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, 2020

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 D04 E5W7
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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 ☒

As of April 28, 2020, 55,330,359 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, 2020

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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, Sunosi® (solriamfetol), Defitelio® (defibrotide sodium), Defitelio® (defibrotide), Erwinaze® (asparaginase *Erwinia chrysanthemi*), Erwinase®, CombiPlex®, Vyxeos® (daunorubicin and cytarabine) liposome for injection and Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion. This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 701,602	$ 637,344
Investments	280,000	440,000
Accounts receivable, net of allowances	317,301	355,987
Inventories	85,610	78,608
Prepaid expenses	38,824	39,434
Other current assets	94,300	78,895
Total current assets	1,517,637	1,630,268
Property, plant and equipment, net	129,562	131,506
Operating lease assets	135,976	139,385
Intangible assets, net	2,238,658	2,440,977
Goodwill	909,226	920,018
Deferred tax assets, net	230,242	221,403
Deferred financing costs	6,887	7,426
Other non-current assets	47,107	47,914
Total assets	$ 5,215,295	$ 5,538,897
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 66,308	$ 47,545
Accrued liabilities	261,041	267,873
Current portion of long-term debt	33,387	33,387
Income taxes payable	31,211	10,965
Deferred revenue	4,176	4,720
Total current liabilities	396,123	364,490
Deferred revenue, non-current	4,225	4,861
Long-term debt, less current portion	1,576,984	1,573,870
Operating lease liabilities, less current portion	147,110	151,226
Deferred tax liabilities, net	165,095	224,095
Other non-current liabilities	117,258	109,374
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	2,294,474	2,266,026
Accumulated other comprehensive loss	(257,436)	(223,393)
Retained earnings	770,929	1,067,815
Total shareholders' equity	2,808,500	3,110,981
Total liabilities and shareholders' equity	$ 5,215,295	$ 5,538,897

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

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

	Three Months Ended March 31,	
	2020	2019
Revenues:		
Product sales, net	$ 530,205	$ 503,331
Royalties and contract revenues	4,521	4,855
Total revenues	534,726	508,186
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technologies)	28,657	33,506
Selling, general and administrative	208,400	167,947
Research and development	86,107	60,105
Intangible asset amortization	62,847	56,885
Acquired in-process research and development	202,250	56,000
Impairment charge	136,139	—
Total operating expenses	724,400	374,443
Income (loss) from operations	(189,674)	133,743
Interest expense, net	(18,496)	(17,922)
Foreign exchange loss	(1,132)	(611)
Income (loss) before income tax provision (benefit) and equity in loss (gain) of investees	(209,302)	115,210
Income tax provision (benefit)	(51,287)	29,116
Equity in loss (gain) of investees	(182)	893
Net income (loss)	$ (157,833)	$ 85,201
Net income (loss) per ordinary share:		
Basic	$ (2.82)	$ 1.49
Diluted	$ (2.82)	$ 1.47
Weighted-average ordinary shares used in per share calculations - basic	55,956	57,206
Weighted-average ordinary shares used in per share calculations - diluted	55,956	58,081

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

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

	Three Months Ended March 31,	
	2020	2019
Net income (loss)	$ (157,833)	$ 85,201
Other comprehensive income (loss):		
Foreign currency translation adjustments	(29,990)	(21,142)
Unrealized loss on hedging activities, net of income tax benefit of $579 and $249, respectively	(4,053)	(1,741)
Other comprehensive income (loss)	(34,043)	(22,883)
Total comprehensive income (loss)	$ (191,876)	$ 62,318

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, 2019	56,140	$ 6	4,000	$ 55	$ 472	$ 2,266,026	$ (223,393)	$ 1,067,815	$ 3,110,981
Issuance of ordinary shares in conjunction with exercise of share options	145	—	—	—	—	13,264	—	—	13,264
Issuance of ordinary shares in conjunction with vesting of restricted stock units	214	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(13,547)	—	—	(13,547)
Share-based compensation	—	—	—	—	—	28,731	—	—	28,731
Shares repurchased	(1,131)	—	—	—	—	—	—	(139,053)	(139,053)
Other comprehensive loss	—	—	—	—	—	—	(34,043)	—	(34,043)
Net loss	—	—	—	—	—	—	—	(157,833)	(157,833)
Balance at March 31, 2020	55,368	$ 6	4,000	$ 55	$ 472	$ 2,294,474	$ (257,436)	$ 770,929	$ 2,808,500

	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

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

	Three Months Ended March 31,	
	2020	2019
Operating activities		
Net income (loss)	$ (157,833)	$ 85,201
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Intangible asset amortization	62,847	56,885
Share-based compensation	28,654	27,552
Impairment charge	136,139	—
Depreciation	4,527	3,539
Acquired in-process research and development	202,250	56,000
Loss on disposal of assets	73	3
Deferred tax benefit	(63,976)	(17,053)
Provision for losses on accounts receivable and inventory	2,620	528
Amortization of debt discount and deferred financing costs	12,000	11,133
Other non-cash transactions	1,902	(738)
Changes in assets and liabilities:		
Accounts receivable	37,861	(56,960)
Inventories	(10,235)	(8,688)
Prepaid expenses and other current assets	(17,843)	(988)
Other non-current assets	323	426
Operating lease assets	3,195	2,108
Accounts payable	19,604	1,554
Accrued liabilities	(12,198)	(3,730)
Income taxes payable	20,829	39,726
Deferred revenue	(1,180)	(1,874)
Other non-current liabilities	7,316	6,773
Operating lease liabilities, less current portion	(3,906)	856
Net cash provided by operating activities	272,969	202,253
Investing activities		
Proceeds from maturity of investments	345,000	345,000
Purchases of property, plant and equipment	(4,830)	(7,948)
Acquired in-process research and development	(202,250)	(56,000)
Acquisition of intangible assets	(13,000)	—
Acquisition of investments	(185,000)	(115,000)
Net cash (used in) provided by investing activities	(60,080)	166,052
Financing activities		
Proceeds from employee equity incentive and purchase plans	13,264	3,057
Payment of employee withholding taxes related to share-based awards	(13,547)	(13,810)
Repayments of long-term debt	(8,347)	(8,347)
Share repurchases	(139,053)	(111,249)
Net cash used in financing activities	(147,683)	(130,349)
Effect of exchange rates on cash and cash equivalents	(948)	(112)
Net increase in cash and cash equivalents	64,258	237,844
Cash and cash equivalents, at beginning of period	637,344	309,622
Cash and cash equivalents, at end of period	$ 701,602	$ 547,466

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 and commercializing life-changing medicines for people with serious diseases – often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep medicine and movement disorders, and in oncology, including hematologic and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative drug delivery technologies.

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 both adult and pediatric patients with narcolepsy;
- **Sunosi® (solriamfetol)**, a product approved by FDA and marketed in the U.S. to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, and also recently approved in Europe in January 2020 by the European Commission;
- **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;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® liposomal 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 AML, or AML with myelodysplasia-related changes.

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 corporate development transactions; 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 and new geographies.

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, 2019.

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, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020, 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, 2019.

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.

Adoption of New Accounting Standards

In August 2018, the Financial Accounting Standards Board, or 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. We adopted this standard on January 1, 2020 and adoption did not have a material impact on our consolidated financial statements.

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. We adopted this standard on January 1, 2020 and adoption did not have a material impact on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" which requires that credit losses on financial assets measured at amortized cost be determined using an expected loss model, instead of the current incurred loss model, and requires that credit losses related to available-for-sale debt securities be recorded through an allowance for credit losses and limited to the amount by which carrying value exceeds fair value. We adopted this standard on January 1, 2020 and adoption did not have a material impact on our consolidated financial statements.

Significant Risks and Uncertainties

With the global impact of the COVID-19 pandemic, we have developed a comprehensive response strategy including establishing cross-functional response teams and implementing business continuity plans to manage the impact of the COVID-19 pandemic on our employees, customers and our business. Given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, we expect that our business, financial condition, results of operations and growth prospects will be adversely affected in the future. With respect to our commercialization activities, the evolving effects of the COVID-19 pandemic are having a negative impact on demand for our products, primarily due to the inherent limitations of telemedicine and a reprioritization of healthcare resources toward COVID-19. The extent of the impact on our ability to generate sales of and revenues from our approved products, execute on new product launches, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of or reemergence of outbreaks, governmental "stay-at-home" orders and travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Ireland and other countries, and the effectiveness of actions taken globally to contain and treat the disease.

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 authorized generic and generic versions of sodium oxybate and/or new products for treatment of cataplexy and/or EDS in narcolepsy in the U.S.

market, the potential impacts of the ongoing COVID-19 pandemic, including disruption of demand for our products and our ability to meet commercial demand, increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, challenges to our intellectual property around Xyrem, and continued acceptance of Xyrem by physicians and patients.

In addition to risks related specifically to Xyrem, we are subject to other challenges and risks related to successfully commercializing a portfolio of hematology/oncology products, including Defitelio, Erwinaze and Vyxeos, and other 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: obtaining regulatory approval of our late-stage product candidates including both JZP-258 and lurbinectedin in the U.S.; effectively commercializing our approved products such as Sunosi in the U.S. and EU and, if approved, JZP-258 and lurbinectedin; 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; identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; 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. In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

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, 2020, we had foreign exchange forward contracts with notional amounts totaling $225.4 million. As of March 31, 2020, the outstanding foreign exchange forward contracts had a net liability fair value of $3.6 million. As of March 31, 2020, we had interest rate swap contracts with notional amounts totaling $300.0 million. These outstanding interest rate swap contracts had a net liability fair value of $6.2 million as of March 31, 2020. 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, 2020 and December 31, 2019, allowances on receivables were not material. As of March 31, 2020, two customers accounted for 88% of gross accounts receivable, Express Scripts Specialty Distribution Services, Inc. and its affiliates, or ESSDS, which accounted for 81% of gross accounts receivable, and McKesson Corporation and affiliates, or McKesson, which accounted for 7% of gross accounts receivable. As of December 31, 2019, two customers accounted for 89% of gross accounts receivable, ESSDS, which accounted for 77% of gross accounts receivable, and McKesson, which accounted for 12% of gross accounts receivable.

We depend on single source suppliers for most of our products, product candidates and their active pharmaceutical ingredients, or 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 December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes", which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. The amendments are effective for annual

reporting periods beginning after December 15, 2020 with early adoption permitted. We are currently evaluating the impact of adopting this new accounting guidance.

2. License Agreement

On December 19, 2019, we entered into an exclusive license agreement with Pharma Mar, S.A., or PharmaMar, for development and U.S. commercialization of lurbinectedin, a product candidate under clinical investigation for the treatment of patients with relapsed small cell lung cancer, or SCLC. Lurbinectedin was granted orphan drug designation for SCLC by FDA in August 2018. In December 2019, PharmaMar submitted a new drug application, or NDA to FDA for accelerated approval of lurbinectedin for relapsed SCLC based on data from a Phase 2 trial, and in February 2020, FDA accepted the NDA for filing with priority review.

Under the terms of this agreement, which became effective in January 2020 upon expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, we paid PharmaMar an upfront payment of $200.0 million, which was recorded as acquired IPR&D expense in our consolidated statements of income (loss) for the three months ended March 31, 2020.

PharmaMar is eligible to receive potential regulatory milestone payments of up to $250.0 million upon the achievement of accelerated and/or full regulatory approval of lurbinectedin by FDA within certain timelines. PharmaMar is also eligible to receive up to $550.0 million in potential commercial milestone payments, as well as incremental tiered royalties on future net sales of lurbinectedin ranging from the high teens up to 30 percent. PharmaMar may receive additional payments on approval of other indications, with any such payments creditable against commercial milestone payment obligations. PharmaMar retains production rights for lurbinectedin and will supply the product to Jazz.

3. Cash and Available-for-Sale Securities

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

	March 31, 2020					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 226,349	$ —	$ —	$ 226,349	$ 226,349	$ —
Time deposits	630,000	—	—	630,000	350,000	280,000
Money market funds	125,253	—	—	125,253	125,253	—
Totals	$ 981,602	$ —	$ —	$ 981,602	$ 701,602	$ 280,000

	December 31, 2019					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 333,172	$ —	$ —	$ 333,172	$ 333,172	$ —
Time deposits	460,000	—	—	460,000	20,000	440,000
Money market funds	284,172	—	—	284,172	284,172	—
Totals	$ 1,077,344	$ —	$ —	$ 1,077,344	$ 637,344	$ 440,000

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 consolidated statements of income (loss). Our investment balances represent time deposits with original maturities of greater than three months and less than one year. Interest income from available-for-sale securities was $4.4 million and $4.8 million in the three months ended March 31, 2020 and 2019, respectively.

4. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of March 31, 2020 and December 31, 2019 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	March 31, 2020			December 31, 2019		
	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	$ —	$ 630,000	$ 630,000	$ —	$ 460,000	$ 460,000
Money market funds	125,253	—	125,253	284,172	—	284,172
Foreign exchange forward contracts	—	316	316	—	2,508	2,508
Totals	$ 125,253	$ 630,316	$ 755,569	$ 284,172	$ 462,508	$ 746,680
Liabilities:						
Interest rate contracts	$ —	$ 6,155	$ 6,155	$ —	$ 1,515	$ 1,515
Foreign exchange forward contracts	—	3,955	3,955	—	182	182
Totals	$ —	$ 10,110	$ 10,110	$ —	$ 1,697	$ 1,697

As of March 31, 2020, 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, 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 2020 or 2019.

As of March 31, 2020, 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 2018.

As of March 31, 2020, 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 $550 million and $502 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, 2020 and December 31, 2019, 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, 2020 and 2019 was as follows (in thousands):

	Three Months Ended March 31,	
Interest Rate Contracts:	**2020**	**2019**
Loss recognized in accumulated other comprehensive loss, net of tax	$ (4,200)	$ (1,341)
Loss (gain) reclassified from accumulated other comprehensive loss to interest expense, net of tax	147	(400)

Assuming no change in LIBOR-based interest rates from market rates as of March 31, 2020, $4.1 million of losses, 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, 2020 and December 31, 2019, the notional amount of foreign exchange contracts where hedge accounting is not applied was $225.4 million and $180.9 million, respectively.

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

	Three Months Ended March 31,	
Foreign Exchange Forward Contracts:	**2020**	**2019**
Loss recognized in foreign exchange loss	$ (6,139)	$ (3,409)

The cash flow effects of our derivative contracts for the three months ended March 31, 2020 and 2019 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, 2020			
	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	$ —	Accrued liabilities	$ 4,708
			Other non-current liabilities	1,447
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	316	Accrued liabilities	3,955
Total fair value of derivative instruments		$ 316		$ 10,110

	December 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	$ —	Accrued liabilities	$ 855
			Other non-current liabilities	660
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	2,508	Accrued liabilities	182
Total fair value of derivative instruments		$ 2,508		$ 1,697

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, 2020					
				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	$ 316	$ —	$ 316	$ (316)	$ —	$ —
Derivative liabilities	(10,110)	—	(10,110)	316	—	(9,794)

	December 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	$ 2,508	$ —	$ 2,508	$ (596)	$ —	$ 1,912
Derivative liabilities	(1,697)	—	(1,697)	596	—	(1,101)

6. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Raw materials	$ 13,901	$ 13,595
Work in process	37,689	36,658
Finished goods	34,020	28,355
Total inventories	$ 85,610	$ 78,608

7. Goodwill and Intangible Assets

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

Balance at December 31, 2019	$ 920,018
Foreign exchange	(10,792)
Balance at March 31, 2020	$ 909,226

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

	March 31, 2020				December 31, 2019		
	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	13.2	$ 3,152,634	$ (913,976)	$ 2,238,658	$ 3,166,485	$ (864,834)	$ 2,301,651
Manufacturing contracts	—	11,728	(11,728)	—	12,025	(12,025)	—
Trademarks	—	2,883	(2,883)	—	2,890	(2,890)	—
Priority review voucher	—	—	—	—	111,101	(111,101)	—
Total finite-lived intangible assets		3,167,245	(928,587)	2,238,658	3,292,501	(990,850)	2,301,651
Acquired IPR&D assets		—	—	—	139,326	—	139,326
Total intangible assets		$ 3,167,245	$ (928,587)	$ 2,238,658	$ 3,431,827	$ (990,850)	$ 2,440,977

The decrease in the gross carrying amount of intangible assets as of March 31, 2020 compared to December 31, 2019 reflects the impairment of our acquired IPR&D asset of $136.1 million following the decision to stop enrollment in our Phase 3 clinical study of defibrotide due to a determination that the study is highly unlikely to reach one of its primary endpoints, the prevention of VOD, the redemption of the Priority Review Voucher in January 2020 and the negative impact of foreign currency translation adjustments due to the weakening of the euro against the U.S. dollar, partially offset by the capitalization of milestone payments of $13.0 million triggered by European Marketing Authorization of Sunosi in January 2020.

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

Based on finite-lived intangible assets recorded as of March 31, 2020, 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
2020 (remainder)	$ 186,372
2021	203,041
2022	159,167
2023	159,167
2024	159,167
Thereafter	1,371,744
Total	$ 2,238,658

8. Certain Balance Sheet Items

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

	March 31, 2020	December 31, 2019
Leasehold improvements	$ 52,275	$ 52,294
Land and buildings	47,040	47,053
Manufacturing equipment and machinery	29,961	28,860
Computer software	23,044	25,680
Computer equipment	16,932	16,577
Furniture and fixtures	11,281	11,152
Construction-in-progress	4,472	5,147
Subtotal	185,005	186,763
Less accumulated depreciation and amortization	(55,443)	(55,257)
Property, plant and equipment, net	$ 129,562	$ 131,506

Accrued liabilities consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Rebates and other sales deductions	$ 121,369	$ 96,860
Employee compensation and benefits	52,080	80,290
Current portion of operating lease liabilities	12,357	12,728
Derivative instrument liabilities	8,663	1,037
Selling and marketing accruals	8,443	11,299
Inventory-related accruals	7,706	7,816
Sales returns reserve	4,519	3,462
Accrued collaboration expenses	3,865	2,494
Professional fees	3,495	4,718
Royalties	2,654	6,931
Accrued interest	2,520	7,386
Clinical trial accruals	2,473	2,551
Accrued construction-in-progress	256	1,564
Other	30,641	28,737
Total accrued liabilities	$ 261,041	$ 267,873

9. Debt

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

	March 31, 2020	December 31, 2019
2021 Notes	$ 575,000	$ 575,000
Unamortized discount and debt issuance costs on 2021 Notes	(33,152)	(38,865)
2021 Notes, net	541,848	536,135
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(112,389)	(117,859)
2024 Notes, net	462,611	457,141
Term loan	605,912	613,981
Total debt	1,610,371	1,607,257
Less current portion	33,387	33,387
Total long-term debt	$ 1,576,984	$ 1,573,870

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, 2020, 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, 2020 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2020 (remainder)	$ 25,040
2021	608,387
2022	33,387
2023	517,494
2024	575,000
Total	$ 1,759,308

10. Leases

The components of the lease expense for the three months ended March 31, 2020 and 2019 were as follows (in thousands):

	Three Months Ended March 31,	
Lease Cost	**2020**	**2019**
Operating lease cost	$ 5,290	$ 5,870
Short-term lease cost	870	601
Variable lease cost	1	3
Sublease income	(157)	(162)
Net lease cost	$ 6,004	$ 6,312

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

Leases	**Classification**	**March 31, 2020**	**December 31, 2019**
Assets			
Operating lease assets	Operating lease assets	$ 135,976	$ 139,385
Liabilities			
Current			
Operating lease liabilities	Accrued liabilities	12,357	12,728
Non-current			
Operating lease liabilities	Operating lease liabilities, less current portion	147,110	151,226
Total operating lease liabilities		$ 159,467	$ 163,954

Lease Term and Discount Rate	**March 31, 2020**	**December 31, 2019**
Weighted-average remaining lease term - operating leases (years)	9.6	9.7
Weighted-average discount rate - operating leases	5.3%	5.3%

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

	Three Months Ended March 31,	
	2020	**2019**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	$ 6,215	$ 4,576
Non-cash operating activities:		
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	$ 201	$ 151,029

(1) The March 31, 2019 disclosure includes the balances recognized on January 1, 2019 on adoption of ASU No. 2016-02, Leases.

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

Year Ending December 31,	Operating leases
2020 (remainder)	$ 15,097
2021	21,023
2022	21,044
2023	21,368
2024	23,711
Thereafter	104,655
Total lease payments	$ 206,898
Less imputed interest	(47,431)
Present value of lease liabilities	$ 159,467

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, 2020 and December 31, 2019. 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.

Other Commitments

As of March 31, 2020, we had $90.5 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.

12. Shareholders' Equity

Share Repurchase Program

In November 2016, our board of directors authorized a share repurchase program and as of March 31, 2020 had authorized the repurchase of ordinary shares having an aggregate purchase price of up to $1.5 billion, exclusive of any brokerage commissions. 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 credit agreement that we entered into in June 2015 and subsequently amended, which we refer to as 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, 2020, we spent a total of $139.1 million to purchase 1.1 million of our ordinary

shares under the share repurchase program at an average total purchase price, including commissions, of $122.91 per share. All ordinary shares repurchased were canceled. As of March 31, 2020, the remaining amount authorized under the share repurchase program was $438.7 million.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of March 31, 2020 and December 31, 2019 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, 2019	$ (1,325)	$ (222,068)	$ (223,393)
Other comprehensive loss before reclassifications	(4,200)	(29,990)	(34,190)
Amounts reclassified from accumulated other comprehensive loss	147	—	147
Other comprehensive loss, net	(4,053)	(29,990)	(34,043)
Balance at March 31, 2020	$ (5,378)	$ (252,058)	$ (257,436)

During the three months ended March 31, 2020, 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 (Loss) per Ordinary Share

Basic net income (loss) per ordinary share is based on the weighted-average number of ordinary shares outstanding. Diluted net income (loss) 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 (loss) per ordinary share were computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2020	2019
Numerator:		
Net income (loss)	$ (157,833)	$ 85,201
Denominator:		
Weighted-average ordinary shares used in per share calculations - basic	55,956	57,206
Dilutive effect of employee equity incentive and purchase plans	—	875
Weighted-average ordinary shares used in per share calculations - diluted	55,956	58,081
Net income (loss) per ordinary share:		
Basic	$ (2.82)	$ 1.49
Diluted	$ (2.82)	$ 1.47

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 (loss) per ordinary share because the average price of our ordinary shares for the three months ended March 31, 2020 and 2019 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 (loss) per ordinary share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended March 31,	
	2020	2019
Exchangeable Senior Notes	5,504	5,504
Options, RSUs and ESPP	5,611	4,988

14. Revenues

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

	Three Months Ended March 31,	
	2020	2019
Xyrem	$ 407,875	$ 368,317
Erwinaze/Erwinase	37,732	60,899
Defitelio/defibrotide	47,432	41,500
Vyxeos	32,720	28,943
Sunosi	1,924	—
Other	2,522	3,672
Product sales, net	530,205	503,331
Royalties and contract revenues	4,521	4,855
Total revenues	$ 534,726	$ 508,186

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

	Three Months Ended March 31,	
	2020	2019
United States	$ 478,483	$ 462,862
Europe	41,556	35,401
All other	14,687	9,923
Total revenues	$ 534,726	$ 508,186

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,	
	2020	2019
ESSDS	76%	72%
McKesson	13%	18%

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, 2020 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 $1.2 million during the three months ended March 31, 2020 relating to these upfront payments.

The deferred revenue balances are being recognized over an average of four years representing the period over which 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, 2020 (in thousands):

	Contract Liabilities
Balance as of December 31, 2019	$ 9,581
Amount recognized within royalties and contract revenues	(1,180)
Balance as of March 31, 2020	$ 8,401

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,	
	2020	2019
Selling, general and administrative	$ 20,596	$ 20,370
Research and development	6,385	5,523
Cost of product sales	1,673	1,659
Total share-based compensation expense, pre-tax	28,654	27,552
Income tax benefit from share-based compensation expense	(3,746)	(3,667)
Total share-based compensation expense, net of tax	$ 24,908	$ 23,885

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,	
	2020	2019
Shares underlying options granted (in thousands)	565	1,297
Grant date fair value	$ 33.65	$ 42.84
Black-Scholes option pricing model assumption information:		
Volatility	32%	32%
Expected term (years)	4.6	4.5
Range of risk-free rates	0.8-1.6%	2.4-2.5%
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,	
	2020	2019
RSUs granted (in thousands)	959	519
Grant date fair value	$ 114.19	$ 139.38

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, 2020, compensation cost not yet recognized related to unvested share options and RSUs was $82.5 million and $166.0 million, respectively, which is expected to be recognized over a weighted-average period of 2.7 years and 3.2 years, respectively.

16. Income Taxes

Our income tax benefit was $51.3 million in the three months ended March 31, 2020 compared to an income tax provision of $29.1 million for the same period in 2019. The effective tax rate was 24.5% in the three months ended March 31, 2020 compared to 25.3% for the same period in 2019. The decrease in the effective tax rate for the three months ended March 31, 2020 compared to the same period in 2019 was primarily due to the impact of the remeasurement of the deferred tax liability related to the Erwinaze intangible asset following the reduction in the estimated remaining useful life in February 2019 following receipt of a contract termination notice from PBL, partially offset by the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the PharmaMar transaction. The effective tax rate for the three months ended March 31, 2020 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.

On April 7, 2020 U.S. Treasury released final regulations implementing the hybrid mismatch rules under Internal Revenue Code Sections 245A(e) and 267A. Our financial statements are based on guidance that existed as of the reporting date and therefore do not include the tax implications of these final regulations. We will include any change in tax related to the regulations in the period in which they were enacted but estimate that they will not have a material impact on us.

Our net deferred tax asset is 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, and is net of deferred tax liabilities related to acquired intangible assets. We maintain a valuation allowance against certain foreign and U.S. 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). For Ireland we are no longer subject to income tax audits by taxing authorities for the years prior to 2015. The U.S. jurisdictions generally have statute 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 2015 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 and December 2019, we received revised tax assessment notices from the French tax authorities for 2012 and 2013 and in December 2018 and September 2019, we received a proposed tax assessment notice for 2015, 2016 and 2017, relating to certain transfer pricing adjustments. The notices propose additional French tax of approximately $41.0 million for 2012 and 2013 and approximately $11.7 million for 2015, 2016 and 2017 including interest and penalties through the respective dates of the proposed assessments, translated at the foreign exchange rate as of March 31, 2020. We disagree with the assessments and are contesting them vigorously. Certain of our Italian subsidiaries are currently under examination by the Italian tax authorities for the year ended December 31, 2017.

17. Subsequent Event

Revolving Credit Facility

In April 2020, in an abundance of caution and as a proactive measure, we drew down $500.0 million under the revolving credit facility provided for under the amended credit agreement to increase our cash position and preserve financial flexibility for corporate development and other investment opportunities in light of the current uncertainties and disruption to the global financial markets resulting from the COVID-19 pandemic.

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 and commercializing life-changing medicines for people with serious diseases – often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep medicine and movement disorders, and in oncology, including hematologic and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative drug delivery technologies.

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 both adult and pediatric patients with narcolepsy;
- **Sunosi® (solriamfetol)**, a product approved by FDA and marketed in the U.S. to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, or OSA, and also recently approved in Europe in January 2020 by the European Commission, or EC;
- **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;
- **Erwinaze® (asparaginase *Erwinia chrysanthemi*)**, a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® liposomal 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 AML with myelodysplasia-related changes.

Over the last five years, we achieved multiple significant regulatory approvals, including most recently the European approval of Sunosi, and executed on five product launches. Over the next two years, we look forward to three additional potential regulatory approvals and related product launches (lurbinectedin, JZP-258 and JZP-458 in the U.S.), as well as the commencement of the rolling launch of Sunosi in Europe by mid-2020.

In February 2020, FDA accepted for filing with priority review the new drug application, or NDA, for lurbinectedin for the treatment of relapsed small cell lung cancer, or SCLC, a product candidate for which we recently acquired exclusive U.S. development and commercialization rights, with a Prescription Drug User Fee Act, or PDUFA, action date of August 16, 2020.

In January 2020, we submitted an NDA to FDA seeking marketing approval for JZP-258, an oxybate product candidate that contains 92% less sodium than Xyrem, for the treatment of cataplexy and EDS in narcolepsy patients seven years of age and older. In March 2020, FDA accepted our NDA for filing with priority review with a PDUFA action date of July 21, 2020. The 92% reduction of sodium in JZP-258 translates into a reduction of approximately 1,000 to 1,500 milligrams per day for a patient prescribed an oxybate product, depending on the dose. 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 the lower sodium content of JZP-258 has the potential to offer a clinically meaningful benefit to patients who are prescribed an oxybate product to treat the chronic condition of narcolepsy.

In December 2019, we enrolled our first patient in our pivotal Phase 2/3 clinical study (conducted in collaboration with the Children's Oncology Group) for JZP-458, a recombinant *Erwinia* asparaginase product candidate, for the treatment of pediatric and adult patients with ALL or lymphoblastic lymphoma, or LBL, who are hypersensitive to *E. coli*-derived asparaginase products. The study continues to enroll, and we expect to submit a biologics license application, or BLA, to FDA for JZP-458 as early as the fourth quarter of 2020. JZP-458 was granted Fast Track designation by FDA in October 2019 for the treatment of this patient population.

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 corporate development transactions; 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 and new geographies.

Continued Emphasis on Research and Development

During the three months ended March 31, 2020, consistent with our strategy, we continued our focus on research and development activities within our sleep/neuroscience and hematology/oncology therapeutic areas, such as our recent expansion into movement disorders and solid tumors, and exploring and investing in adjacent therapeutic areas that could further diversify our portfolio.

Our development activities encompass all stages of development and currently include clinical testing of new product candidates and activities related to clinical improvements of, or additional indications or new clinical data for, our existing marketed products. We have also expanded into preclinical exploration of novel therapies, including precision medicines in hematology and oncology. We conduct a significant number of these activities by leveraging our growing internal research and development function, but we have also entered into collaborations with third parties for the research and development of innovative early-stage product candidates and have supported third party work seeking to perform additional clinical studies of our products. We also seek out investment opportunities in support of development of early-stage technologies in our therapeutic areas and adjacencies. Through third parties, we have a number of licensing and collaboration agreements related to preclinical and clinical research and development activities in hematology and in precision oncology.

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

Sleep and Neuroscience

Product Candidates	Description
Submitted for Regulatory Approval	
JZP-258 (oxybate; 92% sodium reduction)	Cataplexy and EDS in narcolepsy
Phase 3	
JZP-258 (oxybate; 92% sodium reduction)	Idiopathic hypersomnia
Phase 2b	
JZP-385	Essential tremor (planned study)
Preclinical	
JZP-324	Oxybate once-nightly formulation

Hematology and Oncology

Product Candidates	Description
Submitted for Regulatory Approval	
Lurbinectedin	Relapsed SCLC (exclusive U.S. license)
Phase 3	
Vyxeos	AML or high-risk Myelodysplastic Syndrome, or MDS (AML18 and AML19) (cooperative group studies)
	Newly diagnosed adults with standard- and high-risk AML (AML Study Group cooperative group study)
	Newly diagnosed pediatric patients with AML (planned Children's Oncology Group cooperative group study)
Lurbinectedin	Relapsed SCLC (ATLANTIS) (exclusive U.S. license)
Phase 2/3	
JZP-458 (recombinant *Erwinia* asparaginase)	ALL/LBL
Phase 2	
Defitelio	Prevention of aGvHD following allogeneic HSCT
	Prevention of CAR T-cell therapy-associated neurotoxicity
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes Cooperative Group cooperative group study)
	Newly diagnosed older adults with high-risk AML (planned cooperative group study)
Vyxeos + venetoclax	De novo or relapsed/refractory, or R/R, AML (MD Anderson collaboration study)
Phase 1	
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study)
Vyxeos + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study)
	First-line, fit AML (Phase 1b study)
	Low intensity therapy for first-line, unfit AML (Phase 1b study)
IMGN632	R/R CD123+ hematological malignancies (Jazz opt-in opportunity with ImmunoGen, Inc., or ImmunoGen)
	+/- venetoclax/azacitidine in CD123+ AML (Jazz opt-in opportunity with ImmunoGen; Phase 1b/2 study)
Preclinical	
CombiPlex	Hematology/oncology exploratory activities
JZP-341 (long-acting *Erwinia* asparaginase)	ALL and other hematological malignancies (collaboration with Pfenex, Inc., or Pfenex)
Recombinant pegaspargase	Hematological malignancies (Jazz opt-in opportunity with Pfenex)
Pan-RAF inhibitor program	RAF and RAS mutant tumors (acquired from Redx Pharma, which is continuing development)
Exosome targets (NRAS, STAT3 and 3 other candidates)	Hematological malignancies/solid tumors (collaboration with Codiak BioSciences, Inc.)
Defitelio	Exploratory activities

In April 2020, we announced our decision to stop enrollment in our Phase 3 clinical study of defibrotide due to a determination that the study is highly unlikely to reach one of its primary endpoints, the prevention of VOD. This does not impact the approved indication or other ongoing defibrotide studies. In 2020 and beyond, we expect that our research and development expenses will continue to increase from previous 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.

In addition, we remain focused on continuing to build excellence in areas that will give us a competitive advantage, including building an increasingly agile and adaptable commercialization engine and strengthening our customer-focused

market expertise across patients, providers and markets. We are refining our approach to engaging our customers by strengthening alignment and integration across functions and across regions. To that end, in 2020, we have set out to make several important organizational shifts to accelerate our progress, including a more integrated approach to brand planning, a new North American regional business structure, and a new global medical affairs organization. These initiatives mark a significant operational evolution that is directly linked to our corporate strategy and better enable our teams to work collaboratively on an aligned and shared agenda.

COVID-19 Business Update

With the global impact of the COVID-19 pandemic, we have developed a comprehensive response strategy including establishing cross-functional response teams and implementing business continuity plans to manage the impact of the COVID-19 pandemic on our employees, patients and our business. We experienced limited financial impacts during the first quarter of 2020. However, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, we expect that our business, financial condition, results of operations and growth prospects will be adversely affected in future quarters.

We support broad public health strategies designed to prevent the spread of COVID-19 and are focused on the health and welfare of our employees. In accordance with guidance issued by the Centers for Disease Control and Prevention, the World Health Organization and local authorities, in March 2020, our global workforce, including field-based teams, transitioned to working remotely. Our global organization has mobilized to enable our employees to accomplish our most critical goals in new ways, leveraging positivity, innovation and prioritization of resources to overcome new obstacles. In addition to rolling out new technologies and collaboration tools, we have implemented processes and resources to support our employees in the event an employee receives a positive COVID-19 diagnosis. We are now developing plans related to reopening our sites and enabling our employees to return to work in our global offices, the field and our manufacturing facilities, which plans will take into account applicable public health authority and local government guidelines and which are designed to ensure employee safety.

Commercialization

With respect to our commercialization activities, the evolving effects of the COVID-19 pandemic are having a negative impact on demand and new patient starts and treatments for our products, primarily due to the inherent limitations of telemedicine and a reprioritization of healthcare resources toward COVID-19. Due to the nature of the pandemic, we are not able to accurately predict the duration or extent of these impacts on demand for our products. Beginning in March 2020, we transitioned our sales, market access and reimbursement, and medical employees out of the field and suspended work-related travel and in-person customer interactions, including in-person interactions with healthcare professionals and customers. Since then, we have been utilizing technology to continue to engage healthcare professionals virtually to support patient care. As clinics and institutions begin to allow in-person interactions pursuant to health authority and local government guidelines, our field teams will start to re-initiate in-person interactions with healthcare professionals and clinics, but the timing and level of engagement will vary by account, region and country, and may be adversely impacted in the future where reemergence or future outbreaks of COVID-19 occur.

For Xyrem, the impact is related to the reduced ability of prescribers to diagnose narcolepsy patients given the limitations in access to sleep testing, which reduction in demand is evidenced in decreases in new patient enrollments in the Xyrem REMs program. Going forward, a negative impact may potentially be seen on patient compliance and persistence with Xyrem treatment, and the ability to fill, access and pay for prescriptions. For Sunosi, the impact on demand is related to the minimized ability of our field-based teams to interact with new prescribers and patients' ability to fill, access and pay for prescriptions, and is evidenced in slower than budgeted growth of new prescribers and new patient starts in the U.S. We also anticipate delays by certain European regulatory authorities in their pricing and reimbursement reviews due to the pandemic, which is likely to delay our rolling Sunosi launch in certain European Union, or EU, member states. In addition, the reprioritization of healthcare resources and related delays, postponements or suspensions of certain medical procedures such as stem cell transplants is resulting in a decrease in demand for Defitelio. In the U.S., we are also seeing a shift toward less intensive outpatient AML treatments due to COVID-19, which is directly negatively impacting the use of Vyxeos, which prescribers are still primarily utilizing in inpatient settings, despite its availability for use in outpatient settings.

Depending on the scale and ultimate duration the COVID-19 pandemic and the extent of a global economic slowdown, widespread unemployment and resulting loss of employer-sponsored insurance coverage, we may experience a shift from commercial payor coverage to government payor coverage or an increase in demand for patient assistance and/or free drug programs, which would adversely affect access to our products and our net sales. We have seen an upward trend in demand for patient support and free drug program services since the end of the first quarter of 2020.

Supply Chain

We currently expect to have adequate global supply of Xyrem, Sunosi, Defitelio and Vyxeos in 2020, as well as adequate commercial product availability for lurbinectedin and JZP-258 to support planned U.S. launches if these product candidates are approved by FDA this year. However, the manufacturer of Erwinaze continues to have supply disruptions unrelated to the impact of the COVID-19 pandemic, and we are experiencing supply disruptions of Erwinaze in the U.S. and expect to continue to experience supply disruptions globally in 2020. We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to our product supplies as a result of the COVID-19 pandemic.

Our manufacturing facility in Athlone, Ireland, which produces Xyrem and JZP-258, currently continues to be operational, but we are managing operations through limited "essential" on-site staff and flexible work arrangements. In March 2020, we temporarily ceased operations at our Villa Guardia, Italy manufacturing facility, which produces defibrotide, to ensure the safety of our employees and communities in northern Italy. We are developing plans for a phased reopening of our Villa Guardia facility that takes into account applicable public health authority and local government guidelines as well as employee safety. If the COVID-19 pandemic persists for an extended period of time and begins to impact essential distribution systems such as FedEx and postal delivery, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products, which would adversely impact our ability to generate sales of and revenues from our approved products.

Research and Development

We are seeing a COVID-19-related impact on our clinical trial activities. We have taken measures to implement remote and virtual approaches, including remote data monitoring where possible, to maintain patient safety and trial continuity and to preserve study integrity. We are seeing an impact on our ability to initiate trial sites, enroll patients and maintain patient enrollment in our clinical programs and have suspended two of our healthy volunteer clinical development programs, JZP-385 and JZP-324, in the interest of volunteer safety. We could also see an impact on the ability to supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority employee resources or otherwise. In addition, we rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the COVID-19 pandemic continues and persists for an extended period of time or reemerges in the future, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects. For example, while we are continuing to activate sites and enroll our JZP-458 study, we are experiencing a slowdown in site activation or enrollment as lab closures increase and sites begin limiting personnel to "essential" workers.

FDA accepted for filing with priority review the NDAs for lurbinectedin and JZP-258 with PDUFA action dates in the third quarter of 2020. FDA has indicated that an advisory committee meeting is not currently planned for lurbinectedin. However, the timing of NDA review and/or our interactions with FDA may be impacted due to, for example, limited staffing or working hours of governmental employees, governmental "stay-at-home" orders and travel restrictions with respect to physical inspections if required for regulatory approval, or the diversion of FDA's efforts and attention to approval of other therapeutics or other activities related to COVID-19. Such delays and impact may affect approval decisions with respect to our JZP-258 and lurbinectedin NDAs and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals.

Corporate Development and Other Financial Impacts

With our strong cash balance and positive cash flow, we anticipate having sufficient liquidity to make planned investments in our business in support of our long-term growth strategy. However, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. As a result, in April 2020, in an abundance of caution and as a proactive measure, we drew down $500.0 million under our previously undrawn $1.6 billion revolving credit facility to increase our cash position and preserve financial flexibility for corporate development and other investment opportunities. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. The pandemic could also impact our ability to do in-person due diligence, negotiations, and other interactions to identify new opportunities.

While we expect the COVID-19 pandemic to adversely affect our business operations and financial results, the extent of the impact on our ability to generate sales of and revenues from our approved products, execute on new product launches, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of or reemergence of outbreaks, governmental "stay-at-home" orders and travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Ireland and other countries, and the effectiveness

of actions taken globally to contain and treat the disease. For example, the inability of our work-force to return to office and field based work and the ongoing stress and reprioritization within the healthcare systems in our key markets may require us to reassess the timing and scope of key business activities for the year, including our ability to successfully launch JZP-258 and lurbinectedin, if approved.

Corporate Response

The rapid spread of COVID-19 has caused a significant burden on health systems globally and has highlighted the need for companies to evaluate existing therapies to assess if they can be utilized beyond their current indications to treat COVID-19 as well as consider developing new therapies. We have accelerated our efforts to study, build expertise and generate data around defibrotide in the treatment of acute respiratory distress syndrome, a severe and relatively common symptom of COVID-19. We have received and granted requests for investigator-sponsored trials, or ISTs, to evaluate the use of defibrotide in COVID-19 patients experiencing respiratory distress. Currently, two Phase 2 programs are in progress to evaluate the potential use of defibrotide in COVID-19 patients: an IST in Spain for the prevention and treatment of respiratory distress and cytokine release syndrome and a trial in Italy to evaluate the reduction in the rate of respiratory failure in patients with COVID-19 pneumonia.

In addition, we are supporting our local communities and patient-focused organizations in COVID-19 relief efforts including through corporate donations to charitable organizations providing food and medical relief to our communities in which we operate in Italy, Philadelphia and the San Francisco Bay Area, and other localities where the needs related to the impact of COVID-19 are greatest. We are engaging with patient advocacy organizations to better understand the impact of COVID-19 and working to ensure that patients living with sleep disorders and hematology and oncology conditions continue to have access to treatments and that their other needs are addressed given the impact of COVID-19 on the healthcare system. We are committed to enabling our employees to give back, including allowing licensed healthcare practitioners employed by us to support local response efforts.

Other Challenges, Risks and Trends Related to Our Business

Our business is substantially dependent on Xyrem. 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 2020, and there is no guarantee that we will be able to make similar price adjustments in the future or that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes and revenues from Xyrem. In the future, we expect Xyrem to face competition from generic and authorized generic versions of sodium oxybate pursuant to the settlement agreements we have entered into with multiple abbreviated new drug application filers. Generic competition can decrease the prices at which Xyrem is sold and the number of prescriptions written for Xyrem. Xyrem may also face competition from other branded sodium oxybate products and other new and existing branded market entrants.

As for other products and product candidates in our sleep and neuroscience therapeutic area, we obtained approval of Sunosi in the U.S. and EU, and in January 2020, we submitted an NDA for marketing approval of JZP-258. Our future plans assume that, if approved, JZP-258 may be prescribed to patients as a safer and clinically superior alternative to Xyrem as well as being prescribed to patients who may otherwise be ineligible to take Xyrem due to its high sodium content. Although FDA has accepted our NDA for filing and set a PDUFA action date of July 21, 2020, we cannot guarantee that JZP 258 will be approved by that date. For example, FDA could determine that our application is not sufficient to support approval with the label we have requested, and require amendments or additional data, which could delay or preclude the approval of our NDA. In April 2020, Avadel Pharmaceuticals plc, or Avadel, announced positive topline results from its Phase 3 clinical trial of a once-nightly formulation of sodium oxybate that uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy. Avadel has indicated that it intends to seek approval using the Section 505(b)(2) approval pathway referencing the safety and efficacy data for Xyrem. If 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 a narcolepsy indication for seven years unless it can establish clinical superiority to Avadel's product. We cannot predict the timing of Avadel's submission or how FDA will evaluate any clinical superiority arguments that either company may make, but a delay in approval or inability to obtain approval for JZP-258 could materially and adversely affect our business, financial condition, results of operations and growth prospects. If we are unable to successfully commercialize Sunosi and/or JZP-258 (if approved), or if sales of Sunosi and JZP-258 do not reach the levels we expect, our anticipated revenue from our sleep therapeutic area will be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to our sleep and neuroscience products and product candidates, we are commercializing a portfolio of hematology/oncology products, including Defitelio, Erwinaze and Vyxeos. An inability to effectively commercialize Defitelio

and Vyxeos 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.

Our license and supply agreement with Porton Biopharma Limited, a limited liability company wholly owned by the UK Secretary of State for Health, or PBL, which includes an exclusive right to market, sell or distribute Erwinaze, an exclusive license to Erwinaze trademarks, and a non-exclusive license to PBL's manufacturing know-how, will expire on December 31, 2020. In April 2020, PBL announced that it had entered into an agreement with a new partner to commercialize and distribute Erwinaze after our license and supply agreement expires. As a result, our ability to generate revenue through Erwinaze sales in the future will be adversely impacted. Under our agreement with PBL, we have the right to sell certain Erwinaze inventory for a post-termination sales period of 12 months and retain ownership of certain data, know-how and other property interests, including the BLA for Erwinaze in the U.S. and marketing authorizations for Erwinase in several other countries. We intend to work with PBL to address business transition post-termination to ensure continuity of patient care. However, in the past, we have had disagreements with PBL over product quality and supply, the costs of remediation, and other rights and obligations under the existing contract. Our ability to supply the market and generate future sales of product including that related to product we are entitled to receive post-termination during 2021 will depend on PBL's ability to address Erwinaze manufacturing and quality issues and on the level of product supply PBL provides us before and after the termination date. We may not receive Erwinaze product that we expect from PBL to be able to supply the market during the post-termination sales period and may incur costs, including time and distraction of relevant employees, associated with resolution of any disputes with PBL. If PBL is unable to remediate the quality and manufacturing issues that have required oversight by us in order to get product to patients in the U.S., Erwinaze shortages may increase, and we could suffer reputational harm based on our historical and current association with the product. If we are unable to replace the future product sales we will lose from Erwinaze, our business, financial condition, results of operations and growth prospects would be materially adversely affected.

A key aspect of our growth strategy is our continued investment in our evolving and expanding research and development activities. If we are not successful in the clinical development of these or other 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.

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. Failure to identify and acquire, in-license or develop additional products or product candidates, 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, could have a material adverse effect on our business, results of operations and financial condition.

We are increasingly experiencing pressure from third party payors to agree to discounts, rebates or restrictive pricing terms for Xyrem. We also need to obtain adequate formulary positions and reimbursement coverage for newly-launched products such as Sunosi and future products, if approved, such as JZP-258, JZP-458 and lurbinectedin. Entering into agreements with pharmacy benefit managers, or PBMs, and payors to ensure patient access has and will likely continue to result in higher gross to net deductions for future periods for these products. We cannot guarantee we will be able to agree to commercially reasonable terms with PBMs and other third party payors, or that we will be able to ensure patient access to our existing and future products. In addition to increasing pricing pressure from, and restrictions on reimbursement imposed by payors, healthcare cost containment has received global attention, and drug pricing by pharmaceutical companies is currently, and is expected to continue to be, subject to close scrutiny by both federal and state governments. 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 may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

Finally, business practices by pharmaceutical companies, including product formulation improvements, patent settlements, and REMS programs, have increasingly drawn public scrutiny from legislators and regulatory agencies, 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 our business practices, including as they relate to the Xyrem REMS, the launch of JZP-258, our patent settlements 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. In addition, to the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described above. All of these risks and uncertainties are discussed in greater detail, along with other risks and uncertainties, 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/
	2020	2019	(Decrease)
Product sales, net	$ 530,205	$ 503,331	5 %
Royalties and contract revenues	4,521	4,855	(7)%
Cost of product sales (excluding amortization of acquired developed technologies)	28,657	33,506	(14)%
Selling, general and administrative	208,400	167,947	24 %
Research and development	86,107	60,105	43 %
Intangible asset amortization	62,847	56,885	10 %
Impairment charge	136,139	—	N/A(1)
Acquired in-process research and development	202,250	56,000	261 %
Interest expense, net	18,496	17,922	3 %
Foreign exchange loss	1,132	611	85 %
Income tax provision (benefit)	(51,287)	29,116	N/A(1)
Equity in loss (gain) of investees	(182)	893	(120)%

(1) Comparison to prior period not meaningful.

Revenues

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

	Three Months Ended March 31,		Increase/
	2020	2019	(Decrease)
Xyrem	$ 407,875	$ 368,317	11 %
Erwinaze/Erwinase	37,732	60,899	(38)%
Defitelio/defibrotide	47,432	41,500	14 %
Vyxeos	32,720	28,943	13 %
Sunosi	1,924	—	N/A(1)
Other	2,522	3,672	(31)%
Product sales, net	530,205	503,331	5 %
Royalties and contract revenues	4,521	4,855	(7)%
Total revenues	$ 534,726	$ 508,186	5 %

Product Sales, Net

Xyrem product sales increased in the three months ended March 31, 2020 compared to the same period in 2019 primarily due to a higher average net selling price and, to a lesser extent, an increase in sales volume. Price increases were instituted in July 2019 and January 2020. Xyrem product sales volume increased by 5% in the three months ended March 31, 2020 compared to the same period in 2019 primarily driven by an increase in the average number of patients on Xyrem. Erwinaze/ Erwinase product sales decreased in the three months ended March 31, 2020 compared to the same period in 2019 primarily due to limited availability of inventory from the manufacturer. Ongoing supply challenges continue to negatively impact our ability to supply the market. We are experiencing supply disruptions of Erwinaze in the U.S. and expect to continue to experience supply disruptions globally in 2020. Defitelio/defibrotide product sales increased in the three months ended March 31, 2020 compared to the same period in 2019 primarily due to higher sales volumes and, to a lesser extent, the impact of a price increase instituted in July 2019. Vyxeos product sales increased in the three months ended March 31, 2020 compared to the same period in 2019 primarily driven by an increase in sales volume in Europe. Sunosi product sales in the three months ended March 31, 2020 were $1.9 million. Sunosi launched in the U.S. launch in July 2019. We expect total product sales for 2020 will be consistent with 2019 as the evolving effects of the COVID-19 pandemic are having a negative impact, and are

expected to continue to have a negative impact, on demand for our products and growth in our net sales. See "Overview—COVID-19 Business Update" above.

Royalties and Contract Revenues

Royalties and contract revenues in the three months ended March 31, 2020 were consistent with the same period in 2019. We expect royalties and contract revenues to decrease in 2020 compared to 2019 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, 2020 compared to the same period in 2019 primarily due to changes in product mix. Gross margin as a percentage of net product sales was 94.6% for the three months ended March 31, 2020 compared to 93.3% for the same period in 2019. We expect that our gross margin as a percentage of net product sales will not change materially in 2020 compared to 2019.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in the three months ended March 31, 2020 compared to the same period in 2019 primarily due to higher sales and marketing expenses related to our products and pre-launch commercialization activities for product candidates as well as an increase in other expenses related to the expansion of our business. We expect selling, general and administrative expenses in 2020 to increase compared to 2019, primarily due to an increase in expenses related to the continuation of the commercial launch of Sunosi in the U.S., the commercial launch of Sunosi in Europe and, if approved, the planned commercial launches of both lurbinectedin and JZP-258 in the U.S.

Research and Development Expenses

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses 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,	
	2020	2019
Clinical studies and outside services	$ 47,749	$ 30,231
Personnel expenses	25,902	21,310
Other	12,456	8,564
Total	$ 86,107	$ 60,105

Research and development expenses increased by $26.0 million in the three months ended March 31, 2020 compared to the same period in 2019. Clinical studies and outside services costs increased by $17.5 million in the three months ended March 31, 2020 compared to the same period in 2019 primarily due to higher clinical trial costs primarily associated with JZP-458 and JZP-258 in idiopathic hypersomnia, and an increase in expenses related to our ongoing preclinical and clinical development programs and support of partner programs. Personnel expenses increased by $4.6 million in the three months ended March 31, 2020 compared to the same period in 2019 primarily due to increased headcount in support of our development programs.

The COVID-19 pandemic is impacting our research and development activities in 2020 and we expect that our research and development expenses will be consistent with 2019. For 2021 and beyond we anticipate that research and development expenses will increase 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 $6.0 million in the three months ended March 31, 2020 compared to the same period in 2019, primarily due to the reduction in the estimated remaining useful life of the Erwinaze intangible asset resulting from the contract termination notice we received from PBL in February 2019. Intangible asset amortization is expected to decrease in 2020 compared to 2019 as a result of the amortization in full of our priority review voucher intangible asset in the fourth quarter of 2019.

Impairment Charge

In the three months ended March 31, 2020, we recorded an acquired in-process research and development, or IPR&D, asset impairment charge of $136.1 million following the decision to stop enrollment in our Phase 3 clinical study of defibrotide due to a determination that the study is highly unlikely to reach one of its primary endpoints, the prevention of VOD.

Acquired In-Process Research and Development

Acquired IPR&D expense in the three months ended March 31, 2020 primarily related to an upfront payment of $200.0 million to Pharma Mar, S.A. in connection with our license agreement. Acquired 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 increased by $0.6 million in the three months ended March 31, 2020 compared to the same period in 2019, primarily due to higher interest expense. We expect interest expense, net will increase in 2020 compared to 2019, primarily due to the increase in our average debt balance following the drawdown of $500.0 million under our revolving credit facility in April 2020.

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 (Benefit)

Our income tax benefit was $51.3 million in the three months ended March 31, 2020 compared to an income tax provision of $29.1 million for the same period in 2019. The effective tax rate was 24.5% in the three months ended March 31, 2020, compared to 25.3% for the same period in 2019. The decrease in the effective tax rate for the three months ended March 31, 2020 compared to the same period in 2019 was primarily due to the impact of the remeasurement of the deferred tax liability related to the Erwinaze intangible asset following the reduction in the estimated remaining useful life in February 2019 following receipt of a contract termination notice from PBL, partially offset by the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the PharmaMar transaction. The effective tax rate for the three months ended March 31, 2020 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.

Equity in Earnings of Investees

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

Liquidity and Capital Resources

As of March 31, 2020, we had cash, cash equivalents and investments of $1.0 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 $609.3 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 $273.0 million during the three months ended March 31, 2020, and we expect to continue to generate positive cash flows from operations during 2020.

In April 2020, in an abundance of caution and as a proactive measure, we drew down $500.0 million under the revolving credit facility provided for under the amended credit agreement to increase our cash position and preserve financial flexibility for corporate development and other investment opportunities in light of the current uncertainties and disruption to the global financial markets resulting from the COVID-19 pandemic.

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 our Lead Products and Product Candidates" 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 for corporate development transactions, 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. However, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, 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 share repurchase program and as of March 31, 2020 had authorized the repurchase of ordinary shares having an aggregate purchase price of up to $1.5 billion, exclusive of any brokerage commissions. 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, 2020, we spent a total of $139.1 million to purchase 1.1 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $122.91 per share. All ordinary shares repurchased were canceled. As of March 31, 2020, the remaining amount authorized under the share repurchase program was $438.7 million.

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

	Three Months Ended March 31,	
	2020	2019
Net cash provided by operating activities	$ 272,969	$ 202,253
Net cash (used in) provided by investing activities	(60,080)	166,052
Net cash used in financing activities	(147,683)	(130,349)
Effect of exchange rates on cash and cash equivalents	(948)	(112)
Net increase in cash and cash equivalents	$ 64,258	$ 237,844

Operating activities

Net cash provided by operating activities increased by $70.7 million in the three months ended March 31, 2020 compared to the same period in 2019, primarily due to:

- An increase in net cash inflow related to changes in operating assets and liabilities primarily driven by the timing of receipts from customers.

Investing activities

Net cash (used in) provided by investing activities decreased by $226.1 million in the three months ended March 31, 2020 compared to the same period in 2019, primarily due to the following:

- $146.3 million increase in upfront payments for acquired IPR&D primarily driven by the $200.0 million payment under our license agreement with PharmaMar in the three months ended March 31, 2020, compared to the same period in 2019 which included a payment of $56.0 million under our strategic collaboration agreement with Codiak;
- $70.0 million decrease in net proceeds from maturity of investments; and
- $13.0 million increase in acquisition of intangible assets.

Financing activities

Net cash used in financing activities increased by $17.3 million in the three months ended March 31, 2020 compared to the same period in 2019, primarily due to:

- An increase of $27.8 million in share repurchases, partially offset by a $10.2 million increase in proceeds from the exercise of options and our employee stock purchase plan.

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, 2020, no amounts were outstanding under our revolving credit facility. During the three months ended March 31, 2020, there were no material changes to our amended 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, 2019.

In April 2020, in an abundance of caution and as a proactive measure, we drew down $500.0 million under the revolving credit facility provided for under the amended credit agreement to increase our cash position and preserve financial flexibility for corporate development and other investment opportunities in light of the current uncertainties and disruption to the global financial markets resulting from the COVID-19 pandemic.

Contractual Obligations

During the three months ended March 31, 2020, 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, 2019.

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, commercial contracting 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, 2019. 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, 2019.

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, 2020, 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, 2019.

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, 2020.

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, 2020, 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 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 Our Lead Products and Product Candidates

Our inability to maintain or increase sales from our sleep therapeutic area would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our current business is substantially dependent on Xyrem® (sodium oxybate) oral solution, and our financial results are significantly influenced by sales of Xyrem. A significant decline in sales of Xyrem could cause us 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. While our future plans assume that sales of Xyrem will increase, there is no guarantee that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties as discussed in greater detail below, including those related to the introduction of authorized generic and generic versions of sodium oxybate and/or new products for treatment of cataplexy and/or excessive daytime sleepiness, or EDS, in narcolepsy in the U.S. market, the current and potential impacts of the ongoing COVID-19 pandemic, including the current and expected future negative impact on demand for our products and the uncertainty with respect to our ability to meet commercial demand in the future, increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, challenges to our intellectual property around Xyrem, and continued acceptance of Xyrem by physicians and patients.

As for other products and product candidates in our sleep and neuroscience therapeutic area, we obtained approval of Sunosi® (solriamfetol) in 2019 in the U.S. and in January 2020 in the European Union, or EU, for the treatment of EDS associated with narcolepsy or obstructive sleep apnea, or OSA. Our ability to realize the anticipated benefits from our investment in Sunosi is subject to a number of risks and uncertainties, including the potential impacts of the COVID-19 pandemic on the successful commercialization in the U.S., which is still at an early stage, and rolling launch in Europe; market acceptance of Sunosi; our ability, in a competitive retail pharmacy market, to differentiate Sunosi from other products that are prescribed to treat excessive sleepiness in patients with OSA or EDS in patients with narcolepsy; 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 future coverage decisions by payors; restrictions on permitted promotional activities based on any additional limitations on the labeling for the product that may be required by the U.S. Food and Drug Administration, or FDA, in the future and any such limitations that may be required by the European Commission, or the EC, or other regulatory authority on any approved labeling; and our ability to satisfy FDA's post-marketing requirements.

In March 2020, FDA accepted for filing with priority review our new drug application, or NDA, for marketing approval of JZP-258, an oxybate product candidate that contains 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, for the treatment of cataplexy and EDS in narcolepsy patients seven years of age and older. The Prescription Drug User Fee Act, or PDUFA, action date for FDA's review of our JZP-258 NDA is July 21, 2020. Our future plans assume that, if approved, JZP-258 may be prescribed to patients as a safer and clinically superior alternative to Xyrem as well as being prescribed to patients who may otherwise be ineligible to take Xyrem due to its high sodium content. Our ability to realize the anticipated benefits from our investment in JZP-258 is subject to a number of risks and uncertainties, including delay or failure in obtaining approval of JZP-258, including as a result of the ongoing COVID-19 pandemic; our receipt of approval for narrower indications than sought or burdens in the approved label; obtaining FDA approval of a risk evaluation and mitigation strategy, or REMS; obtaining and maintaining adequate coverage and reimbursement for JZP-258; the introduction of new products in the U.S. market that compete with JZP-258 in the treatment of cataplexy and/or EDS in narcolepsy, including generic or authorized generic versions of sodium oxybate or new sodium oxybate products; and acceptance of JZP-258 by payors, physicians and patients.

If we are unable to successfully commercialize Sunosi and/or JZP-258 (if approved), or if sales of Sunosi and JZP-258 do not reach the levels we expect, our anticipated revenue from our sleep therapeutic area will be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates.

While Xyrem is currently the only product approved by FDA and marketed in the U.S. for the treatment of both cataplexy and EDS in both adult and pediatric patients with narcolepsy, we and others have launched and may in the future launch products that are competitive with or disrupt the market for Xyrem.

For example, in the future, we expect Xyrem to face competition from authorized generic and generic versions of sodium oxybate. 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, FDA has approved or tentatively approved four of these ANDAs, and we believe that it is likely that FDA will approve or tentatively approve some or all of the others. In our patent litigation settlement with the first filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC and now known as Hikma in the U.S.), or Hikma, we granted Hikma the right to sell an authorized generic product, or AG Product, with royalties back to us, in the U.S. beginning on January 1, 2023, or earlier under certain circumstances. Hikma has a right to elect to continue to sell the Hikma AG Product for a total of up to five years. We also granted Hikma a license to launch its own generic sodium oxybate product as early as six months after it has the right to sell the Hikma AG Product, but if it elects to launch its own generic product, Hikma will no longer have the right to sell the Hikma 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, and ending on December 31, 2025, with royalties back to us. AG Products will be distributed through the same REMS as Xyrem and, if approved, JZP 258. 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 the circumstance where Hikma elects to launch its own generic product. If Amneal, Lupin or Par elects to launch its own generic product under such circumstance, it will no longer have the right to sell an AG Product. 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 circumstances where Hikma launches 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.

Any ANDA holder launching an AG Product or another generic sodium oxybate product will independently 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 will likely 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 royalties and other revenue based on sales of an AG Product in accordance with the terms of our settlement agreements.

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 if, for example, our patents covering Xyrem were all invalidated. 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. 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 Hikma'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.

Another circumstance that could trigger acceleration of Hikma'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. Other companies may 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. In April 2020, Avadel Pharmaceuticals plc, or Avadel, announced positive topline results from its Phase 3 clinical trial of a once-nightly formulation of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy and expects to announce top-line results in the second quarter of 2020. Xyrem may also face competition from new branded entrants to treat EDS in narcolepsy such as pitolisant. Other companies have announced that they have product candidates in various phases of development to treat the symptoms of narcolepsy, such as Axsome Therapeutics, Inc.'s reboxetine.

We expect that, if approved, JZP-258, will face competition similar to that described above for Xyrem, including from generic or authorized generic sodium oxybate product or new branded entrants in narcolepsy such as Avadel's sodium oxybate product. Avadel has announced that it has obtained an orphan drug designation from FDA for its once-nightly sodium oxybate formulation. To obtain orphan drug exclusivity upon approval, Avadel will have to show clinical superiority to Xyrem and possibly to JZP-258, if approved. If 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 a narcolepsy indication for seven years unless it can establish clinical superiority to Avadel's product. We cannot predict the timing of Avadel's submission or how FDA will evaluate any clinical superiority arguments that either company may make, but a delay in approval or inability to obtain approval for JZP-258 could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Moreover, non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy, including new market entrants, even if not directly competitive with Xyrem or JZP-258 (if approved), could have the effect of changing treatment regimens and payor or formulary coverage of Xyrem or JZP-258 in favor of other products, and indirectly materially and adversely affect sales of Xyrem (and if approved, JZP-258). Examples of such new market entrants include our product, Sunosi, and pitolisant, a drug that was approved by FDA in August 2019 for the treatment of EDS in adult patients with narcolepsy and that became commercially available in the U.S. in the fourth quarter of 2019. Pitolisant has also been approved and marketed in Europe to treat adult patients with narcolepsy with or without cataplexy, and a marketing authorization application is pending with the European Medicines Agency, or EMA, for approval of pitolisant in the treatment of EDS in OSA. In addition, prescribers often prescribe stimulants or wake-promoting agents for treatment of EDS, and anti-depressants for cataplexy, before or instead of prescribing Xyrem, and payors often require patients to try such medications before they will cover Xyrem. Examples of such products are described in "Business—Competition" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2019.

We expect that the approval and 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. We also expect that the approval and launch of any other sodium oxybate (including JZP-258 or Avadel's once-nightly sodium oxybate formulation) or alternative product that treats narcolepsy could have a material adverse effect on our sales of and revenues from Xyrem, which could have the additional impact of potentially triggering acceleration of market entry of AG Products or other generic sodium oxybate products under our ANDA litigation settlement agreements.

The distribution and sale of our oxybate products 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 and if approved, JZP-258.

The active pharmaceutical ingredient, or API, 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, 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. Any failure to demonstrate our substantial compliance with our REMS obligations, including as a result of business or other interruptions resulting from the ongoing COVID-19 pandemic, or a determination by FDA that the Xyrem REMS is not meeting its goals, could result in enforcement action by 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. Similarly, we expect that FDA will require approval of a REMS for JZP-258, and a delay in obtaining such approval could delay our anticipated launch of JZP-258, which could adversely affect our business, financial condition, results of operations and growth prospects.

FDA has stated that it will evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. We cannot predict whether 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 including JZP-258, new oxybate indications, the introduction of authorized generics, or to accommodate generics, or whether FDA will approve modifications to the Xyrem REMS that we consider warranted in connection with the submission of applications for new oxybate products including JZP-258. Any modifications approved, required or rejected by 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 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.

We depend on outside vendors, including the central certified pharmacy, to implement the requirements of the Xyrem REMS. 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, moves 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, whether due to business or other interruptions resulting from the ongoing COVID-19 pandemic or otherwise, 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.

In its approval of Hikma's ANDA, FDA waived the requirement of a single shared REMS between the brand drug and generic versions, approving Hikma's ANDA with a generic sodium oxybate REMS separate from the Xyrem REMS, except for the requirement that the generic sodium oxybate REMS program pharmacies contact the Xyrem REMS by phone to verify and report certain information. The generic sodium oxybate REMS was approved with the condition that it be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. 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 new 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 FDA's approval of the generic sodium oxybate REMS or another oxybate REMS that may be submitted or approved in the future. Our settlement agreements with ANDA filers do not directly impact FDA's waiver of the single shared system REMS requirement, any other ANDA or NDA filer's ability to develop and implement the generic sodium oxybate REMS for its sodium oxybate product, or our ability to take any action with respect to the safety of 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 FDA's waiver of the single shared system REMS requirement, its approval and tentative approval of generic versions of sodium oxybate or the consequences of distribution of sodium oxybate through the generic sodium oxybate REMS approved by FDA or another separate REMS.

REMS programs have increasingly drawn public scrutiny from the U.S. Congress, the Federal Trade Commission, or FTC, and FDA, with allegations that such programs are used as a means of improperly blocking or delaying competition. In December 2019, as part of the Further Consolidated Appropriations Act of 2020, the U.S. Congress passed legislation known as the Creating and Restoring Equal Access To Equivalent Samples Act, or CREATES. CREATES is intended to prevent companies from using REMS and other restricted distribution programs as a means to deny potential competitors access to product samples that are reasonably necessary to conduct testing in support of an application that references a listed drug or biologic, and provides such potential competitors a potential private right of action if the innovator fails to timely provide samples upon request. CREATES also grants FDA additional authority regarding approval of generic products with REMS.

It is possible that the FTC, 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, 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 FDA. The patient counseling and monitoring requirements of the Xyrem REMS provide more extensive information about adverse events experienced by patients taking Xyrem, including deaths, than is generally available for other products that are not subject to similar REMS requirements. As required by FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to FDA and could result in 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 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 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.

While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize products outside our sleep and neuroscience therapeutic area.

In addition to Xyrem and our other sleep and neuroscience products and product candidates, we are commercializing a portfolio of products, including our other lead marketed products, Defitelio, Erwinaze and Vyxeos. An inability to effectively commercialize Defitelio and Vyxeos and to maximize their potential where possible through successful research and development activities, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, and an inability to retain marketing rights to Erwinaze after 2020, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Defitelio

Our ability to maintain and grow sales and to realize the anticipated benefits from our investment in Defitelio® (defibrotide sodium) is subject to a number of risks and uncertainties, including continued acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries; 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 hepatic veno-occlusive disease, or 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; and the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in hematopoietic stem cell transplantation treatment protocols reduce the incidence of VOD diagnosis and demand for Defitelio). In addition, due to COVID-19, the reprioritization of healthcare resources and related delays, postponements or suspensions of certain medical procedures such as stem cell transplants is resulting in a decrease in demand for Defitelio. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product would be negatively affected and our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, 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.

Erwinaze

Erwinaze® (asparaginase *Erwinia chrysanthemi*), which is approved to treat a limited population of patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase, 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. Our license and supply agreement with PBL, which includes an exclusive right to market, sell or distribute Erwinaze, an exclusive license to Erwinaze trademarks, and a non-exclusive license to PBL's manufacturing know-how, will expire on December 31, 2020. In April 2020, PBL announced that it had entered into an agreement with a new partner to commercialize and distribute Erwinaze after our license and supply agreement expires. As a result, our ability to generate revenue through Erwinaze sales in the future will be adversely impacted. Under our agreement with PBL, we have the right to sell certain Erwinaze inventory for a post-termination sales period of 12 months and retain ownership of certain data, know-how and other property interests, including the biologics license application, or BLA, for Erwinaze in the U.S. and marketing authorizations for Erwinase in several other countries. We intend to work with PBL to address business transition post-termination to ensure continuity of patient care. However, in the past, we have had disagreements with PBL over product quality and supply, the costs of remediation, and other rights and obligations under the existing contract. Our ability to supply the market and generate future sales of product including that related to product we are entitled to receive post-termination during 2021 will depend on PBL's ability to address Erwinaze manufacturing and quality issues and on the level of product supply PBL provides us before and after the termination date. We may not receive Erwinaze product that we expect from PBL to be able to supply the market during the post-termination sales period and may incur costs, including time and distraction of relevant employees, associated with resolution of any disputes with PBL. If PBL is unable to remediate the quality and

manufacturing issues that have required oversight by us in order to get product to patients in the U.S., Erwinaze shortages may increase, and we could suffer reputational harm based on our historical and current association with the product. If we are unable to replace the future product sales we will lose from Erwinaze, our business, financial condition, results of operations and growth prospects would be materially adversely affected.

In addition, a continuing and significant challenge to maintaining sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product that meets specifications in quantities that are adequate to meet market demand. Other challenges facing Erwinaze include 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; difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements; and potential competition from future biosimilar products.

Vyxeos

Our ability to realize the anticipated benefits from our investment in Vyxeos® (daunorubicin and cytarabine) liposome for injection by successfully and sustainably growing sales is subject to a number of risks and uncertainties, including our ability to differentiate Vyxeos from other liposomal chemotherapies and generically available chemotherapy combinations with which physicians and treatment centers are more familiar; acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries; the increasing complexity of the acute myeloid leukemia, or 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 increasing use of venetoclax, bolstered by the recent announcement of Phase 3 clinical data supporting the use of venetoclax in AML treatment; the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos, particularly as a result of the shift of healthcare resources toward less intensive outpatient AML treatments in the U.S. in light of COVID-19 which is directly negatively impacting the use of Vyxeos, as well as the suspension of in-person interactions with healthcare professionals due to COVID-19; 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 would be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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, including generic drugs, product candidates currently under development by us and others and/or future product candidates, including new chemical entities that may be safer or more effective or more convenient 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. Many of our competitors, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources 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. In addition, many of our competitors deploy more personnel to market and sell their products than we do, and we compete with other companies to recruit, hire, train and retain pharmaceutical sales and marketing personnel. 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. In any event, 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, are more convenient or are less expensive than our products. For a description of the competition that our lead marketed products and most advanced product candidates face or may face, see the discussion in "Business—Competition" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2019 and the risk factor under the heading "*The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates"* in this Part II, Item 1A.

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, including governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health

insurers. Without third party payor reimbursement, patients may not be able to obtain or afford prescribed medications. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness and ability to prescribe our products. The demand for, and the profitability of, our products could be materially harmed if the Medicaid program, Medicare program, other federal healthcare program, or other third party commercial 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. In particular, we cannot predict to what extent the COVID-19 pandemic, depending on its scale and duration, may disrupt global healthcare systems and access to our products or result in a widespread loss of individual health insurance coverage due to unemployment, a shift from commercial payor coverage to government payor coverage, or an increase in demand for patient assistance and/or free drug programs, any of which would adversely affect access to our products and our net sales.

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. 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.

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. If our competitors offer their products at prices that provide purportedly 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.

Third party pharmacy benefit managers, or PBMs, and payors can 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, make a complex and time-intensive request for medical exemptions, or pay 100% of the cost of a drug. In addition, in many instances, certain PBMs and third party payors may exert negotiating leverage by requiring incremental rebates, discounts or other concessions from manufacturers in order to maintain formulary positions, which could result in higher gross to net deductions for affected products. In this regard, we have started to enter into agreements with PBMs and payor accounts regarding formulary coverage for Xyrem and Sunosi, but we cannot guarantee that we will be able to agree to coverage terms with other PBMs and other third party payors.

Payors could decide to exclude Sunosi from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for Sunosi, limit the types of diagnoses for which coverage will be provided or impose a moratorium on coverage for products while the payor makes a coverage decision. An inability to obtain or maintain adequate formulary positions could increase patient cost-sharing for Sunosi and cause some patients to determine not to use Sunosi. Any delays or unforeseen difficulties in obtaining access or reimbursement approvals could limit patient access, depress therapy adherence rates, and adversely impact our ability to successfully commercialize Sunosi. If we are unsuccessful in obtaining broad coverage for Sunosi, our anticipated revenue from and growth prospects for Sunosi could be negatively affected. We anticipate similar payor coverage risks with respect to JZP-258, if approved.

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. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the EU member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. If we are unable to maintain favorable pricing and reimbursement approvals in EU member states that represent significant markets, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. For example, the EC

granted marketing authorization for Vyxeos in August 2018 and for Sunosi in January 2020, and, as part of our rolling launches of Vyxeos and Sunosi in Europe, we are making pricing and reimbursement submissions in European countries. Due to the COVID-19 pandemic, we currently anticipate delays by certain European regulatory authorities in their pricing and reimbursement reviews. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, including as a result of regulatory review delays due to the COVID-19 pandemic, planned launches in the affected EU member states would be delayed, which could negatively impact anticipated revenue from and growth prospects for Vyxeos and/or Sunosi.

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. For example, we anticipate that the U.S. Congress, state legislatures, and regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on government-funded reimbursement for drugs (including Medicare, Medicaid) and commercial health plans, new or increased requirements to pay prescription drug rebates and penalties to government health care programs, and additional pharmaceutical cost transparency bills that aim to require drug companies to justify their prices through required disclosures. Additionally, proposals made part of proposed legislation and executive rule-making may seek to utilize an "international pricing index" as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B to more closely align with international drug prices. If the U.S. were to move to such a pricing system that were to apply to any of our products, our revenues from U.S. sales of such products could decrease.

Legislative and regulatory proposals that have recently been considered include the potential authorization of prescription drug importation from other countries, legislative proposals to limit the terms of patent litigation settlements with generic sponsors, and proposals to define certain conduct around patenting and new product development as unfair competition. All such considerations may adversely affect our business and industry in ways that we cannot accurately predict.

There is also ongoing activity related to the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, together, the Healthcare Reform Act. 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. Certain provisions of the Healthcare Reform Act have been subject to judicial challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. 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.

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 2020, and there is no guarantee that we will be able to make similar price adjustments in the future or that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes and revenues from Xyrem. We also have made and may in the future make similar price increases on our other products. There is no guarantee that such price increases 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.

We expect that legislators, policymakers and healthcare insurance funds in Europe will continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we will be able to charge for our products or the level of reimbursement available for these products from governmental authorities or third party payors. Further, an increasing number of European and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory.

Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

In addition 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 and other risks in relation to the benefits of our products;
- 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 any 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. JZP-258 includes the same API as Xyrem, but uses a different mixture of salts. Patients, physicians and regulators may therefore view Xyrem or JZP 258, if approved, 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, and potentially other oxybate products generally because of their connection to GHB. Xyrem's label includes information about adverse events from GHB.

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 FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and equivalent rules and regulations prescribed by non-U.S. regulatory authorities. If we or any of our suppliers encounter manufacturing, quality or compliance difficulties with respect to any of our products, whether due to the impacts of the ongoing COVID-19 pandemic (including as a result of disruptions of global shipping and the transport of products) or otherwise, 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, we could be subject to enforcement action by regulatory authorities for our failure to comply with cGMP with respect to the products we manufacture in our facilities as well as for our failure to adequately oversee compliance with cGMP by any of our third party suppliers operating under contract. Moreover, failure to comply with applicable legal and regulatory requirements subjects us and our suppliers to possible 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.

We have a manufacturing and development facility in Athlone, 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. Our manufacturing facility in Athlone, Ireland currently continues to

be operational, but we are managing operations through limited "essential" on-site staff and flexible work arrangements. In March 2020, we temporarily ceased operations at our Villa Guardia, Italy manufacturing facility, which produces defibrotide, to ensure the safety of our employees and communities in northern Italy. We are developing plans for a phased reopening of our Villa Guardia facility that takes into account applicable public health authority and local government guidelines as well as employee safety.

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. Single sourcing puts us at risk of interruption in supply in the event of manufacturing, quality or compliance difficulties. 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. FDA and similar international or national regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. 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. A continuing and significant challenge to maintaining sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product that meets specifications in quantities that are adequate to meet market demand. All Erwinaze that PBL has been able to supply is currently completely absorbed by demand for the product, and erratic supply patterns have prevented us from meeting patient demand in some markets or from being able to expand to new markets or indications. 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 are experiencing supply disruptions of Erwinaze in the U.S. and expect to continue to experience supply disruptions globally in 2020. In addition, FDA has issued a warning letter and FDA Forms 483 to PBL citing, among other things, significant violations of cGMP for finished pharmaceuticals and significant deviations from cGMP for APIs. We cannot predict whether the required remediation activities by PBL in connection with its prior warning letter and FDA Forms 483 will further strain PBL's manufacturing capacity or otherwise further adversely affect Erwinaze supply. We also cannot predict whether a delay in the ability of FDA to conduct inspections as a result of COVID-19 impacts could result in a delay in obtaining regulatory discretion required for release of Erwinaze supply in the U.S.

As capacity constraints and supply disruptions continue, whether as a result of continued quality or manufacturing challenges at PBL, the impacts of the ongoing COVID-19 pandemic, regulatory issues or an inability to enforce our contractual rights, 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. In addition, any inability to comply with regulatory requirements of FDA, the UK Medicines and Healthcare Products Regulatory Agency, or MHRA, or other competent authorities in the EU member states in which Erwinaze is subject to marketing authorizations, including any failure by PBL to correct the violations and deviations referenced above to the satisfaction of FDA, or failure to meet regulatory specifications for the product, could further adversely affect Erwinaze supply, particularly in light of the historical limitations on the supply of Erwinaze, and could result in enforcement actions by FDA, the 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 FDA or other competent authorities being suspended, varied, or revoked, product release being delayed or suspended, including potentially 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.

Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location. Baxter has experienced batch failures due to mechanical, component and other issues in the production of Vyxeos, 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 related to Vyxeos. 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, 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 FDA. As a result, we have qualified other suppliers for each API, and we provided the qualification data to FDA. If 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.

In addition, in order to conduct our ongoing and any future clinical trials of, complete marketing authorization submissions for, and potentially launch our other product candidates, we also need to have sufficient quantities of product manufactured. Moreover, to obtain approval from FDA or a similar international or national regulatory body of any product candidate, we or our suppliers for that product must obtain approval by the applicable regulatory body to manufacture and supply product, in some cases based on qualification data provided to the applicable body as part of our regulatory submission. Any delay in generating, or failure to generate, data required in connection with submission of the chemistry, manufacturing and controls portions of any regulatory submission could negatively impact our ability to meet our anticipated submission dates, and therefore our anticipated timing for obtaining FDA or similar international or national regulatory body approval, or our ability to obtain regulatory approval at all. In addition, any failure of us or a supplier to obtain approval by the applicable regulatory body 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.

We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to our product supplies as a result of the COVID-19 pandemic; however, if the COVID-19 pandemic persists for an extended period of time and begins to impact essential distribution systems such as FedEx and postal delivery, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products, which would adversely impact our ability to generate sales of and revenues from our approved products and our business, financial condition, results of operations and growth prospects would be materially adversely affected.

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.

The testing, manufacturing and marketing of our products require regulatory approvals, including approval from FDA and similar bodies in Europe and other countries. If 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 for a product candidate, 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 or preclude the approval of our application. Our inability to obtain and maintain regulatory approval for our product candidates in the U.S. and Europe and to successfully commercialize new products that are approved would prevent us from receiving a return on our investments and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Due to the ongoing COVID-19 pandemic, it is possible that we could experience delays in the timing of marketing application review and/or our interactions with regulatory authorities due to limited staffing or working hours of governmental employees, governmental "stay-at-home" orders and travel restrictions with respect to physical inspections if required for regulatory approval, or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals. In March 2020, FDA accepted for filing with priority review our NDA for JZP-258, with a PDUFA action date of July 21, 2020. In February 2020, FDA accepted for filing with priority review the NDA for lurbinectedin for the treatment of relapsed small cell lung cancer, a product candidate for which we recently acquired exclusive U.S. development and commercialization rights, with a PDUFA action date of August 16, 2020. It is possible that we could experience delays in the timing of NDA review due to COVID-19 impacts described above. A delay or failure in obtaining approval of JZP-258 or lurbinectedin would have a negative impact on our ability to recoup our research and development costs and to successfully commercialize JZP-258 and/or lurbinectedin, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Even if we receive approval of a product, regulatory authorities may impose significant labeling restrictions or requirements, including limitations on the dosing of the product, requirements around the naming or strength of a product, restrictions on 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. FDA requires a REMS and a boxed warning for Xyrem, and similar restrictions could be imposed on other products in the future. For example, we expect that FDA will require a REMS for approval of JZP-258. Our receipt of approval for narrower indications than sought, restrictions on marketing through a REMS, or significant labeling restrictions or requirements in an approved label such as a boxed warning, could have a negative impact on our ability to recoup our research and development costs and to successfully commercialize that product, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Regulatory authorities may also impose post-marketing obligations as part of their approval, which 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 Defitelio, Erwinaze, Vyxeos and Sunosi. These post-marketing requirements and commitments include satisfactorily conducting multiple post-marketing clinical trials and safety studies. 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.

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., or Pfenex. Among the product candidates being developed under our Pfenex agreement is JZP-458, a recombinant *Erwinia* asparaginase product candidate, for the potential treatment of ALL and lymphoblastic lymphoma who have hypersensitivity to *E. coli*-derived asparaginase. We also have clinical development efforts focused on expanding the potential of Defitelio, Vyxeos and Sunosi, as well as clinical development efforts focused on JZP-385 for the treatment of essential tremor. 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 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 transactions.

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. However, we may be unable to identify or consummate suitable acquisition or in-licensing opportunities, and this inability could impair our ability to grow our business. Other companies, many of which may have substantially greater financial, sales and marketing resources, compete with us for these opportunities. 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.

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. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively, could have a material adverse effect on our business, results of operations and financial condition. In addition, product and product candidate acquisitions, particularly when the acquisition takes the form of a merger or other business consolidation, have required, and any similar future transactions will also require, significant efforts and expenditures, including with respect to transition and integration activities. We may encounter unexpected difficulties, or incur substantial costs, in connection with potential acquisitions and similar transactions, which include:

- 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 integrating acquired products and product candidates into our portfolio;
- the difficulties in assimilating employees and corporate cultures;
- the failure to retain key managers and other personnel;
- 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.

Moreover, if the COVID-19 pandemic persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments.

As a result of these or other factors, products or product candidates we acquire, or obtain licenses to, may not produce the revenues, earnings or business synergies that we anticipated, acquired or in-licensed product candidates may not result in regulatory approvals, and acquired or licensed products may not perform as expected. Failure to manage effectively our growth through acquisitions or in-licensing transactions could adversely affect our growth prospects, business, results of operations and financial condition.

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. If FDA determines that the safety or efficacy data submitted for the NDAs for JZP-258 or lurbinectedin, or to be submitted to FDA in the planned BLA for JZP-458, do not warrant marketing approval, we may be required to conduct additional clinical trials, which could be costly and time-consuming. Even if we believe we have successfully completed testing, FDA or any equivalent non-U.S. regulatory agency may determine our data is not sufficiently compelling to warrant marketing approval for the indications sought, if at all, and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. 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 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:

- direct and indirect effects of the ongoing COVID-19 pandemic on various aspects and stages of the clinical development process, including the inherent limitations of remote and virtual approaches;
- difficulty identifying, recruiting 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;
- significant reprioritization and diversion of healthcare resources away from the conduct of clinical trials as a result of the ongoing COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- difficulty identifying a clinical development pathway, including viable indications and appropriate clinical trial protocol design, particularly where there is no applicable regulatory precedent;
- 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;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic;
- 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;
- failure of our clinical trials and clinical investigators, including contract research organizations or other third parties assisting us with clinical trials, to satisfactorily perform their contractual duties, meet expected deadlines and comply with FDA and other regulatory agencies' requirements, including good clinical practices;
- unforeseen safety issues;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites; or
- insufficient funds to complete the trials.

In light of the ongoing COVID-19 pandemic, we have taken measures to implement remote and virtual approaches, including remote data monitoring where possible, to maintain patient safety and trial continuity and to preserve study integrity. We are seeing an impact on our ability to initiate trial sites, enroll patients and maintain patient enrollment in our clinical programs and have suspended two of our healthy volunteer clinical development programs, JZP-385 and JZP-324, in the

interest of volunteer safety. We could also see an impact on the ability to supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority employee resources or otherwise. In addition, we rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the pandemic persists for an extended period of time or reemerges in the future, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects. For example, while we are continuing to activate sites remotely and enrolling our JZP-458 study, we are experiencing a slowdown in site activation or enrollment as lab closures increase and sites begin limiting personnel to "essential" workers. In addition, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations.

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 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.

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. 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.

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 portfolio. 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.

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 (and in certain cases, an authorized generic version of Xyrem) in advance of the expiration of the last of our patents. Notwithstanding our Xyrem 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. Such third parties 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 FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book, that expire in 2033 that cover treatment methods included in the Xyrem label related to a drug-drug interaction, or DDI, with divalproex sodium. Although 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 label 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 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.

We also currently rely on trade secret protection for several of our products, including Erwinaze and Defitelio. Trade secret protection does not protect information or inventions if another party develops that information or invention independently, and establishing that a competitor developed a product through trade secret misappropriation rather than through legitimate means may be difficult to prove. Trade secret protection also requires that information be secret and subject to reasonable efforts to maintain secrecy, and this requirement may come into conflict with requirements to provide information to employees, consultants, business partners, and regulatory bodies. 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. Moreover, if a dispute arises with our employees, consultants, advisors or partners over the ownership of rights to inventions, including jointly developed intellectual property, we could lose patent protection or the confidentiality of our proprietary information, and possibly also lose the ability to pursue the development of 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 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 through a proceeding before the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office.

There is a risk that a court or the PTAB 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 six of our patents covering the Xyrem REMS, which were invalidated through the IPR process and delisted from the Orange Book. 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.

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). The U.S. Congress and state legislatures have also identified pharmaceutical patent settlements as potential impediments to generic competition and have introduced, and in states like California passed, legislation to regulate them. Third party payors have also challenged such settlements on the grounds that they increase drug prices. 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. 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.

Other Risks Related to Our Business and Industry

Our business is currently adversely affected and could be materially and adversely affected in the future by the ongoing COVID-19 pandemic and related global economic slowdown as a result of the current and potential future impacts on our commercialization efforts, clinical trial activity, research and development activities, supply chain and corporate development activities and other business operations, in addition to the impact of a global economic slowdown.

Our business could be materially and adversely affected by the ongoing COVID-19 pandemic, a disease caused by a novel strain of coronavirus, SARS-CoV-2, which has been spreading globally since December 2019. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The COVID-19 pandemic is having significant impact on the global healthcare delivery system. Many healthcare systems have had to restructure operations to prioritize caring for COVID-19 patients and limit or cease other activities. The severe burden on healthcare systems caused by this pandemic has impaired the ability to diagnose and treat patients with non-COVID-19 related conditions and impaired the ability of many clinical research sites to start new studies, enroll new patients and monitor patients in clinical trials. The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business related activities have occurred, supply chains have been disrupted, and manufacturing and clinical development activities have been curtailed or suspended.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic may materially and adversely affect our business, our ability to generate sales of and revenues from our approved products, our supply chain, regulatory, clinical development and corporate development activities. With respect to our commercialization activities, the evolving effects of the COVID-19 pandemic are having a negative impact on demand for our products, primarily due to the inherent limitations of telemedicine and a reprioritization of healthcare resources toward COVID-19. Beginning in March 2020, we transitioned our sales, market access and reimbursement and medical employees out of the field and suspended work-related travel and in-person customer interactions, including in-person interactions with healthcare professionals and customers. Since then, we have been utilizing virtual means to continue to engage with and support healthcare professionals. As clinics and institutions begin to allow in-person interactions pursuant to health authority and local government guidelines, our field teams will start to re-initiate in-person interactions with healthcare professionals and clinics, but the timing and level of engagement will vary by account, region and country, and may be adversely impacted in the future where reemergence or future outbreaks of COVID-19 occur.

For Xyrem, the impact is related to the reduced ability of prescribers to diagnose narcolepsy patients given the limitations in access to sleep testing, which reduction in demand is evidenced in decreases in new patient enrollments in the Xyrem REMs program. Going forward, a negative impact may potentially be seen on patient compliance and persistence with Xyrem treatment, and the ability to fill, access and pay for prescriptions. For Sunosi, the impact on demand is related to the minimized ability of our field-based teams to interact with new prescribers and patients' ability to fill, access and pay for prescriptions, and is evidenced in slower than budgeted growth of new prescribers and new patient starts in the U.S. We also anticipate delays by certain European regulatory authorities in their pricing and reimbursement reviews due to the pandemic, which is likely to delay our rolling Sunosi launch in certain EU member states. In addition, the reprioritization of healthcare resources and related delays, postponements or suspensions of certain medical procedures such as stem cell transplants is resulting in a decrease in demand for Defitelio. In the U.S., we are also seeing a shift toward less intensive outpatient AML treatments due to COVID-19, which is directly negatively impacting the use of Vyxeos, which prescribers are still primarily utilizing in inpatient settings, despite its availability for use in outpatient settings. Depending on the scale and ultimate duration the COVID-19 pandemic and the extent of a global economic slowdown, widespread unemployment and resulting loss of employer-sponsored insurance coverage, we may experience a shift from commercial payor coverage to government payor coverage or an increase

in demand for patient assistance and/or free drug programs, which would adversely affect access to our products and our net sales.

In addition, the ongoing COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital or an impact on liquidity, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, a recession or market correction resulting from the impact of COVID-19 could materially affect our business and the value of our ordinary shares. While we expect the COVID-19 pandemic to adversely affect our business operations and financial results, the extent of the impact on our ability to generate sales of and revenues from our approved products, execute on new product launches, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of or reemergence of outbreaks, governmental "stay-at-home" orders and travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Ireland and other countries, and the effectiveness of actions taken globally to contain and treat the disease. For example, the inability of our work-force to return to office and field based work and the ongoing stress and reprioritization within the healthcare systems in our key markets may require us to reassess the timing and scope of key business activities for the year, including our ability to successfully launch JZP-258 and lurbinectedin, if approved. These effects could materially and adversely affect our business, financial condition, results of operations and growth prospects, as further described in the risks and uncertainties described elsewhere in this "Risk Factors" section.

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. We may further expand our international operations into other countries in the future, either organically or by acquisition. Conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations, financial condition and growth prospects, including:

- the diverse regulatory, financial and legal requirements in the countries where we are located or do business, 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
- public health risks, such as the current global COVID-19 pandemic and potential related effects on supply chain, travel and employee health and availability.

In addition, there can be no guarantee that we will effectively manage the increasing, global complexity of our business 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 withdrawal from the EU, commonly referred to as Brexit, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

Brexit will continue to create significant uncertainty concerning the future relationship between the UK and the EU, particularly if the recent UK withdrawal from the EU in January 2020 is followed by a failure to agree to a future trading relationship between the EU and the UK. Since a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, there is a risk that the scope of a marketing authorization for a medicinal product granted by the EC or by the competent authorities of EU member states will not encompass the UK. In these circumstances, a separate authorization granted by the UK competent authorities will be required to place medicinal products on the UK market. In addition, our ability to rely on UK manufacturing sites for products intended for the EU market will depend on the terms of the trade agreements concluded between the EU and the UK in the coming months 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 to manufacture products for supply to the EU market. All of these changes, if they occur, could increase our costs and otherwise adversely affect our business. 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, and may be continue to be, negatively affected by Brexit, which 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 recent withdrawal from 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 member states, 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 business and 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, including our executive management team. We do not carry "key person" insurance. The loss of services and institutional knowledge of one or more additional members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities and may negatively impact our operations and future growth. In addition, changes in our organization as a result of executive management transition may have a disruptive impact on our ability to implement our strategy. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business. In any event, if we are unable to attract, retain and motivate quality individuals, or if there are delays, or if we do not successfully manage personnel and executive management transitions, our business, financial condition, results of operations and growth prospects could be adversely affected.

Significant disruptions of information technology systems or data security breaches could adversely affect 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. 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, and those of our vendors, 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 and our vendors 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, including in our remote work environment as a result of COVID-19, 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.

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. The failure by us or any of our third party partners, including our corporate development and collaboration partners, 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 or manufacturing authorizations, 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. FDA and the competent authorities of the EU member states on behalf of the EMA, also periodically inspect our records related to safety reporting. 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.

Erwinaze, defibrotide and Vyxeos are available on a named patient basis or through a compassionate use process 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. 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.

FDA, the competent authorities of the EU member states and other governmental authorities require advertising and promotional materials 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. A determination that we have promoted an approved product for off-label uses could subject us 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 and/or civil or criminal penalties that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products.

Other Regulatory Authorities

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the DOJ, the FTC, the United States Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, 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 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. These laws are described in "Business—Government Regulation" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2019. 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 available statutory exceptions and regulatory 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.

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. 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.

Public reporting under the Physician Payment Sunshine Act, or Sunshine provisions, and other similar state laws, the requirements of which are discussed in "Business—Government Regulation" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2019, has resulted in increased scrutiny of the financial relationships between industry, teaching hospitals, physicians and other healthcare providers. 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. 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, and administrative penalties, damages or fines.

We have various programs to help patients access our products, including patient assistance programs, which include co-pay coupons for certain of our products, assistance to 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 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 issued guidance for how pharmaceutical manufacturers can lawfully 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. In April 2019, we finalized our civil settlement agreement with the DOJ and 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. Although we have structured our programs to follow available guidance and the requirements of our corporate integrity agreement, 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 or other enforcement agencies or private litigants, or 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 of our patient assistance programs or other business practices, which could result in damages, fines, penalties, exclusion from participation in federal health care programs or other criminal, civil or administrative sanctions or enforcement actions, as well as negative publicity, reduction in 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. 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 and the DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violation of these laws by us or our suppliers and other third party agents for which we may be liable 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.

Outside the U.S., interactions between pharmaceutical companies and physicians are also governed by strict laws, such as national anti-bribery laws of European countries, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Xyrem and Sunosi are controlled substances under the Controlled Substances Act. Our suppliers, distributors, clinical sites and prescribers, as well as retail pharmacies for Sunosi 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 these drugs and their APIs. 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.

We are also subject to data protection and privacy laws and regulations governing the processing of personal data. Because of the remote work policies we implemented due to COVID-19, information that is normally protected, including company confidential information, may be less secure. We may also need to collect more extensive health-related information from our employees to manage our workforce. If we or our third party partners fail to comply or are alleged to have failed to comply with applicable data protection and privacy laws and regulations, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits. In addition, 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.

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

We participate in the Medicaid Drug Rebate program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule, or FSS, pricing program, the Tricare Retail Pharmacy program, and have obligations to report the average sales price for certain of our drugs to the Medicare program. All of these programs are described in more detail 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, 2019.

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, which can change and evolve over time. 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 or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, 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. Centers for Medicare and Medicaid Services, or CMS, could also decide 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.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively impact our financial results. 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.

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. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. 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.

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.

Pursuant to applicable law, knowing provision of false information in connection with price reporting under the U.S. Department of Veterans Affairs, FSS or Tricare Retail Pharmacy, or Tricare, 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 or hostile bids, 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. Recent stock price declines due to COVID-19 may also increase our vulnerability to unsolicited approaches. If we become the subject of certain forms of shareholder activism, such as proxy contests or hostile bids, 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 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 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 FDA, the EC or the competent authorities of the EU member states could lead to product liability lawsuits as well.

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. 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.

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. If an accident or contamination involving pollutants or hazardous substances 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 with sufficient coverage on acceptable terms, or at all. 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.

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, and our business would be adversely affected if we are unable to service our debt obligations.

As of March 31, 2020, we had total indebtedness of approximately $1.8 billion. Our substantial indebtedness 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, investments 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, or our ability to take specified actions to take advantage of certain business opportunities that may be presented to us;
- result in dilution to our existing shareholders in the event exchanges of our 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.

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 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. In addition, if we are unable to repay amounts under our secured credit agreement that we entered into in June 2015 and subsequently amended, which we refer to as 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.

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 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;
- 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; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

The amended credit agreement also includes certain financial covenants that require us to maintain a maximum secured leverage ratio and a minimum interest coverage ratio. 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. Moreover, our failure to repurchase our exchangeable senior notes at a time when the repurchase is required by the indentures governing our exchangeable senior notes or to pay any cash payable on future exchanges of our exchangeable senior notes as required by those indentures would constitute a default under those indentures. A default under those indentures could also lead to a default under other debt agreements or obligations, including the amended credit agreement. Likewise, a default under the amended credit agreement could also lead to a default under other debt agreements or obligations, including the indentures governing our exchangeable senior notes.

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 and grow our business.

The scope of our business and operations has grown substantially since 2012, including through a series of business combinations and acquisitions. 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. 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. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the ongoing COVID-19 pandemic. An inability to borrow or raise additional capital on attractive terms, or at all, could prevent us from expanding our business and otherwise could have a material adverse effect on our business and growth prospects. 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 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 and are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should future impairments of intangible assets or goodwill occur. For example, in the first quarter of 2020, we recorded a $136.1 million asset impairment charge following the decision to stop enrollment in our Phase 3 clinical study of defibrotide due to a determination that the study is highly unlikely to reach one of its primary endpoints, the prevention of VOD.

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

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. 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, which could adversely affect our operating results. Although we utilize foreign exchange forward contracts to manage currency risk primarily related to certain intercompany balances denominated in non-functional currencies, our efforts to manage currency risk may not be successful.

Changes in our effective tax rates 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 changes to or differences in interpretation of tax laws. 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.

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 when the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company were combined in a merger transaction in January 2012, or 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. 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.

Changes to 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.

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 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.

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. 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. 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 is likely to continue to be volatile in the future, and the value of your investment could decline significantly.

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, including recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased market prices, notwithstanding the lack of a fundamental change in the underlying business models of those companies. Worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. The market price for our ordinary shares is likely to continue to be volatile, particularly due to the ongoing COVID-19 pandemic, and subject to significant price and volume fluctuations in response to market, industry and other factors, including the risk factors described in this "Risk Factors" section.

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.

In addition, the market price of our ordinary shares may decline if the effects of our strategic transactions 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 our exchangeable senior notes who may view our 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 our 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, mergers, amalgamations and acquisitions, takeovers and shareholder lawsuits. 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 our 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. In addition to our articles of association, several mandatory provisions of Irish law could prevent or delay an acquisition of us. 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 our exchangeable senior notes require us to repurchase our exchangeable senior notes for cash if we undergo certain fundamental changes and, in certain circumstances, to increase the exchange rate for a holder of our exchangeable senior notes. A takeover of us may trigger the requirement that we purchase our 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.

Future sales and issuances of our ordinary shares, securities convertible into our ordinary shares or rights to purchase ordinary shares or convertible securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.

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. To the extent we raise additional capital by issuing equity securities or securities convertible into or exchangeable for ordinary shares, our shareholders may experience substantial dilution. We may sell ordinary shares, and we may sell convertible or exchangeable securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell such ordinary shares, convertible or exchangeable securities or other equity securities in subsequent transactions, existing shareholders may be materially diluted.

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

We do not currently plan to pay cash dividends in the foreseeable future. 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.

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, 2020:

	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, 2020	88,300	$ 147.12	88,300	$ 564,742,952
February 1 - February 29, 2020	144,000	$ 135.55	144,000	$ 545,227,319
March 1 - March 31, 2020	899,000	$ 118.51	899,000	$ 438,702,778
Total	1,131,300	$ 122.91	1,131,300	

(1) This table does not include ordinary shares that we withheld in order to satisfy minimum tax withholding requirements in connection with the vesting and release 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 2018, December 2018, and October 2019, our board of directors increased the existing share repurchase program authorization by $320.0 million, $400.0 million, and $500.0 million respectively thereby increasing the total amount authorized for repurchase to $1.5 billion.

(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 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+	Offer Letter, dated as of February 23, 2020, by and between Jazz Pharmaceuticals, Inc. and Renée Galá.

10.2+	Amendment to Employment Contract, dated as of February 26, 2020, by and between Jazz Pharmaceuticals Ireland Limited and Finbar Larkin.
10.3+	Amendment to Transition and Termination Agreement, dated as of March 31, 2020, by and between Jazz Pharmaceuticals, Inc. and Michael Miller.
10.4+	Amendment to Employment Contract, dated as of April 21, 2020, by and between Jazz Pharmaceuticals UK Limited and Samantha Pearce.
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 - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

\+ 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 certification attached as Exhibit 32.1 accompanies 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 5, 2020

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Registrant)

/s/ Bruce C. Cozadd

Bruce C. Cozadd

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

/s/ Renée Galá

Renée Galá

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

/s/ Patricia Carr

Patricia Carr

Vice President, Finance
(Principal Accounting Officer)

Exhibit 10.1

[Jazz Pharmaceuticals Letterhead]

February 20, 2020

Renée Galá

Re: Offer of employment with Jazz Pharmaceuticals

Dear Renée,

I am very pleased to invite you to join Jazz Pharmaceuticals. This letter sets out the terms of your employment with Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals" or the "Company").

1. ***Duties and Responsibilities***. Your initial assignment will be as Executive Vice President and Chief Financial Officer, reporting to me. This offer is for a full-time position, located at Jazz Pharmaceuticals' offices in Palo Alto. The position may require you to travel from time to time to other locations as may be necessary to fulfill your responsibilities. As part of your employment relationship, you agree to comply with Jazz Pharmaceuticals' policies and procedures in effect from time to time during your employment. As an exempt employee, you are expected to work the number of hours required to do your job well, and you are not eligible for overtime compensation.

2. ***Salary; Annual Bonus; Signing Bonus***. Your initial annual base salary rate will be $600,000 payable in accordance with Jazz Pharmaceuticals' customary payroll practices, for all hours worked. Salary is subject to periodic review and adjustment by Jazz Pharmaceuticals, in accordance with its normal practices; we have a company-wide performance review process that takes place early in each calendar year.

   You will be eligible to participate in the Jazz Pharmaceuticals plc Cash Bonus Plan (U.S. Affiliates) under which annual bonuses may be given based on the Company meeting its annual objectives, and each employee's meeting of his or her objectives, subject to the terms and conditions of the cash bonus plan. Bonuses are not guaranteed, and whether there will be a bonus in any year, and the amount of any bonus, is within the discretion of the Board of Directors. In this role, you will be eligible for consideration of an annual incentive bonus target currently set at 55%; your bonus amount for 2020 will be prorated due to your partial year of employment.

In addition, Jazz Pharmaceuticals will pay you a signing bonus of $25,000, less all required withholdings, paid to you in a lump sum on the first regular pay date occurring 30 days after your employment start date, subject to your continued employment in good standing with Jazz Pharmaceuticals through such payment date. You will be required to repay the signing bonus if you resign your employment with Jazz within one year of your employment start date. You will be expected to repay to Jazz Pharmaceuticals the full amount of the signing bonus on your last day of employment or within 30 days thereafter.

3. ***Benefits***. You generally will be eligible to receive all benefits which are extended to other similarly-situated employees at Jazz Pharmaceuticals, subject to the terms and conditions of the benefit plans, including medical and dental benefits, life insurance and other benefits offered to regular employees. You will be eligible for paid time off and holidays in accordance with Jazz Pharmaceuticals' policies, and you will be a participant in the Company's Amended and Restated Executive Change in Control and Severance Benefit Plan.

4. ***Equity***. Your offer includes a grant of options to purchase 41,500 Jazz Pharmaceuticals plc ordinary shares and a grant of 16,600 restricted stock units (RSUs) giving you a right to receive Jazz Pharmaceuticals plc ordinary shares at a future date, subject to approval by the Compensation Committee, the terms and conditions of the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan, and the terms and conditions of the applicable award agreements, which will be provided to you as soon as practicable after the grant date. Subject to your continued employment on each vesting date, the options will vest 1/4th on the first annual anniversary of your start date and 1/48th of the total granted per month thereafter, and the RSUs will vest 1/4th annually over four years. The options will have an exercise price that equals the fair market value of Jazz Pharmaceuticals plc ordinary shares on the date of grant. The RSUs will have no exercise price. The options and RSUs will be granted on the second trading day following the filing date of the Company's next quarterly report filed with the U.S. Securities and Exchange Commission following your start date in accordance with the Company's Equity Incentive Grant Policy.

5. ***Confidential Information; Employee Confidential Information and Inventions Agreement***. To enable Jazz Pharmaceuticals to safeguard its proprietary and confidential information, it is a condition of employment that you sign Jazz Pharmaceuticals' standard form of "Employee Confidential Information and Inventions Agreement." We understand that you are likely to have signed similar agreements with prior employers, and wish to impress upon you that Jazz

Pharmaceuticals does not want to receive the confidential or proprietary information of others, and will support you in respecting your lawful obligations to prior employers. By accepting this offer, you are representing to Jazz Pharmaceuticals that your performance of your duties will not violate any agreements you may have with, or trade secrets of, any third parties. You agree that, during your employment with Jazz Pharmaceuticals, you will not engage in any business activity that competes with Jazz Pharmaceuticals, and you will notify your supervisor if you are considering accepting outside work.

6. ***Code of Conduct***. Jazz Pharmaceuticals is committed to integrity and the pursuit of excellence in all we do. We fulfill these commitments while upholding a high level of ethical conduct. The Code of Conduct is one element of Jazz Pharmaceuticals' efforts to ensure lawful and ethical conduct by the company and its subsidiaries and their employees, officers and directors. It is a condition of employment that you read, agree to and sign Jazz Pharmaceuticals' Code of Conduct in the first week of employment. If you have questions about the Code of Conduct, please let Human Resources know and we will ensure that you receive answers to your inquiries as quickly as possible.

7. ***At-Will Employment***. Should you decide to accept our offer, you will be an "at-will" employee of Jazz Pharmaceuticals. This means that either you or Jazz Pharmaceuticals may terminate the employment relationship with or without cause at any time. Participation in any benefit, compensation or bonus program does not change the nature of the employment relationship, which remains "at-will".

8. ***Authorization to Work***. Federal government regulations require that all prospective employees present documentation verifying their identity and demonstrating that they are authorized to work in the United States. If you have any questions about this requirement, which applies to U.S. citizens and non-U.S. citizens alike, please contact Heidi Manna, our Senior Vice President, Human Resources. Your employment is contingent on your ability to prove your identity and authorization to work in the United States, and you're complying with the government's employment verification requirements.

9. ***Complete Offer and Agreement***. This letter contains our complete understanding and agreement regarding the terms of your employment by Jazz Pharmaceuticals. There are no other, different or prior agreements or understandings on this or related subjects. Changes to the terms of your employment can be made only in a writing signed by you and the Chief Executive Officer of Jazz Pharmaceuticals, although it is understood that as part of the policy of employment at will, Jazz Pharmaceuticals may, from time to time, in its sole discretion, adjust your salary,

incentive compensation and benefits, as well as your job title, location, duties, responsibilities, assignments and reporting relationships.

10. ***Start Date; Acceptance of Offer***. We hope that you will accept this offer promptly and begin your full-time employment at Jazz Pharmaceuticals by March 16, 2020. If our offer is acceptable to you, please sign the enclosed copy of this letter in the space indicated and return it to me by February 24, 2020.

11. ***Severability***. If any provision of this offer is held to be invalid, void or unenforceable, the remainder of the agreement set forth herein will remain unaffected, and you and Jazz Pharmaceuticals will work together to achieve the intent of the affected provisions.

Renée, we are impressed by your accomplishments and potential, and we are enthusiastic at the prospect of you joining us. I look forward to your early acceptance of this offer, and to your contributions to the growth and success of Jazz Pharmaceuticals.

Sincerely,

Bruce Cozadd
Chairman & CEO

ACCEPTANCE OF EMPLOYMENT OFFER:

I accept the offer of employment by Jazz Pharmaceuticals on the terms set forth in this letter.

Signature:	/s/ Renée Galá RG
Date:	23-Feb-2020
My start date will be	March 16, 2020

Exhibit 10.2

Amendment to Finbar Larkin's Terms and Conditions of Employment

This amendment (the "**Amendment**") applies to the Terms and Conditions of Employment agreement between Finbar Larkin (the "**Executive**") and Jazz Pharmaceuticals Ireland Limited which was signed by the Executive on 22 February 2013 (the "**Employment Agreement**"). The Employment Agreement is amended as set forth herein.

1. **New Employment Terms Due to Promotion.** The below employment terms were amended effective 31 October 2019 in connection with Executive's promotion to the role of SVP, Technical Operations on a non-interim basis.

    a. **Position:** Clause 1 is amended to state Executive's role of SVP, Technical Operations.

    b. **Reporting Relationship:** Clause 5 is amended to state Executive's reporting relationship to the President and Chief Operating Officer.

    c. **Salary:** Clause 6.1 is amended to state Executive's annual basic salary rate of €309,000.

    d. **Bonus:** Clause 7.1 is amended to state that Executive's eligibility for an annual bonus for 2020 will be governed by the terms and conditions of the Jazz Pharmaceuticals Cash Bonus Plan (Ireland and Other Specified Affiliates) (Calendar Year 2020). Bonus eligibility for other calendar years will be governed by the terms and conditions of any approved bonus plan or program in effective during the relevant calendar year.

2. **Change in Control Severance Benefits.** The attached ***Schedule 1***, effective as of 11 February 2020, contains the terms and conditions of Executive's eligibility for certain change in control severance benefits.

3. **Miscellaneous.** This Amendment, including ***Schedule 1***, sets forth all modifications to the Employment Agreement, and the other terms of the Employment Agreement remain in full force and effect. This Amendment can only be modified in a written agreement signed by both parties.

Signed as follows:

/s/ Heidi Manna	*/s/ Finbar Larkin*
Heidi Manna **Chief Human Resources Officer** **Jazz Pharmaceuticals**	**Finbar Larkin**
Date: 23-Feb-2020	Date: 26-Feb-2020

SCHEDULE 1

Change in Control Severance Benefits for Finbar Larkin

1. **Covered Termination:** Finbar Larkin (the "**Executive**") will be eligible for the severance benefits set forth in this Schedule 1 (the "**Severance Benefits**") in the event of a Covered Termination which is effective on or within twelve (12) months following a Change in Control, subject to the requirements set forth in this Schedule 1.

2. **Severance Benefits:** The Severance Benefits will consist of cash severance payment and payments for continued health care insurance coverage, as follows:

   a. **Cash Severance Benefits:** A lump sum cash severance payment will be paid to the Executive in a gross amount equal to the sum of the following three components (the "**Severance Payment**"):

      (1) Executive's annual basic salary in effect as of the effective date of the Executive's Covered Termination (without giving effect to any reduction in base salary that would constitute grounds for Constructive Termination) (the "**Severance Base**") multiplied by 150%;

      (2) The product of the Severance Base multiplied by the Bonus Percentage (defined below) multiplied by 150%; and

      (3) The product of the Severance Base multiplied by the Bonus Percentage multiplied by the Bonus Multiplier (defined below).

   Notwithstanding the foregoing, to the extent applicable, the Severance Payment shall be reduced by any amounts paid to Executive: (i) during any period of garden leave immediately preceding the Covered Termination; (ii) qualifying as pay-in-lieu of notice; or (iii) any other severance benefits whether contractual or statutory (including but not limited to any statutory redundancy pay) or other similar benefits payable to the Executive in connection with the termination of Executive's employment.

   By way of example, if the effective date of the Covered Termination is 30 June, Executive's annual basic salary in effect as of the Covered Termination is €300,000, and his target bonus is 45% of basic salary (and Executive has not received any higher annual bonus in either of the last two calendar years prior to the Covered Termination), the Severance Payment shall be calculated as follows:

   (1) €300,000 x 150% (1.5) = €450,000
   (2) €300.000 x bonus percentage (.45) x 150% (1.5) = €202,500
   (3) €300,000 x bonus percentage (.45) x 6/12 = €67,500

   Total Gross Severance Payment: €450,000 + €202,500 + €67,500 = €720,000

   b. **Health Continuation Coverage Benefits:** To the extent that Executive elects continued private health insurance coverage following the Covered Termination at a level equivalent to the private health insurance coverage provided to Executive during his employment, the Employer shall pay the applicable premiums (inclusive of premiums for the Executive's participating dependents, if any) for such plan coverage for a period of eighteen (18) months following the date of the Covered Termination (or such earlier date if the Executive dies, if Executive and/or his dependents are no longer eligible for coverage, or if Executive obtains new employment which includes eligibility for health plan coverage). The provision of these benefits is subject to commensurate health insurance coverage being

obtained on normal terms and subject to medical and other underwriting requirements and other terms and conditions. The Executive shall be required to notify the Employer immediately if the Executive becomes covered by a health insurance plan of a subsequent employer or if the Executive or his participating dependents otherwise cease to be eligible for coverage during the period provided above. Upon the conclusion of such period of insurance premium payments made by the Employer, the Executive will be responsible for the entire payment of premiums.

3. Certain Definitions:

a. "**Affiliate**" means any "parent" or "subsidiary" of Employer as such terms are defined in Rule 405 of the United States Securities Act of 1933, as amended.

b. "**Bonus Percentage**" means the greater of (i) any annual bonus, expressed as a percentage of annual base salary paid in the year of determination, paid to the Executive by the Company or an Affiliate in respect of either of the last two calendar years prior to the date of a Covered Termination or (ii) the Executive's target bonus, expressed as a percentage of annual base salary, for the calendar year in which the Covered Termination occurs.

c. "**Bonus Multiplier**" means the quotient obtained by dividing the number of full months that the Executive is employed by the Company or an Affiliate in the calendar year of a Covered Termination by twelve (12).

d. "**Change in Control**" means "Change in Control" as defined in the Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan.

e. "**Cause**" means the occurrence of any one or more of the following:

i. the Executive's unauthorised use or disclosure of the confidential information or trade secrets of the Employer or its Affiliates which use or disclosure causes material harm to the Employer or an Affiliate;
ii. the Executive's material breach of any agreement between the Executive and the Employer or an Affiliate which remains uncured for ten (10) business days after receiving written notification of the breach from the Employer;
iii. the Executive's material failure to comply with the written policies or rules of the Employer or an Affiliate which remains uncured for ten (10) business days after receiving written notification of the breach from the Employer;
iv. the Executive's conviction of, or plea of guilty or no contest to, any crime involving fraud, dishonesty, or moral turpitude under the laws of any United States or Irish Federal, state, local, or foreign governmental authority;
v. the Executive's gross misconduct;
vi. the Executive's continuing failure to perform assigned duties after receiving written notification of the failure from the Employer;
vii. the Executive's failure to cooperate in good faith with a governmental or internal investigation of the Employer, its Affiliates, directors, officers, or employees, if the Employer has requested the Executive's cooperation; or
viii. any action of Executive warranting summary dismissal or termination without prior notice under Executive's Terms and Conditions of Employment dated 22 February 2013, as amended, or such other employment agreement with the Employer as in effect on the Covered Termination (as applicable, the "**Employment Agreement**") or under applicable employment laws.

f. "**Constructive Termination**" means a resignation of employment by Executive after an action or event which constitutes Good Reason is undertaken by Employer or an Affiliate, or otherwise occurs, provided such action or event is not agreed to by Executive in writing; provided, however, that in order for Executive's resignation to constitute a Constructive Termination, Executive must (i) provide written notice to Employer's General Counsel within thirty (30) days after the first occurrence of the event giving rise to Good Reason setting forth the basis for such resignation, (ii) allow Employer at least thirty (30) days from receipt of such written notice to cure such event, and (iii) if such event is not reasonably cured within such period, resign from all positions Executive then holds with Employer and any Affiliate effective not later than ninety (90) days after the expiration of the cure period.

g. "**Covered Termination**" means either (i) an Involuntary Termination Without Cause, or (ii) a Constructive Termination. Termination of employment of Executive due to death or disability shall not constitute a Covered Termination unless a resignation of employment by Executive immediately prior to Executive's death or disability would have qualified as a Constructive Termination.

h. "**Employer**" means the corporate entity which employed Executive as of the effective date of the Covered Termination (including any predecessor or successor entity).

i. "**Executive**" means Finbar Larkin.

j. "**Good Reason**" means the occurrence of any one or more of the following actions or events without Executive's written consent:

i. a reduction in Executive's base salary by more than ten percent (10%) (other than a reduction in conjunction with (x) a Company-wide salary reduction, or (y) a salary reduction involving senior management of Employer which results in salary reductions for employees similarly-situated to Executive);

ii. a relocation of Executive's place of employment that increases Executive's one-way commute by more than thirty-five (35) miles;

iii. a substantial reduction in Executive's duties or responsibilities (and not simply a change in reporting relationships) in effect immediately prior to the effective date of the Change in Control; provided, however, that it shall not constitute "Good Reason" if, following the effective date of the Change in Control, either (x) Employer is retained as a separate legal entity or business unit and Executive holds the same position in such legal entity or business unit as Executive held before such effective date, (y) Executive holds a position with duties and responsibilities comparable (although not necessarily identical, in view of the relative sizes of Employer and the entity involved in the Change in Control) to the duties and responsibilities of Executive prior to the effective date of the Change in Control; or

iv. a reduction in the Executive's title.

k. "**Involuntary Termination Without Cause**" means a termination by the Employer of the Executive's employment relationship with the Employer or an Affiliate for any reason other than for Cause and other than as a result of death or disability.

4. Additional Terms for Severance Benefits: The following additional terms shall apply:

a. **Release:** In order to be eligible to receive, and prior to receipt of, any of the Severance Benefits, the Executive must execute a general waiver and release and return such release to Employer within the time period specified therein, but in no event more than forty-five (45) days following the date of the Covered Termination, and such release must become effective in accordance with its terms but in all cases

not later than the sixtieth (60th) day following the Covered Termination. No release shall require the Executive to forego any unpaid salary, any accrued but unpaid vacation pay, or any vested or earned benefits payable pursuant to the Executive's Employment Agreement or by law. The Employer, in its sole discretion, may modify the form of the required release to comply with applicable law and shall determine the form of the required release.

b. **Mitigation:** The Executive shall not be required to mitigate damages as a condition of the Severance Benefits by seeking other employment or otherwise. Similarly, no amount of the Severance Benefits shall be reduced by any compensation earned by the Executive as a result of employment by another employer or any retirement benefits received by such Executive after the date of the Executive's termination of employment with the Employer, except for Severance Benefits relating to payments for health continuation coverage provided above.

c. **Tax Withholding, Contributions:** All payments under this Schedule will be subject to all applicable deductions and withholdings of tax, PRSI, Universal Social Charge, and any other deductions which are required pursuant to the terms of the Executive's employment or by law, or which are provided for in the Executive's Employment Agreement and/or this Schedule.

Exhibit 10.3

[Jazz Pharmaceuticals Letterhead]

March 30, 2020

Michael P. Miller
[Address on file]

Re: Amendment to Transition and Termination Agreement

Dear Mike,

As discussed, this letter amends the Transition and Termination Agreement (the "**Agreement**") between you and Jazz Pharmaceuticals, Inc. (the "**Company**") dated October 31, 2019, as set forth below:

- The time period that you will remain in your current position of Executive Vice President, U.S. Commercial is extended through May 31, 2020, or such later date if deemed appropriate by Bruce Cozadd and Dan Swisher. Thereafter, you will move into the project-based role of EVP, Special Projects and you will cease to be a Section 16 officer or a member of the Company's Executive Committee. You will remain in the EVP, Special Projects role for a period of three (3) months, and then your employment will end (this date is referred to as the "Termination Date" in the Agreement). During your period of continued employment (both in your current role, and once you move into the role of EVP, Special Projects), you will continue to be paid your current full-time base salary, you will receive regular employee benefits coverage (subject to the terms and conditions of the benefit plans), and your equity awards will continue to vest on their regular vesting schedules.
- As already provided under Section 3(c) of the Agreement, the 2020 prorated bonus that you will be eligible to receive will be calculated based on the period of time that you remain in your current role of Executive Vice President, U.S. Commercial. Thus, if you move out of that role effective May 31, 2020, the 2020 prorated bonus will be calculated as 5/12th of the applicable "at target" amount as set forth in the Cash Bonus Plan (which is a total of $100,312.50).

The other terms of the Agreement are not affected by this Amendment and will continue in effect, including but not limited to the terms relating to the Final Payment and Company-paid COBRA as set forth in Section 3. Any further modification or amendment of the Agreement must be contained in a writing signed by both you and a duly authorized officer of the Company.

March 30, 2020
Michael P. Miller

We appreciate your continued leadership and support for our patients during this unprecedented period.

Sincerely,

JAZZ PHARMACEUTICALS, INC.

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

REVIEWED, UNDERSTOOD, AND AGREED:
/s/ Mike Miller
Michael P. Miller

31-Mar-2020
Date

Exhibit 10.4

Amendment to Samantha Pearce's Employment Contract

This amendment (the "**Amendment**") applies to the Employment Contract between Samantha Pearce (the "**Executive**") and Jazz Pharmaceuticals UK Limited dated 13 December 2019 (the "**Employment Contract**"). The Employment Contract is amended as set forth herein.

1. **Change in Control Severance Benefits.** The attached ***Schedule 1***, effective as of 11 February 2020, contains the terms and conditions of Executive's eligibility for certain change in control severance benefits.

2. **Miscellaneous.** This Amendment, including ***Schedule 1***, sets forth all modifications to the Employment Contract, and the other terms of the Employment Contract remain in full force and effect. This Amendment can only be modified in a written agreement signed by both parties.

Signed as follows:

/s/ Heidi Manna	*/s/ Samantha Pearce*
Heidi Manna **Chief Human Resources Officer** **Jazz Pharmaceuticals**	**Samantha Pearce**
Date: 21-Apr-2020	Date: 18-Apr-2020

SCHEDULE 1

Change in Control Severance Benefits for Samantha Pearce

1. **Covered Termination**: Samantha Pearce (the "**Executive**") will be eligible for the severance benefits set forth in this Schedule 1 (the "**Severance Benefits**") in the event of a Covered Termination which is effective on or within twelve (12) months following a Change in Control, subject to the requirements set forth in this Schedule 1.

2. **Severance Benefits**: The Severance Benefits will consist of cash severance payment and payments for continued health care insurance coverage, as follows:

   a. **Cash Severance Benefits**: A lump sum cash severance payment will be paid to the Executive in a gross amount equal to the sum of the following three components (the "**Severance Payment**"):

      (1) Executive's annual basic salary in effect as of the effective date of the Executive's Covered Termination (without giving effect to any reduction in base salary that would constitute grounds for Constructive Termination) (the "**Severance Base**") multiplied by 150%;

      (2) The product of the Severance Base multiplied by the Bonus Percentage (defined below) multiplied by 150%; and

      (3) The product of the Severance Base multiplied by the Bonus Percentage multiplied by the Bonus Multiplier (defined below).

   Notwithstanding the foregoing, to the extent applicable, the Severance Payment shall be reduced by any amounts paid to Executive: (1) during any period of garden leave immediately preceding the Covered Termination; (ii) qualifying as pay-in-lieu of notice; or (iii) any other severance benefits whether contractual or statutory (including but not limited to any statutory redundancy pay) or other similar benefits payable to the Executive in connection with the termination of Executive's employment.

   By way of example, if the effective date of the Covered Termination is 30 June, Executive's annual basic salary in effect as of the Covered Termination is £300,000, and her target bonus is 45% of basic salary (and Executive has not received any higher annual bonus in either of the last two calendar years prior to the Covered Termination), the Severance Payment shall be calculated as follows:

   (1) £300,000 x 150% (1.5) = £450,000
   (2) £300.000 x bonus percentage (.45) x 150% (1.5) = £202,500
   (3) £300,000 x bonus percentage (.45) x 6/12 = £67,500

   Total Gross Severance Payment: £450,000 + £202,500 + £67,500 = £720,000

   b. **Health Continuation Coverage Benefits**: To the extent that Executive elects continued private health insurance coverage following the Covered Termination at a level equivalent to the private health insurance coverage provided to Executive during her employment, the Employer shall pay the applicable premiums (inclusive of premiums for the Executive's participating dependents, if any) for such plan

coverage for a period of eighteen (18) months following the date of the Covered Termination (or such earlier date if the Executive dies, if Executive and/or her dependents are no longer eligible for coverage, or if Executive obtains new employment which includes eligibility for health plan coverage). The provision of these benefits is subject to commensurate health insurance coverage being obtained on normal terms and subject to medical and other underwriting requirements and other terms and conditions. The Executive shall be required to notify the Employer immediately if the Executive becomes covered by a health insurance plan of a subsequent employer or if the Executive or her participating dependents otherwise cease to be eligible for coverage during the period provided above. Upon the conclusion of such period of insurance premium payments made by the Employer, the Executive will be responsible for the entire payment of premiums.

3. Certain Definitions:

a. "**Affiliate**" means any "parent" or "subsidiary" of the Employer as such terms are defined in Rule 405 of the United States Securities Act of 1933, as amended.

b. "**Bonus Percentage**" means the greater of (i) any annual bonus, expressed as a percentage of annual base salary paid in the year of determination, paid to the Executive by the Company or an Affiliate in respect of either of the last two calendar years prior to the date of a Covered Termination or (ii) the Executive's target bonus, expressed as a percentage of annual base salary, for the calendar year in which the Covered Termination occurs.

c. "**Bonus Multiplier**" means the quotient obtained by dividing the number of full months that the Executive is employed by the Company or an Affiliate in the calendar year of a Covered Termination by twelve (12).

d. "**Change in Control**" means "Change in Control" as defined in the Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan.

e. "**Cause**" means the occurrence of any one or more of the following:

i. the Executive's unauthorised use or disclosure of the confidential information or trade secrets of the Employer or its Affiliates which use or disclosure causes material harm to the Employer or an Affiliate;
ii. the Executive's material breach of any agreement between the Executive and the Employer or an Affiliate which remains uncured for ten (10) business days after receiving written notification of the breach from the Employer;
iii. the Executive's material failure to comply with the written policies or rules of the Employer or an Affiliate which remains uncured for ten (10) business days after receiving written notification of the breach from the Employer;
iv. the Executive's conviction of, or plea of guilty or no contest to, any crime involving fraud, dishonesty, or moral turpitude under the laws of any United States, England, Federal, state, local, or foreign governmental authority;
v. the Executive's gross misconduct;
vi. the Executive's continuing failure to perform assigned duties after receiving written notification of the failure from the Employer;

vii. the Executive's failure to cooperate in good faith with a governmental or internal investigation of the Employer, its Affiliates, directors, officers, or employees, if the Employer has requested the Executive's cooperation; or

viii. any action of Executive warranting summary dismissal or termination without prior notice under Executive's employment agreement with the Employer as in effect on the Covered Termination (as applicable, the "**Employment Agreement**") or under applicable employment laws.

f. "**Constructive Termination**" means a resignation of employment by Executive after an action or event which constitutes Good Reason is undertaken by Employer or an Affiliate, or otherwise occurs, provided such action or event is not agreed to by Executive in writing; provided, however, that in order for Executive's resignation to constitute a Constructive Termination, Executive must (i) provide written notice to Employer's General Counsel within thirty (30) days after the first occurrence of the event giving rise to Good Reason setting forth the basis for such resignation, (ii) allow Employer at least thirty (30) days from receipt of such written notice to cure such event, and (iii) if such event is not reasonably cured within such period, resign from all positions Executive then holds with Employer and any Affiliate effective not later than ninety (90) days after the expiration of the cure period.

g. "**Covered Termination**" means either (I) an Involuntary Termination Without Cause, or (ii) a Constructive Termination. Termination of employment of Executive due to death or disability shall not constitute a Covered Termination unless a resignation of employment by Executive immediately prior to Executive's death or disability would have qualified as a Constructive Termination.

h. "**Employer**" means the corporate entity which employed Executive as of the effective date of the Covered Termination (including any predecessor or successor entity).

i. "**Executive**" means Samantha Pearce.

j. "**Good Reason**" means the occurrence of any one or more of the following actions or events without Executive's written consent:

i. a reduction in Executive's base salary by more than ten percent (10%) (other than a reduction in conjunction with (x) a Company-wide salary reduction, or (y) a salary reduction involving senior management of Employer which results in salary reductions for employees similarly-situated to Executive);

ii. a relocation of Executive's place of employment that increases Executive's one-way commute by more than thirty-five (35) miles;

iii. a substantial reduction in Executive's duties or responsibilities (and not simply a change in reporting relationships) in effect immediately prior to the effective date of the Change in Control; provided, however, that it shall not constitute "Good Reason" if, following the effective date of the Change in Control, either (x) Employer is retained as a separate legal entity or business unit and Executive holds the same position in such legal entity or business unit as Executive held before such effective date, (y) Executive holds a position with duties and responsibilities comparable (although not necessarily identical, in view of the relative sizes of Employer and the entity involved in the Change in Control) to the duties and responsibilities of Executive prior to the effective date of the Change in Control; or

iv. a reduction in the Executives title.

k. "**Involuntary Termination Without Cause**" means a termination by the Employer of the Executive's employment relationship with the Employer or an Affiliate for any reason other than for Cause and other than as a result of death or disability.

4. Additional Terms for Severance Benefits: The following additional terms shall apply:

a. **Release**: In order to be eligible to receive, and prior to receipt of, any of the Severance Benefits, the Executive must execute a general waiver and release and return such release to Employer within the time period specified therein, but in no event more than forty-five (45) days following the date of the Covered Termination, and such release must become effective in accordance with its terms but in all cases not later than the sixtieth (60th) day following the Covered Termination. No release shall require the Executive to forego any unpaid salary, any accrued but unpaid vacation pay, or any vested or earned benefits payable pursuant to the Executive's Employment Agreement or by law. The Employer, in its sole discretion, may modify the form of the required release to comply with applicable law and shall determine the form of the required release.

b. **Mitigation**: The Executive shall not be required to mitigate damages as a condition of the Severance Benefits by seeking other employment or otherwise. Similarly, no amount of the Severance Benefits shall be reduced by any compensation earned by the Executive as a result of employment by another employer or any retirement benefits received by such Executive after the date of the Executive's termination of employment with the Employer, except for Severance Benefits relating to payments for health continuation coverage provided above.

c. **Tax Withholding, Contributions**: All payments under this Schedule will be subject to all applicable deductions and withholding of the Employer, including, without limitation, all obligations to withhold or make deductions for federal, state and local income and employment taxes, as well as national contributions and any other required deductions or withholdings which are required pursuant to the terms of the Executive's employment or by law, or which are provided for in the Executive's Employment Agreement and/or this Schedule (including for the avoidance of doubt deductions for income tax and national insurance contributions required under English law).

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 5, 2020

By: /s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION

I, Renée Galá, 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 5, 2020

By: /s/ Renée Galá

Renée Galá
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 Renée Galá, 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, 2020, 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 5, 2020

/s/ Bruce C. Cozadd

Bruce C. Cozadd

Chairman and Chief Executive Officer and Director

/s/ Renée Galá

Renée Galá

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.