements by complying with the provisions set forth below in Sections III.C.4, V.A.7, and V.B.6. Provided that Jazz complies with the requirements of Sections III.C.4, V.A.7, and V.B.6, Jazz shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

8. The term "Board of Directors" or "Board" refers to the Board of Directors of Jazz Pharmaceuticals plc.

III. CORPORATE INTEGRITY OBLIGATIONS

Jazz shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations.

1. *Compliance Officer.* Within 90 days after the Effective Date, Jazz shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Jazz; shall report directly to the Chief Executive Officer of Jazz; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Jazz. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Nominating and Governance Committee of the Board of Directors and shall be authorized to report on such matters to the Nominating and Governance Committee at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Jazz and any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Jazz shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Jazz shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, clinical, human resources, and finance). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Jazz's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Jazz shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Nominating and Governance Committee of the Board of Directors (NGC) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The NGC must include independent (i.e., non-executive) members.

The NGC shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Jazz's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the NGC, summarizing its review and oversight of Jazz's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

> "The Nominating and Governance Committee of the Board of Directors (NGC) has made a reasonable inquiry into the operations of Jazz Pharmaceuticals' Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the NGC has concluded that, to the best of its knowledge, Jazz Pharmaceuticals has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

If the NGC is unable to provide such a conclusion in the resolution, the NGC shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Jazz.

Jazz shall report to OIG, in writing, any changes in the composition of the NGC, or any actions or changes that would affect the NGC's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Jazz employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Jazz division or business unit is in compliance with applicable Federal health care program requirements and the obligations of this CIA.

These Certifying Employees shall include, at a minimum, the following: Business Unit Head, Sleep; Business Unit Head, Hematology and Oncology; Vice President, Market Access; and Vice President, Corporate Affairs and Government Relations. For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Jazz policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department or functional area] of Jazz is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Jazz shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed,

sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards.

Within 120 days after the Effective Date, Jazz shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Jazz's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Jazz shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element in evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons as applicable to their job functions.

At a minimum, the Policies and Procedures shall address the following:

a. appropriate ways to conduct Contribution and Assistance Related Functions in compliance with all applicable Federal health care program requirements, including but not limited to, the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);

b. arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs. These Policies and Procedures shall be designed to ensure that Jazz's arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Jazz's arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);

c. the operation of, or participation in, any patient assistance program by Jazz or any entity acting on behalf of Jazz. These Policies and Procedures shall be designed to ensure that Jazz's operation of or in participation in such programs complies with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Jazz's operation of or participation in any such patient assistance program complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

d. the materials and information that may be distributed by appropriate Jazz personnel about Independent Charity PAPs or Contribution and Assistance Related Functions and the manner in, and circumstances under, which appropriate Jazz personnel may respond to requests for information about Independent Charity PAPs or Contribution and Assistance Related Functions; and

e. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act, and (ii) applicable Federal Food and Drug Administration (FDA) requirements.

At least annually (and more frequently, if appropriate), Jazz shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Covered Persons Training.* Within 90 days after the Effective Date, Jazz shall develop a written plan (Training Plan) that outlines the steps Jazz will take to ensure that: (a) all Covered Persons receive at least annual training regarding Jazz's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Jazz Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Jazz shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, each member of the Board shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board shall receive the Board Training described above within 30 days after becoming a Board member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* Jazz shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

4. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Jazz shall send a letter, either in hard copy or electronic form, to each entity employing Third Party Personnel. The letter shall outline Jazz's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of the Jazz Compliance Program. Jazz shall attach or otherwise make available a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make Jazz's Code of Conduct and a description of the Jazz Compliance Program available to its Third Party Personnel; or (b) represent to Jazz that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

D. Risk Assessment and Mitigation Process.

Within 120 days after the Effective Date, Jazz shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each of Jazz's Government Reimbursed Products and with applicable Federal health care program requirements. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products and risks associated with Jazz's operation of any patient assistance program and the company's arrangements and interactions with any Independent Charity PAPs, (2) develop audit work plans related to the identified risk areas, (3) implement the audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Jazz shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Jazz shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records.* The IRO and Jazz shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Jazz) related to the reviews.

c. *Access to Records and Personnel.* Jazz shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Review and Transactions Review. The Systems Review shall assess Jazz's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Jazz's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the second and fourth Reporting Periods. If Jazz materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the second and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review.

As set forth more fully in Appendix B, the Transactions Review shall include several components. In addition to the items specifically identified in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Jazz identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, OIG will consult with Jazz and may consider internal audit and monitoring work conducted by Jazz, the Government Reimbursed Product portfolio, the nature and scope of Jazz's promotional practices and arrangements with health care professionals and health care institutions, and other information known to it.

As set forth more fully in Appendix B, Jazz may propose to OIG that its internal audit(s) or monitoring be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. OIG retains sole discretion over whether, and in what manner, to allow Jazz's internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

OIG shall notify Jazz of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Jazz shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendix A and Appendix B.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Jazz a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A. The IRO's certification shall include a summary of current and prior engagements between Jazz and the IRO.

F. Disclosure Program.

Within 90 days after the Effective Date, Jazz shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Jazz's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Jazz shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Jazz's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Jazz. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Jazz shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded from participation in any Federal health care program; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

2. *Screening Requirements.* Jazz shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Jazz shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Jazz shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.

c. Jazz shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G. affects Jazz's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Jazz understands that items or services furnished, ordered, or prescribed by an excluded person are not payable by Federal health care programs and that Jazz may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Jazz meets the requirements of Section III.G.

3. *Removal Requirement.* If Jazz has actual notice that a Covered Person has become an Ineligible Person, Jazz shall remove such Covered Person from responsibility for, or involvement with, Jazz's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Jazz has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Jazz shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding.

Within 30 days after discovery, Jazz shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Jazz conducted or brought by a governmental entity or its agents involving an allegation that Jazz has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Jazz also shall provide written notice to OIG within 30 days after the resolution of the matter, and

shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

I. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

c. the filing of a bankruptcy petition by Jazz.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Jazz determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Jazz shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. Jazz shall not be required to report as a Reportable Event a matter that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents if disclosed under Section III.H above.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

c. the Federal health care programs affected by the Reportable Event; and

d. a description of Jazz's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section.* For Reportable Events under Section *III.I.1.b*, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion List screening that Jazz completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

J. Independent Charity Patient Assistance Program Activities

To the extent that Jazz makes monetary donations to Independent Charity PAPs, it shall implement the policies, procedures, and practices set forth in this Section III.J within 90 days after the Effective Date. Jazz shall continue the Independent Charity PAP policies, procedures, and practices described below (or equivalent processes) throughout the term of the CIA, and shall notify OIG in writing at least 60 days prior to the implementation of any modifications to such policies, procedures, and practices.

1. *Independent Charity Group.* Jazz shall vest sole responsibility and authority for budgeting and all other activities relating to Independent Charity PAPs in its existing Corporate Giving Executive Review Committee and Corporate Affairs Grant Manager (referred to herein as the "Independent Charity Group"), including the following roles and responsibilities:

a. The Independent Charity Group shall be separate and independent from Jazz's commercial organization.

b. The Independent Charity Group shall operate independently from Jazz's commercial organization and Jazz's commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Independent Charity PAPs.

c. Jazz shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding Jazz's donations to such PAPs and Jazz's commercial organization shall not communicate with, influence, or be involved in any communications with, or receive information from the Independent Charity PAPs.

d. Jazz's Independent Charity Group shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the PAP or over its assistance program.

e. For purposes of this CIA, the "commercial organization" shall be defined to include the sales, marketing, and similar commercial business units of Jazz.

2. *Budgeting Process.* Jazz's Independent Charity Group shall establish a budget process to be followed for Jazz's donations to Independent Charity PAPs that meets the following requirements:

a. The Independent Charity Group shall develop an annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the compliance department.

b. Jazz shall approve the annual budget for donations to Independent Charity PAPs at a level within the organization above the commercial organization (e.g., at the executive level).

c. The Independent Charity Group shall have sole responsibility for allocating the approved budget across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.

e. The Independent Charity Group shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget using standardized, objective criteria established by the Independent Charity Group. Any such requests also shall be subject to legal and compliance personnel review and approval, to ensure that any supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and Jazz Policies and Procedures.

f. The commercial organization shall have no involvement in the budget process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the Independent Charity Group from the commercial organization.

3. *Criteria Relating to Donations to Independent Charity PAPs.* The Independent Charity Group (with input from the legal department and compliance departments) shall establish objective written criteria that govern all donations to Independent Charity PAPs and any specific disease state funds of such PAPs. The criteria shall be designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from Jazz to patients and does not impermissibly influence patients' drug choices. In addition, Jazz agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

a. Jazz does not and shall not exert (directly or through any affiliate) any influence or control over the identification, delineation, establishment, or modification of any specific disease funds operated by the Independent Charity PAP. Among other things, Jazz has not made and shall not make (directly or through any affiliate) suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds.

b. Jazz does not and shall not exert (directly or through any affiliate) any direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program.

c. Jazz does not and shall not solicit or receive (directly or indirectly through third parties) any data or information from the Independent Charity PAP that would enable it to correlate the amount or frequency of its donations with support for Jazz's products or services.

d. Jazz does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Jazz's products.

e. Personnel from Jazz's legal and/or compliance departments shall review all proposed donations and arrangements between Jazz and any Independent Charity PAP prior to such donations being made or arrangements being entered into by Jazz.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Jazz proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are engaged in any of the Covered Functions; or (b) purchases or establishes a new business, business unit or location engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined

and agreed to in writing by OIG. Jazz shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Jazz wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Jazz must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within 150 days after the Effective Date, Jazz shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the NGC members who are responsible for satisfying the compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4 and a written copy of the process to be followed by Certifying Employees in connection with completing the required certifications;

5. a list of the Policies and Procedures required by Section III.B.3;

6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);

7. (a) a copy of the letter (including all attachments) required by Section III.C.4 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to Jazz's letter;

8. a description of the risk assessment and internal review process required by Section III.D;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO

has the qualifications outlined in Appendix A; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Jazz;

10. a description of the Disclosure Program required by Section III.F;

11. a description of the Ineligible Persons screening and removal process required by Section III.G.;

12. a description of the Independent Charity PAP policies, procedures, and practices required by Section III.J;

13. a list of all of Jazz's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

14. a description of Jazz's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

15. the certifications required by Section V.C.

B. Annual Reports.

Jazz shall submit to OIG a written report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. (a) any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; (b) a current list of the Compliance Committee members; (c) a current list of the NGC members; (d) a current list of the Certifying Employees, along with any changes made during the Reporting Period to the Compliance Committee, NGC, and Certifying Employees; and (e) a description of any changes to the process to be followed by Certifying Employees including the reasons for the changes;

2. the dates of each report made by the Compliance Officer to the NGC (written documentation of such reports shall be made available to OIG upon request);

3. the NGC resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the NGC, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

4. a list of any new or revised Policies and Procedures developed during the Reporting Period under Section III.B;

5. a description of any changes to Jazz's Training Plan developed pursuant to Section III.C and a summary of any Board training provided during the Reporting Period;

6. (a) a copy of the letter (including all attachments) required by III.C.4 sent to each party employing Third Party Personnel; (b) a list of all entities employing Third Party

Personnel with whom Jazz has entered into such co-promotion and other similar agreements; and (c) a description of the entities' response to Jazz's letter;

7. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;

8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

9. a complete copy of all reports prepared pursuant to Section III.E and Appendix B and Jazz's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

10. a certification from the IRO regarding its professional independence and objectivity with respect to Jazz;

11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure; (b) the date the disclosure was received; (c) the resolution of the disclosure; and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

15. a description of any changes to the Independent Charity PAP policies, procedures, and practices outlined in section III.J including the reasons for such changes;

16. a description of all changes to the most recently provided list of Jazz's locations as required by Section V.A.13;

17. a description of any changes to Jazz's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business engaged in the Covered Functions; and

18. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. *Certifying Employees.* In each Annual Report, Jazz shall include the certifications of Certifying Employees required by Section III.A.4;

2. *Implementation Report Certifications.* The Implementation Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, Jazz is in compliance with all of the requirements of this CIA; and

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

3. *Annual Report Certifications:* Each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, Jazz is in compliance with all of the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

c. he or she understands that the certification is being provided to and relied upon by the United States;

d. for each disease fund of an Independent Charity PAP to which Jazz made a donation during the Reporting Period, the facts and circumstances relating to the donation were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Jazz policies and procedures (including those outlined in Section III.J); and

e. for each patient assistance program that Jazz or any entity acting on behalf of Jazz operates or participates in (e.g., through cash or in-kind donations), the facts and circumstances relating to the program were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Jazz policies and procedures.

D. Designation of Information.

Jazz shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Jazz shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Jazz:

Eric Siegel, Esq.
Chief Compliance Officer
Jazz Pharmaceuticals, Inc.
2005 Market Street, Suite 2100
Philadelphia, PA 19103
215-372-9679
eric.siegel@jazzpharma.com

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Jazz may be required to provide OIG with an additional copy of each notification or report required by this CIA in the OIG's requested format (electronic or paper).

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy Jazz's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Jazz's locations for the purpose of verifying and evaluating: (a) Jazz's compliance with the terms of this CIA and (b) Jazz's compliance with the requirements of Federal health care programs. The documentation described above shall be made available by

Jazz to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Jazz's owners, employees, contractors and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Jazz shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Jazz's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Jazz present.

VIII. DOCUMENT AND RECORD RETENTION

Jazz shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Jazz prior to any release by OIG of information submitted by Jazz pursuant to its obligations under this CIA and identified upon submission by Jazz as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Jazz shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

Jazz is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Jazz and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Jazz fails to establish, implement or comply with any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. the NGC compliance obligations;

d. the management certification obligations;

e. written Policies and Procedures;

f. the development of a written training plan and the training and education of Covered Persons and Board Members;

g. a risk assessment and internal review process;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. reporting of Reportable Events; and

1. the Independent Charity PAP policies, procedures, and practices required by Section III.J.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Jazz fails to engage and use an IRO as required by Section III.E, Appendix A, or Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Jazz fails to submit a complete Implementation Report, Annual Report or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Jazz fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

5. A Stipulated Penalty of $1,500 for each day Jazz fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Jazz fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Jazz as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $2,500 for each day Jazz fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E, and for each day Jazz fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

8. A Stipulated Penalty of $1,000 for each day Jazz fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Jazz stating the specific grounds for its determination that Jazz has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Jazz shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Jazz receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 7 of this Section.

B. Timely Written Requests for Extensions. Jazz may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any

notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Jazz fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Jazz receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Jazz has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Jazz of: (a) Jazz's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Jazz shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an MIS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Jazz elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Jazz cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Jazz has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

   a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

   b. a failure by Jazz to report a Reportable Event and take corrective action as required in Section III.I;

c. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B; or

d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Jazz constitutes an independent basis for Jazz's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Jazz has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Jazz of: (a) Jazz's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Jazz shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

a. the alleged material breach has been cured; or

b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Jazz has begun to take action to cure the material breach; (ii) Jazz is pursuing such action with due diligence; and (iii) Jazz has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Jazz fails to satisfy the requirements of Section X.D.3, OIG may exclude Jazz from participation in the Federal health care programs. OIG shall notify Jazz in writing of its determination to exclude Jazz. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Jazz's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Jazz may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Jazz of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Jazz shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures

relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Jazz was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Jazz shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Jazz to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Jazz requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Jazz was in material breach of this CIA and, if so, whether:

a. Jazz cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Jazz's receipt of the Notice of Material Breach: (i) Jazz had begun to take action to cure the material breach within that period; (ii) Jazz pursued such action with due diligence; and (iii) Jazz provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Jazz, only after a DAB decision in favor of OIG. Jazz's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Jazz upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Jazz may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Jazz shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Jazz, Jazz shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Jazz and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Jazz's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

D. The undersigned Jazz signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF JAZZ PHARMACEUTICALS PLC

/s/ BRUCE COZADD	4/1/2019
BRUCE COZADD Chief Executive Officer Jazz Pharmaceuticals plc	DATE

/s/ MITCH LAZRIS	4/2/2019
MITCH LAZRIS, ESQ. MICHELE SARTORI, ESQ. Hogan Lovells US LLP Counsel for Jazz Pharmaceuticals plc	DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/s/ LISA M. RE — 4/02/2019

LISA M. RE — DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

/s/ MARY E. RIORDAN — 4/3/2019

MARY E. RIORDAN — DATE
Senior Counsel
Office of Counsel to the Inspector General

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. Jazz shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Jazz in response to a request by OIG, whichever is later, OIG will notify Jazz if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Jazz may continue to engage the IRO.

2. If Jazz engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Jazz shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Jazz at the request of OIG, whichever is later, OIG will notify Jazz if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Jazz may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in Federal health care program requirements (including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act) applicable to the Covered Functions being reviewed;

2. assign individuals to design and select any samples for the Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program requirements in making assessments in the IRO Review;

3. request clarification from the appropriate authority (e.g., OIG or CMS), if in doubt of the application of a particular Federal health care program requirement;

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Jazz Responsibilities

Jazz shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.E of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the IRO Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. Jazz *and IRO.* If Jazz terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Jazz must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Jazz must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. OIG Removal of IRO. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Jazz in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Jazz shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Jazz regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Jazz in writing that Jazz shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Jazz must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Jazz to engage a new IRO shall be made at the sole discretion of OIG.

CIA with Jazz Pharmaceuticals PLC

Appendix B

I. IRO Engagement, General Description

As specified more fully below, Jazz shall retain an Independent Review Organization (IRO) to perform engagements to assist Jazz in assessing and evaluating its systems, processes, policies, and procedures related to Covered Functions as defined in the CIA (IRO Reviews). The IRO Reviews shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Jazz may engage, at its discretion, a single entity to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Jazz's systems, processes, policies, and procedures relating to Contribution and Assistance Related Functions, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If Jazz materially changes its systems, processes, policies, and procedures relating to Contribution and Assistance Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

The Systems Review shall be a review of Jazz's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to select Contribution and Assistance Related Functions. Where practical, Jazz personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Jazz pursuant to the preceding sentence.

More specifically, the IRO shall review Jazz's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Jazz's systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) independent third-party patient assistance programs (Independent Charity PAPs).

   This review shall include an assessment of the following:

   a. Jazz's organizational structure as it relates to arrangements and interactions with Independent Charity PAPS, including:

i. the identification of those individuals, departments, or groups within Jazz (e.g., the Corporate Giving Executive Review Committee, Corporate Affairs, Finance, Legal and Compliance) that have responsibility for, or involvement with, such arrangements and interactions;
ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, arrangements and interactions with Independent Charity PAPs;
iii. the identification of those individuals, departments, or groups within Jazz (e.g., the commercial organization) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
iv. the methods that Jazz uses to separate Independent Charity PAP-related responsibilities from the commercial organization.

b. Jazz's written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:

i. the criteria governing whether and under what circumstances Jazz would donate to an Independent Charity PAP or any specific disease state fund of such a PAP;
ii. communications (including any limitations on such communications) between any representatives of Jazz and any Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications including the exchange of any data);
iii. communications (including any limitations on such communications) between those individuals, departments, or groups within Jazz with responsibility for Independent Charity PAPs and the commercial organization of Jazz (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications); and
iv. communications (including any limitations on such communications) between representatives of Jazz and health care providers or patients regarding assistance available through any Independent Charity PAP.

c. Jazz's policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.J.2 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;

d. Jazz's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to donate (or continue to donate) to a particular Independent Charity PAP; and ii) the amount of the donation (including any initial or annual amount and any supplemental amount);

e. Jazz's criteria, policies, and practices as they relate to donations made by Jazz to any Independent Charity PAPs as referenced in Section III.J.3, including the internal review process followed in connection with any donations to Independent Charity PAPs; and

f. Jazz's policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for Jazz's products.

2) Jazz's systems, policies, processes, and procedures relating to any patient assistance program that was formed or is funded, controlled, or operated (directly or indirectly) by Jazz or any person or entity acting on behalf of (or affiliated with) Jazz (including, but not limited to, its employees, agents, vendors, officers, shareholders, or contractors). This shall include any programs designed to provide free product or to provide other assistance (e.g., coupons or vouchers) to patients to reduce or eliminate the cost of copayments for drugs. These programs shall be collectively referred to as "Pharmaceutical Manufacturer PAPs".

This review shall include an assessment of the following:

a. The general elements of Pharmaceutical Manufacturer PAPs, including: i) the types of assistance that are made available through the Pharmaceutical Manufacturer PAPs; ii) the types of patients to whom each type of assistance is made available; iii) the eligibility criteria for the various types of assistance provided; and iv) the controls used to implement the eligibility criteria (i.e., controls employed to ensure that appropriate patients receive the various types of assistance);

b. Jazz's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to provide (or continue to provide) the various types of assistance through any Pharmaceutical Manufacturer PAP; and ii) the amount (or value) of the assistance to be provided through each program (including any initial or annual amount and any supplemental amount); and

c. Jazz's policies and practices as they relate to any contracts or agreements entered between Jazz and outside entities relating to any Pharmaceutical Manufacturers PAPs or the distribution of free product, including the individuals, groups, or departments involved in the negotiation process, the

requirements and terms of the contracts or agreements, and the review and approval of such contracts or agreements.

III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II above, the report shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of Jazz's systems, policies, processes, and procedures relating to the items identified in Sections II.1-2 above, including a general description of Jazz's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.1-2 above are made known or disseminated within Jazz;

4) a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP;

5) a detailed description of any system(s) used to track donations or other assistance provided in response to requests from Independent Charity PAPs;

6) a detailed description of any system(s) used to track assistance provided through any Pharmaceutical Manufacturer PAP;

7) findings and supporting rationale regarding any weaknesses in Jazz's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

8) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of Jazz's arrangements with selected Independent Charity PAPs; and (2) a review of up to three additional items identified by OIG in accordance with Section III.E.2 of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Arrangements with Independent Charity PAPs

The IRO shall conduct a review and assessment of Jazz's compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.J of the CIA. More specifically, the IRO shall review the arrangements and interactions with all Independent Charity PAPs or disease state funds with which Jazz entered charitable donation arrangements during the Reporting Period for which the IRO is conducting the review.

For purposes of this IRO review, the term "Reviewed Materials" shall include the following for each Independent Charity PAP arrangement reviewed:

1) the information on Jazz's website regarding Corporate Giving, including the online application portal through which Independent Charity PAPs must submit written requests for contributions;

2) donation requests from Independent Charity PAPs (which includes information on the particular disease state funds; details regarding patient eligibility criteria used by the Independent Charity PAPs; and information about the Independent Charity PAPs (e.g., information about administrative fees, patient grant amounts, average processing time to assist patients, etc.));

3) the approved annual budget for charitable giving, allocating the budget for donations to Independent Charity PAPs, and to any disease state funds established by the Independent Charity PAPs;

4) documentation that shows the objective criteria used to evaluate Independent Charity PAPs and the allocation of the approved budget across disease states and Independent Charity PAPs (e.g., Corporate Giving Executive Review Committee presentations and related documentation; documentation of due diligence performed by Jazz; and other relevant information, as applicable);

5) documents regarding donations to Independent Charity PAPs required by Jazz policy to evidence or document the review and approval of a decision to provide a donation to a particular fund of an Independent Charity PAP (i.e., minutes from Jazz's Corporate Giving Executive Review Committee that memorialize donation decisions, including budget allocation across disease states and Independent Charity PAPs, and final determinations (approvals or rejections) on proposed donations to Independent Charity PAPs);

6) to the extent not covered by item 2 above, all correspondence between Jazz and an Independent Charity PAP relating to any donation arrangement with the Independent Charity PAP;

7) any donation agreement documents entered into between Jazz and an Independent Charity PAP during the relevant Reporting Period; and

8) payment documentation required by Jazz policy reflecting: a) the total amount of donations Jazz agreed to make to an Independent Charity PAP broken down by disease fund, if applicable; b) the schedule of such payments, if applicable; c) the actual payments made; and d) any decisions to change the initial donation amount agreed to by Jazz.

In addition to reviewing documents and written materials, the IRO may also interview individuals at Jazz who have responsibility for arrangements and interactions with Independent Charity PAPs.

For each Independent Charity PAP selected as part of the IRO review, the IRO shall assess the Reviewed Materials and conduct any interviews to evaluate whether the Independent Charity PAP-related activities were conducted in a manner consistent with Jazz's policies and procedures including those described in Section III.J and with OIG guidance. More specifically, the IRO Review shall evaluate and identify:

1) Whether activities relating to arrangements with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within Jazz in accordance with the company's policies and procedures including those outlined in Section III.J;

2) Whether Jazz's commercial organization (as defined in Section III.J) influenced or were involved in Jazz's decisions to enter into an arrangement with an Independent Charity PAP in violation of Jazz's policies and procedures or OIG guidance;

3) Whether Jazz followed the budgeting policies and practices outlined in Section III.J.2 with regard to any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;

4) Whether Jazz followed the decision-making and approval process outlined in Section III.J of the CIA with regard to any decisions: i) whether to donate (or continue to donate) to the Independent Charity PAP; ii) the amount of the donation (including any initial or annual amount and any supplemental amount); and iii) the criteria governing whether Jazz would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;

5) Whether Jazz followed the criteria, policies, and practices outlined in Section III.J.3 of the CIA in connection with all donations made by Jazz to any Independent Charity PAP, including as they pertain to the internal review of potential donations and the adherence to the criteria specified in Section III.J.3;

6) Any communications that occurred between any representatives of Jazz and the Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications (including the exchange of any

data)) and whether any such communications complied with Jazz's policies and procedures and OIG guidance;

7) Whether, for each donation from Jazz to any Independent Charity PAP, Jazz complied with the requirements outlined in Section III.J.3; and

8) Whether, based on its review, the IRO found that Jazz exerted influence or control over the Independent Charity PAP in violation of Jazz's policies and procedures, including those outlined in Section III.J.3.

B. IRO Review of Additional Items

As set forth in Section III.E.2 of the CIA, for each Reporting Period, OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). The Additional Items may include activities undertaken by Jazz in connection with Promotional Functions, as defined in Section II.C.3 of the CIA. For the second through fifth Reporting Periods, the Additional Items Review may include activities undertaken by Jazz in connection with any Pharmaceutical Manufacturer PAP, including the provision of free product to patients.

No later than 150 days prior to the end of the applicable Reporting Period, OIG shall notify Jazz of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Jazz shall submit an audit work plan to OIG for approval.

The IRO shall conduct the review of the Additional Items based on a work plan approved by OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Jazz's systems, processes, policies, and procedures based on its review of each Additional Item).

Jazz may propose to OIG that relevant internal audit(s) or monitoring and/or other reviews conducted by outside entities at Jazz's request be substituted for one or more of the Additional Item reviews that would otherwise be conducted by the IRO for the applicable Reporting Period. OIG retains sole discretion over whether, and in what manner, to allow Jazz's internal audit work or monitoring and/or other reviews conducted by outside entities to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, OIG agrees to consider, among other factors, the nature and scope of Jazz's planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Jazz's demonstrated audit capabilities to perform the proposed audit work internally. If OIG denies Jazz's request to permit its internal audit work or monitoring and/or other reviews conducted by outside entities to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Jazz shall engage the IRO to perform the Review as outlined in this Section IV.

If OIG agrees to permit certain of Jazz's internal audit work or other reviews for a given Reporting Period to be substituted for a portion of an Additional Items review, such internal work or reviews may be subject to verification by the IRO (Verification Review). In such an instance, OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

C. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

1. General Elements to Be Included in Report

a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2. Results to be Included in Report

The following results shall be included in each Transactions Review Report:

(for the review of Independent Charity PAP arrangements)

a) a list of the Independent Charity PAPs to which Jazz made donations during the Reporting Period;

b) for each Independent Charity PAP arrangement reviewed by the IRO during the Reporting Period: i) a description of the review conducted by IRO; and ii) a summary of all instances in which it appears that Jazz failed to follow its policies and procedures and/or OIG guidance regarding its arrangements or interactions with an Independent Charity PAP;

c) for each Independent Charity PAP reviewed by the IRO, findings regarding each element specified above in Sections IV.A.1-8;

d) the findings and supporting rationale regarding any overall weaknesses in Jazz's systems, processes, policies, procedures,

and practices relating to its arrangements and interactions with Independent Charity PAPs; and

e) recommendations, if any, for changes in Jazz's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its arrangements and interactions with Independent Charity PAPs.

(Relating to the Review of Additional Items)

a) for each Additional Item reviewed, a description of the review conducted;

b) for each Additional Item reviewed, the IRO's findings based on its review;

c) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Jazz's systems, processes, policies, procedures, and practices relating to the Additional Item; and

d) for each Additional Item reviewed, recommendations, if any, for changes in Jazz's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the "United States") and Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland, Ltd. (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Jazz Pharmaceuticals plc is an Ireland public limited company with principal executive offices located in Dublin, Ireland; Jazz Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Delaware having a principal place of business in Palo Alto, California; and Jazz Pharmaceuticals Ireland, Ltd., is a corporation organized and existing under the laws of Ireland having a principal place of business in Dublin, Ireland (collectively, "Jazz"). During the relevant period of time, Jazz manufactured pharmaceutical products marketed in the United States, including Xyrem and Prialt. Xyrem is approved to treat both cataplexy and excessive daytime sleepiness in narcolepsy; its active ingredient is Gamma Hydroxybutyrate (GHB), a central nervous system depressant and controlled substance. From January 1, 2011 through May 31, 2014, Jazz increased Xyrem's list price by approximately 150%. Prialt is a non-opioid, non-NSAID analgesic agent approved for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or intrathecal morphine (collectively, the "Subject Drugs").

B. The United States contends that Jazz caused to be submitted claims for payment for the Subject Drugs to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395-1395lll ("Medicare").

C. When a beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a payment, which may take the form of a "copayment," "coinsurance," or "deductible" (collectively "copays"). The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare.

D. Caring Voice Coalition ("CVC"), an entity claiming 501(c)(3) status for tax purposes, operated funds that paid the copays of certain patients, including Medicare patients.

E. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against Jazz for engaging in the conduct below during the period from January 1, 2011, through May 31, 2014 (hereinafter referred to as the "Covered Conduct"). Specifically, the United States alleges that:

Jazz made donations to CVC and used CVC as a conduit to pay the copay obligations of Medicare patients taking the Subject Drugs.

In 2011, Jazz asked CVC to create a fund that would pay the copays of certain Xyrem patients, including Medicare patients. CVC then agreed to establish a "Narcolepsy Fund," and Jazz was the sole donor to the fund. Xyrem accounted for a small share of the overall narcolepsy drug market. Theoretically, the CVC Narcolepsy Fund could cover patients taking any narcolepsy medication, but, in practice, it almost exclusively assisted patients taking Xyrem. Jazz donated to CVC with this understanding. Moreover, CVC disadvantaged any patients seeking assistance for two competing narcolepsy drugs by requiring them to obtain a denial letter

from another assistance plan before being eligible for CVC assistance. Jazz knew or should have known that CVC favored patients taking Xyrem, and disadvantaged patients taking other medications. In conjunction with the establishment of CVC's Narcolepsy Fund, Jazz changed the eligibility criteria for its program that provided free Xyrem to patients who could not afford it and, as a result of this change, Medicare patients no longer qualified for the program. Instead, Jazz directed its distribution vendor to refer any Xyrem Medicare patients with unaffordable copays to CVC in order for Jazz to generate revenue from Medicare and to induce purchases of the drug, which resulted in claims to Medicare to cover the cost of the drug.

With respect to Prialt, Jazz asked CVC to create a fund ostensibly to assist patients with the co-pays of any severe chronic pain drugs, and CVC then created a "Severe Chronic Pain Fund." In practice, this fund almost exclusively assisted patients taking Prialt. Shortly after the creation of the fund, CVC told Jazz that, when severe chronic pain patients seeking assistance with drugs other than Prialt contacted CVC, CVC would refer them to another assistance program. Jazz further knew that the CVC Severe Chronic Pain Fund would not appear on the CVC website, which would result in fewer patients taking medications other than Prialt accessing the CVC fund.

As a result of the foregoing conduct, the United States contends that Jazz caused false claims to be submitted to Medicare.

F. In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Jazz shall pay to the United States fifty-seven million dollars ($57,000,000), plus interest at a rate of 2.75% from April 10, 2018, through the day before full payment (the "Settlement Amount"), no later than ten business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for District of Massachusetts. Of the Settlement Amount, $28,500,000 is restitution to the United States.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Jazz's full payment of the Settlement Amount, the United States releases Jazz, together with its predecessors, and its current and former divisions, parents, subsidiaries, successors and assigns, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of Jazz in this Agreement and the Corporate Integrity Agreement ("CIA") entered into between OIG-HHS and Jazz, and conditioned upon Jazz's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Jazz under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 4 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to

exclude Jazz from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the releases given in paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

5. Jazz waives and shall not assert any defenses Jazz may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the

Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. Jazz fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that Jazz has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Jazz agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

8. Jazz agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Jazz, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s), and any civil or criminal investigations of the matters covered by this Agreement;

(3) Jazz's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and any civil or criminal

investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Jazz makes to the United States pursuant to this Agreement; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP") (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 8.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Jazz.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Jazz, and Jazz shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Jazz or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Jazz further agrees that, within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph)

included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Jazz or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Jazz agrees that the United States, at a minimum, shall be entitled to recoup from Jazz any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Jazz or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Jazz or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Jazz's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Jazz agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors,

legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on Jazz's successors, transferees, heirs, and assigns.

18. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 4/4/19 **BY:** /s/ Gregg Shapiro

GREGG SHAPIRO
ABRAHAM GEORGE
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 4/3/19 **BY:** /s/ Augustine Ripa

AUGUSTINE RIPA
SARAH ARNI
Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 04/02/2019 **BY:** /s/ Lisa M. Re

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

JAZZ PHARMACEUTICALS plc
JAZZ PHARMACEUTICALS, INC.
JAZZ PHARMACEUTICALS IRELAND LTD

DATED: 3 Apr 2019 **BY:** /s/ Patricia Carr

PATRICIA CARR
Authorized Signatory
Jazz Pharmaceuticals plc

DATED: 4/3/2019 **BY:** /s/ Matthew Young

MATTHEW YOUNG
Executive Vice President and Chief Financial Officer
Jazz Pharmaceuticals, Inc.

DATED: 4-3-19 **BY:** /s/ Hugh Kiely

HUGH KIELY
Director
Jazz Pharmaceuticals Ireland Ltd.

DATED: 4/3/19 **BY:** /s/ Mitchell Lazris

MITCHELL J. LAZRIS
MICHELE W. SARTORI
Hogan Lovells LLP
Counsel for Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Ltd.

AMENDMENT NO. 1 TO PHARMACY MASTER SERVICES AGREEMENT

THIS AMENDMENT NO. 1 (the "Amendment") by and between Jazz Pharmaceuticals, Inc. and Express Scripts Specialty Distribution Services, Inc. ("ESSDS"), is entered into by and between the parties as of June 30, 2019 (the "Effective Date").

WHEREAS Jazz Pharmaceuticals and Company previously entered into that Pharmacy Master Services Agreement dated July 1, 2017 and any amendments thereto (the "Agreement");

WHEREAS, Jazz Pharmaceuticals and ESSDS now desire to amend the Agreement as set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and for other good and valuable consideration, the sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. In accordance Section 11.1 of the Pharmacy Master Services agreement, Jazz Pharmaceuticals is extending the term of the agreement. It shall be extended through June 30, 2020.

2. Except as expressly amended herein, the Agreement shall remain unchanged and in full force and effect.

Intending to be bound by the provisions hereof, the parties hereto have caused this Amendment to be executed personally or by their duly authorized representatives, to be effective as of the Effective Date.

AGREED TO:

Jazz Pharmaceuticals, Inc.

/s/ Michele Taylor

Name: Michele Taylor
Title: VP, Channel & Contract Operations

ACKNOWLEDGED:

Express Scripts Specialty Distribution Services, Inc.

/s/ Joshua Parker

Name: Joshua Parker
Title: Title: VP, Pharma Strategy & Contracting

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 7, 2019

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 7, 2019

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 period ended March 31, 2019, 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 7, 2019

/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.