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 September 30, 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 October 27, 2020, 55,714,006 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 SEPTEMBER 30, 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, Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion, Zepzelca™ (lurbinectedin), and Xywav™ (calcium, magnesium, potassium, and sodium oxybates) oral solution. 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)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 741,942	$ 637,344
Investments	1,175,000	440,000
Accounts receivable, net of allowances	361,664	355,987
Inventories	91,404	78,608
Prepaid expenses	58,305	39,434
Other current assets	127,258	78,895
Total current assets	2,555,573	1,630,268
Property, plant and equipment, net	128,204	131,506
Operating lease assets	130,717	139,385
Intangible assets, net	2,241,107	2,440,977
Goodwill	937,099	920,018
Deferred tax assets, net	254,810	221,403
Deferred financing costs	5,802	7,426
Other non-current assets	38,646	47,914
Total assets	$ 6,291,958	$ 5,538,897
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 67,063	$ 45,732
Accrued liabilities	302,071	269,686
Current portion of long-term debt	243,999	33,387
Income taxes payable	25,910	10,965
Deferred revenue	3,090	4,720
Total current liabilities	642,133	364,490
Deferred revenue, non-current	2,951	4,861
Long-term debt, less current portion	1,843,685	1,573,870
Operating lease liabilities, less current portion	141,925	151,226
Deferred tax liabilities, net	141,588	224,095
Other non-current liabilities	142,475	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	2,537,989	2,266,026
Accumulated other comprehensive loss	(187,801)	(223,393)
Retained earnings	1,026,480	1,067,815
Total shareholders' equity	3,377,201	3,110,981
Total liabilities and shareholders' equity	$ 6,291,958	$ 5,538,897

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	$ 596,949	$ 532,321	$ 1,685,357	$ 1,559,075
Royalties and contract revenues	3,939	5,381	12,693	20,946
Total revenues	600,888	537,702	1,698,050	1,580,021
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	42,095	31,400	98,760	92,582
Selling, general and administrative	207,255	178,706	607,061	522,667
Research and development	78,647	79,855	243,676	202,344
Intangible asset amortization	66,684	62,863	192,505	181,324
Acquired in-process research and development	10,000	51,775	215,250	109,975
Impairment charge	—	—	136,139	—
Total operating expenses	404,681	404,599	1,493,391	1,108,892
Income from operations	196,207	133,103	204,659	471,129
Interest expense, net	(27,428)	(17,861)	(72,134)	(54,017)
Foreign exchange loss	(639)	(1,033)	(2,235)	(3,577)
Income before income tax provision (benefit) and equity in loss of investees	168,140	114,209	130,290	413,535
Income tax provision (benefit)	19,283	10,903	22,750	(38,631)
Equity in loss of investees	623	1,030	2,338	2,791
Net income	$ 148,234	$ 102,276	$ 105,202	$ 449,375
Net income per ordinary share:				
Basic	$ 2.67	$ 1.80	$ 1.89	$ 7.90
Diluted	$ 2.64	$ 1.78	$ 1.87	$ 7.80
Weighted-average ordinary shares used in per share calculations - basic	55,545	56,674	55,637	56,860
Weighted-average ordinary shares used in per share calculations - diluted	56,236	57,438	56,297	57,647

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income	$ 148,234	$ 102,276	$ 105,202	$ 449,375
Other comprehensive income (loss):				
Foreign currency translation adjustments	47,139	(48,448)	37,879	(56,271)
Unrealized gain (loss) on hedging activities, net of income tax provision (benefit) of $167, ($80), ($327) and ($769), respectively	1,169	(558)	(2,287)	(5,380)
Other comprehensive income (loss)	48,308	(49,006)	35,592	(61,651)
Total comprehensive income	$ 196,542	$ 53,270	$ 140,794	$ 387,724

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
Issuance of Exchangeable Senior Notes, due 2026	—	—	—	—	—	176,260	—	—	176,260
Partial repurchase of Exchangeable Senior Notes, due 2021	—	—	—	—	—	(12,069)	—	—	(12,069)
Issuance of ordinary shares in conjunction with exercise of share options	74	—	—	—	—	4,440	—	—	4,440
Issuance of ordinary shares under employee stock purchase plan	65	—	—	—	—	6,547	—	—	6,547
Issuance of ordinary shares in conjunction with vesting of restricted stock units	19	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(1,116)	—	—	(1,116)
Share-based compensation	—	—	—	—	—	30,599	—	—	30,599
Shares repurchased	(70)	—	—	—	—	—	—	(7,484)	(7,484)
Other comprehensive income	—	—	—	—	—	—	21,327	—	21,327
Net income	—	—	—	—	—	—	—	114,801	114,801
Balance at June 30, 2020	55,456	$ 6	4,000	$ 55	$ 472	$2,499,135	$ (236,109)	$ 878,246	$3,141,805
Partial repurchase of Exchangeable Senior Notes, due 2021	—	—	—	—	—	(444)	—	—	(444)
Issuance of ordinary shares in conjunction with exercise of share options	96	—	—	—	—	10,088	—	—	10,088
Issuance of ordinary shares in conjunction with vesting of restricted stock units	40	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(1,097)	—	—	(1,097)
Share-based compensation	—	—	—	—	—	30,307	—	—	30,307
Other comprehensive income	—	—	—	—	—	—	48,308	—	48,308
Net income	—	—	—	—	—	—	—	148,234	148,234
Balance at September 30, 2020	55,592	$ 6	4,000	$ 55	$ 472	$2,537,989	$ (187,801)	$1,026,480	$3,377,201

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

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2018	57,504	$ 6	4,000	$ 55	$ 472	$2,113,630	$ (197,791)	$ 841,050	$2,757,422
Cumulative effect adjustment from adoption of new accounting standards	—	—	—	—	—	—	—	4,848	4,848
Issuance of ordinary shares in conjunction with exercise of share options	54	—	—	—	—	3,057	—	—	3,057
Issuance of ordinary shares in conjunction with vesting of restricted stock units	203	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(13,810)	—	—	(13,810)
Share-based compensation	—	—	—	—	—	27,861	—	—	27,861
Shares repurchased	(858)	—	—	—	—	—	—	(111,249)	(111,249)
Other comprehensive loss	—	—	—	—	—	—	(22,883)	—	(22,883)
Net income	—	—	—	—	—	—	—	85,201	85,201
Balance at March 31, 2019	56,903	$ 6	4,000	$ 55	$ 472	$2,130,738	$ (220,674)	$ 819,850	$2,730,447
Issuance of ordinary shares in conjunction with exercise of share options	98	—	—	—	—	7,033	—	—	7,033
Issuance of ordinary shares under employee stock purchase plan	57	—	—	—	—	6,032	—	—	6,032
Issuance of ordinary shares in conjunction with vesting of restricted stock units	15	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(1,003)	—	—	(1,003)
Share-based compensation	—	—	—	—	—	28,658	—	—	28,658
Shares repurchased	(447)	—	—	—	—	—	—	(59,869)	(59,869)
Other comprehensive income	—	—	—	—	—	—	10,238	—	10,238
Net income	—	—	—	—	—	—	—	261,898	261,898
Balance at June 30, 2019	56,626	$ 6	4,000	$ 55	$ 472	$2,171,458	$ (210,436)	$1,021,879	$2,983,434
Issuance of ordinary shares in conjunction with exercise of share options	110	—	—	—	—	9,968	—	—	9,968
Issuance of ordinary shares in conjunction with vesting of restricted stock units	32	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(1,087)	—	—	(1,087)
Share-based compensation	—	—	—	—	—	28,817	—	—	28,817
Shares repurchased	(149)	—	—	—	—	—	—	(19,997)	(19,997)
Other comprehensive loss	—	—	—	—	—	—	(49,006)	—	(49,006)
Net income	—	—	—	—	—	—	—	102,276	102,276
Balance at September 30, 2019	56,619	$ 6	4,000	$ 55	$ 472	$2,209,156	$ (259,442)	$1,104,158	$3,054,405

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

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities		
Net income	$ 105,202	$ 449,375
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	192,505	181,324
Share-based compensation	89,614	84,626
Impairment charge	136,139	—
Depreciation	14,076	10,885
Acquired in-process research and development	215,250	109,975
Deferred tax benefit	(120,909)	(167,935)
Provision for losses on accounts receivable and inventory	9,148	3,847
Loss on extinguishment of debt	5,089	—
Amortization of debt discount and deferred financing costs	40,613	34,415
Other non-cash transactions	12,672	(1,638)
Changes in assets and liabilities:		
Accounts receivable	(5,004)	(4,307)
Inventories	(21,861)	(23,028)
Prepaid expenses and other current assets	(64,902)	(22,858)
Other non-current assets	13,941	(540)
Operating lease assets	9,730	10,919
Accounts payable	20,645	29,104
Accrued liabilities	26,510	(37,369)
Income taxes payable	15,089	42,813
Deferred revenue	(3,540)	(4,234)
Other non-current liabilities	33,254	(3,634)
Operating lease liabilities, less current portion	(9,884)	(3,137)
Net cash provided by operating activities	713,377	688,603
Investing activities		
Proceeds from maturity of investments	920,000	820,000
Purchases of property, plant and equipment	(10,889)	(32,998)
Acquisitions, net of cash acquired	—	(55,074)
Acquired in-process research and development	(215,250)	(61,700)
Acquisition of intangible assets	(113,000)	(80,500)
Acquisition of investments	(1,661,750)	(585,975)
Net cash provided by (used in) investing activities	(1,080,889)	3,753
Financing activities		
Net proceeds from issuance of Exchangeable Senior Notes, due 2026	981,381	—
Proceeds from revolving credit facility	500,000	—
Proceeds from employee equity incentive and purchase plans	34,339	26,090
Payment of employee withholding taxes related to share-based awards	(15,760)	(15,900)
Repayments of long-term debt	(25,040)	(25,040)
Share repurchases	(146,537)	(191,115)
Payments for partial repurchase of Exchangeable Senior Notes, due 2021	(356,188)	—
Repayments under revolving credit facility	(500,000)	—
Net cash provided by (used in) financing activities	472,195	(205,965)
Effect of exchange rates on cash and cash equivalents	(85)	(838)
Net increase in cash and cash equivalents	104,598	485,553
Cash and cash equivalents, at beginning of period	637,344	309,622
Cash and cash equivalents, at end of period	$ 741,942	$ 795,175

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 that transform the lives of patients 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 malignancies and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, a 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 narcolepsy patients seven years of age and older;
- **Xywav™ (calcium, magnesium, potassium, and sodium oxybates) oral solution**, a product that contains 92% less sodium than Xyrem, approved by FDA and launched in the U.S. in November 2020 for the treatment of cataplexy or EDS in narcolepsy patients seven years of age and older;
- **Sunosi® (solriamfetol)**, a product approved by FDA and marketed in the U.S. and in Europe to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea;
- **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;
- **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; and
- **Zepzelca™ (lurbinectedin)**, a product approved by FDA in June 2020 and launched in July 2020 in the U.S. for the treatment of adult patients with metastatic small cell lung cancer, or SCLC, with disease progression on or after platinum-based chemotherapy.

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 and nine months ended September 30, 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 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 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.

In March 2020, the FASB issued ASU No. 2020-04, "Reference Rate Reform (ASC 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting" which contains optional expedients and exceptions for applying GAAP to contracts, hedging relationships and other transactions affected by reference rate reform. ASC 848 allows for different elections to be made at different points in time, and the timing of those elections will be documented as applicable. For the avoidance of doubt, we intend to reassess the elections of optional expedients and exceptions included within ASC 848 related to our hedging activities and will document the election of these items on a quarterly basis. ASC 848 is effective for us as of January 1, 2020 and will no longer be available to apply after December 31, 2022. In June 2020, we elected the expedient in ASC 848-50-25-2, which allows us to assume that our hedged interest payments will probably occur regardless of any expected modification in their terms related to reference rate reform.

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, patients and our business. Since the second quarter of 2020, we have been experiencing financial and other impacts of the pandemic, and 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 continue to be adversely affected in future quarters. With respect to our commercialization activities, the evolving effects of the COVID-19 pandemic continue to have a negative impact on demand, 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. 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 and severity of the

pandemic, 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 future plans assume that our newly launched oxybate product Xywav, with 92% lower sodium compared to Xyrem, absence of a sodium warning and dosing titration option, will become the treatment of choice for patients who can benefit from oxybate treatment, current Xyrem patients, and patients who previously were not prescribed Xyrem, including those patients for whom sodium content is a concern. While we expect that our business will continue to be substantially dependent on oxybate product sales from both Xyrem and Xywav, there is no guarantee that we can maintain oxybate sales at or near historical levels, or that oxybate sales will continue to grow. Our ability to maintain or increase oxybate sales is subject to a number of risks and uncertainties including, without limitation, those related to 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 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, including our ability to obtain and maintain adequate coverage and reimbursement for Xywav, challenges to our intellectual property around Xyrem and Xywav, and continued acceptance of Xyrem by physicians and patients and acceptance of Xywav by payors, physicians and patients.

In addition to risks related specifically to Xyrem and Xywav, we are subject to other challenges and risks related to successfully commercializing a portfolio of oncology products and other neuroscience products, including Sunosi, Defitelio, Erwinaze, Vyxeos and Zepzelca, 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; effectively commercializing our recently approved products such as Sunosi, Zepzelca and Xywav; 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 COVID-19 pandemic continues to adversely affect 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 September 30, 2020, we had foreign exchange forward contracts with notional amounts totaling $300.5 million. As of September 30, 2020, the outstanding foreign exchange forward contracts had a net liability fair value of $0.1 million. As of September 30, 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 $4.1 million as of September 30, 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 September 30, 2020 and December 31, 2019, allowances on receivables were not material. As of September 30, 2020, two customers accounted for 81% of gross accounts

receivable, Express Scripts Specialty Distribution Services, Inc. and its affiliates, or ESSDS, which accounted for 73% of gross accounts receivable, and McKesson Corporation and affiliates, or McKesson, which accounted for 8% 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. The new guidance is not expected to have a material impact on our results of operations and financial position.

In August 2020, the FASB issued ASU No. 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity”, which simplifies the accounting for convertible instruments by eliminating the requirement to separate embedded conversion features from the host contract when the conversion features are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-in capital. By removing the separation model, a convertible debt instrument will be reported as a single liability instrument with no separate accounting for embedded conversion features. This new standard also removes certain settlement conditions that are required for contracts to qualify for equity classification and eliminates the treasury stock method to calculate diluted earnings per share for convertible instruments and requires the use of the if-converted method. This new standard will be effective for us for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than the fiscal year beginning after December 15, 2020. We may elect to apply the amendments on a retrospective or modified retrospective basis. We are currently evaluating the timing, method of adoption and overall impact of this standard on our consolidated financial statements.

2. License Agreement

On December 19, 2019, we entered into an exclusive license agreement, or original license agreement, with Pharma Mar, S.A., or PharmaMar, for development and U.S. commercialization of Zepzelca. Zepzelca was granted orphan drug designation for relapsed SCLC by FDA in August 2018. In December 2019, PharmaMar submitted a new drug application, or NDA, to FDA for accelerated approval of Zepzelca for relapsed SCLC based on data from a Phase 2 trial, and in February 2020, FDA accepted the NDA for filing with priority review. In June 2020, FDA approved the NDA for Zepzelca for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.

Under the terms of the original license 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 in-process research and development, or IPR&D expense in our condensed consolidated statements of income for the nine months ended September 30, 2020. In June 2020, we made a milestone payment of $100.0 million to PharmaMar following FDA accelerated approval of Zepzelca, which was capitalized as an intangible asset on our condensed consolidated balance sheet.

PharmaMar is eligible to receive potential future regulatory milestone payments of up to $150.0 million upon the achievement of continued U.S. regulatory approval of Zepzelca following the successful completion of confirmatory trials within certain timelines. PharmaMar is also eligible to receive up to $550.0 million in potential U.S. commercial milestone payments, as well as incremental tiered royalties on future net sales of Zepzelca 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 Zepzelca and will supply the product to us.

In October 2020, we entered into an amendment and restatement of the original license agreement with PharmaMar, or the amended license agreement, which expanded our exclusive license to include rights to develop and commercialize Zepzelca in Canada.

3. Cash and Available-for-Sale Securities

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

	September 30, 2020					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 406,338	$ —	$ —	$ 406,338	$ 406,338	$ —
Time deposits	1,255,000	—	—	1,255,000	80,000	1,175,000
Money market funds	255,604	—	—	255,604	255,604	—
Totals	$ 1,916,942	$ —	$ —	$ 1,916,942	$ 741,942	$ 1,175,000

	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 condensed consolidated statements of income. 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 $2.1 million and $9.7 million in the three and nine months ended September 30, 2020, respectively, and $5.4 million and $15.2 million in the three and nine months ended September 30, 2019, respectively.

4. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of September 30, 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):

	September 30, 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	$ —	$ 1,255,000	$ 1,255,000	$ —	$ 460,000	$ 460,000
Money market funds	255,604	—	255,604	284,172	—	284,172
Foreign exchange forward contracts	—	4,079	4,079	—	2,508	2,508
Totals	$ 255,604	$ 1,259,079	$ 1,514,683	$ 284,172	$ 462,508	$ 746,680
Liabilities:						
Interest rate contracts	$ —	$ 4,143	$ 4,143	$ —	$ 1,515	$ 1,515
Foreign exchange forward contracts	—	4,221	4,221	—	182	182
Totals	$ —	$ 8,364	$ 8,364	$ —	$ 1,697	$ 1,697

As of September 30, 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 September 30, 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 September 30, 2020, the estimated fair values of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, and our 2.00% exchangeable senior notes due 2026, or the 2026 Notes, were approximately $222 million, $584 million and $1.2 billion, respectively. The fair values of the 2021 Notes, the 2024 Notes and the 2026 Notes, which we refer to collectively 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 September 30, 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 and nine months ended September 30, 2020 and 2019 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Interest Rate Contracts:	**2020**	**2019**	**2020**	**2019**
Gain (loss) recognized in accumulated other comprehensive loss, net of tax	$ 9	$ (322)	$ (4,515)	$ (4,361)
Loss (gain) reclassified from accumulated other comprehensive loss to interest expense, net of tax	1,160	(236)	2,228	(1,019)

Assuming no change in London Inter-Bank Offered Rate, or LIBOR, based interest rates from market rates as of September 30, 2020, $3.6 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 September 30, 2020 and December 31, 2019, the notional amount of foreign exchange contracts where hedge accounting is not applied was $300.5 million and $180.9 million, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Foreign Exchange Forward Contracts:	**2020**	**2019**	**2020**	**2019**
Gain (loss) recognized in foreign exchange loss	$ 9,549	$ (7,430)	$ 6,943	$ (10,718)

The cash flow effects of our derivative contracts for the nine months ended September 30, 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):

	September 30, 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	$ 4,143
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	4,079	Accrued liabilities	4,221
Total fair value of derivative instruments		$ 4,079		$ 8,364

	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):

	September 30, 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	$ 4,079	$ —	$ 4,079	$ (2,255)	$ —	$ 1,824
Derivative liabilities	(8,364)	—	(8,364)	2,255	—	(6,109)

	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):

	September 30, 2020	December 31, 2019
Raw materials	$ 17,338	$ 13,595
Work in process	46,278	36,658
Finished goods	27,788	28,355
Total inventories	$ 91,404	$ 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	17,081
Balance at September 30, 2020	$ 937,099

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

	September 30, 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	12.7	$3,324,806	$ (1,083,699)	$2,241,107	$3,166,485	$ (864,834)	$2,301,651
Manufacturing contracts	—	12,533	(12,533)	—	12,025	(12,025)	—
Trademarks	—	2,903	(2,903)	—	2,890	(2,890)	—
Priority review voucher	—	—	—	—	111,101	(111,101)	—
Total finite-lived intangible assets		3,340,242	(1,099,135)	2,241,107	3,292,501	(990,850)	2,301,651
Acquired IPR&D assets		—	—	—	139,326	—	139,326
Total intangible assets		$3,340,242	$ (1,099,135)	$2,241,107	$3,431,827	$ (990,850)	$2,440,977

The decrease in the gross carrying amount of intangible assets as of September 30, 2020 compared to December 31, 2019 reflects the impairment of our acquired IPR&D assets of $136.1 million following the decision to stop enrollment in our Phase 3 clinical study of defibrotide for the prevention of VOD due to a determination that the study is highly unlikely to reach one of its primary endpoints and the redemption of our priority review voucher in January 2020, partially offset by the capitalization of milestone payments of $100.0 million and $13.0 million triggered by FDA approval of Zepzelca in June 2020 and European Marketing Authorization of Sunosi in January 2020, respectively, and the positive impact of foreign currency translation adjustments due to the strengthening of the euro against the U.S. dollar.

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

Based on finite-lived intangible assets recorded as of September 30, 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)	$ 66,819
2021	219,309
2022	172,424
2023	172,424
2024	172,424
Thereafter	1,437,707
Total	$ 2,241,107

8. Certain Balance Sheet Items

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

	September 30, 2020	December 31, 2019
Leasehold improvements	$ 53,670	$ 52,294
Land and buildings	47,385	47,053
Manufacturing equipment and machinery	32,077	28,860
Computer software	22,868	25,680
Computer equipment	17,850	16,577
Furniture and fixtures	11,447	11,152
Construction-in-progress	6,072	5,147
Subtotal	191,369	186,763
Less accumulated depreciation and amortization	(63,165)	(55,257)
Property, plant and equipment, net	$ 128,204	$ 131,506

Accrued liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Rebates and other sales deductions	$ 113,062	$ 96,860
Employee compensation and benefits	76,890	80,531
Sales returns reserve	13,574	3,462
Current portion of operating lease liabilities	13,078	12,728
Royalties	10,186	6,931
Inventory-related accruals	9,318	7,816
Consulting and professional services	8,430	7,665
Derivative instrument liabilities	8,364	1,037
Accrued interest	7,762	7,540
Clinical trial accruals	7,614	3,141
Selling and marketing accruals	7,721	10,946
Accrued collaboration expenses	730	2,494
Accrued construction-in-progress	474	3,015
Other	24,868	25,520
Total accrued liabilities	$ 302,071	$ 269,686

9. Debt

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

	September 30, 2020	December 31, 2019
2021 Notes	$ 218,812	$ 575,000
Unamortized discount and debt issuance costs on 2021 Notes	(8,207)	(38,865)
2021 Notes, net	210,605	536,135
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(101,099)	(117,859)
2024 Notes, net	473,901	457,141
2026 Notes	1,000,000	—
Unamortized discount and debt issuance costs on 2026 Notes	(186,595)	—
2026 Notes, net	813,405	—
Term loan	589,773	613,981
Total debt	2,087,684	1,607,257
Less current portion	243,999	33,387
Total long-term debt	$ 1,843,685	$ 1,573,870

2026 Notes

In the second quarter of 2020, Jazz Investments I Limited, our wholly owned subsidiary, completed a private placement of $1,000.0 million principal amount of the 2026 Notes. We used a portion of the net proceeds from this offering to repurchase for cash $332.9 million aggregate principal amount of the 2021 Notes through privately-negotiated transactions concurrently with the offering of the 2026 Notes. Interest on the 2026 Notes is payable semi-annually in cash in arrears on June 15 and December 15 of each year, beginning on December 15, 2020, at a rate of 2.00% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2026 Notes. The 2026 Notes mature on June 15, 2026, unless earlier exchanged, repurchased or redeemed.

The holders of the 2026 Notes have the ability to require us to repurchase all or a portion of their 2026 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from any of The New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market or The Nasdaq Capital Market (or any of their respective successors). Additionally, the terms and covenants in the indenture related to the 2026 Notes include certain events of default after which the 2026 Notes may be due and payable immediately. Prior to June 15, 2026, we may redeem the 2026 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2026 Notes additional amounts as a result of certain tax-related events. We also may redeem the 2026 Notes on or after June 20, 2023 and prior to March 15, 2026, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2026 Notes are exchangeable at an initial exchange rate of 6.4182 ordinary shares per $1,000 principal amount of 2026 Notes, which is equivalent to an initial exchange price of approximately $155.81 per ordinary share. Upon exchange, the 2026 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2026 Notes in cash upon exchange. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2026 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2026 Notes who elect to exchange their 2026 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to March 15, 2026, the 2026 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods,

and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

In accounting for the issuance of the 2026 Notes, we separated the 2026 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the estimated fair value of a similar liability that does not have an associated exchange feature. The carrying amount of the equity component representing the exchange option was determined by deducting the fair value of the liability component from the face value of the 2026 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount will be amortized to interest expense over the expected life of the 2026 Notes using the effective interest method with an effective interest rate of 5.98% per annum. We have determined the expected life of the 2026 Notes to be equal to the original 6-year term. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

We allocated the total issuance costs incurred of $18.6 million to the liability and equity components based on their relative values. Issuance costs attributable to the liability component will be amortized to expense over the term of the 2026 Notes, and issuance costs attributable to the equity component were included with the equity component in our shareholders' equity.

Concurrently with the offering of the 2026 Notes, we repurchased $332.9 million aggregate principal amount of the 2021 Notes. In the third quarter of 2020, we repurchased a further $23.3 million aggregate principal amount of the 2021 Notes. We recorded a loss on extinguishment of debt of $0.6 million and $5.1 million, in the three and nine months ended September 30, 2020, respectively, due to the write-off of unamortized debt issuance costs and debt discount related to the partial repurchase of the 2021 Notes. We accounted for the difference between the consideration transferred and the fair value of the liability component of the 2021 Notes that were repurchased, of $12.5 million, as a reduction to the equity component. As of September 30, 2020, the principal amount of the 2021 Notes remaining was $218.8 million.

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 September 30, 2020, the carrying values of the equity component of the 2021 Notes, 2024 Notes and the 2026 Notes, net of equity issuance costs, were $114.4 million, $149.8 million and $176.3 million, respectively.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of September 30, 2020 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2020 (remainder)	$ 8,347
2021	252,198
2022	33,387
2023	517,494
2024	575,000
Thereafter	1,000,000
Total	$ 2,386,426

10. Leases

The components of the lease expense for the three and nine months ended September 30, 2020 and 2019 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Lease Cost	**2020**	**2019**	**2020**	**2019**
Operating lease cost	$ 5,501	$ 5,746	$ 16,201	$ 17,672
Short-term lease cost	942	396	2,702	1,616
Variable lease cost	1	—	2	4
Sublease income	—	(158)	(224)	(478)
Net lease cost	$ 6,444	$ 5,984	$ 18,681	$ 18,814

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

Leases	**Classification**	**September 30, 2020**	**December 31, 2019**
Assets			
Operating lease assets	Operating lease assets	$ 130,717	$ 139,385
Liabilities			
Current			
Operating lease liabilities	Accrued liabilities	13,078	12,728
Non-current			
Operating lease liabilities	Operating lease liabilities, less current portion	141,925	151,226
Total operating lease liabilities		$ 155,003	$ 163,954

Lease Term and Discount Rate	**September 30, 2020**	**December 31, 2019**
Weighted-average remaining lease term - operating leases (years)	9.1	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):

	Nine Months Ended September 30,	
	2020	**2019**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	$ 16,915	$ 11,758
Non-cash operating activities:		
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	$ 1,034	$ 153,048

(1) The September 30, 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)	$ 4,812
2021	21,618
2022	21,619
2023	21,778
2024	23,992
Thereafter	104,794
Total lease payments	198,613
Less imputed interest	(43,610)
Present value of lease liabilities	$ 155,003

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 September 30, 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 September 30, 2020, we had $75.4 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

On June 17, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by Blue Cross and Blue Shield Association, or BCBS, against Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited, or, collectively, the Company Defendants (hereinafter referred to as the BCBS Lawsuit). The BCBS Lawsuit also names Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc., Eurohealth (USA), Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceuticals, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., and Lupin Inc., or, collectively, the BCBS Defendants.

On June 18 and June 23, 2020, respectively, two additional class action lawsuits were filed against the Company Defendants and the BCBS Defendants: one by the New York State Teamsters Council Health and Hospital Fund in the United States District Court for the Northern District of California, and another by the Government Employees Health Association Inc. in the United States District Court for the Northern District of Illinois (hereinafter referred to as the GEHA Lawsuit).

On June 18, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of California by the City of Providence, Rhode Island, on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals plc, and Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals USA Inc., and Hikma Pharmaceuticals plc, or, collectively, the City of Providence Defendants.

On June 30, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by UFCW Local 1500 Welfare Fund on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals Ireland

Ltd., Jazz Pharmaceuticals, Inc., Roxane Laboratories, Inc., Hikma Pharmaceuticals plc, Eurohealth (USA), Inc. and West-Ward Pharmaceuticals Corp., or collectively the UFCW Defendants (hereinafter referred to as the UFCW Lawsuit).

On July 13, 2020, the plaintiffs in the BCBS Lawsuit and the GEHA Lawsuit dismissed their complaints in the United States District Court for the Northern District of Illinois, and refiled their respective lawsuits in the United States District Court for the Northern District of California. On July 14, 2020, the plaintiffs in the UFCW Lawsuit dismissed their complaint in the United States District Court for the Northern District of Illinois and on July 15, 2020, refiled their lawsuit in the United States District Court for the Northern District of California.

On July 31, 2020, a class action lawsuit was filed in the United States District Court for the Southern District of New York by the A.F. of L.-A.G.C Building Trades Welfare Plan on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals plc (hereinafter referred to as the AFL Plan Lawsuit). The AFL Plan Lawsuit also names Roxane Laboratories Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceuticals Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc.

On August 14, 2020, an additional class action lawsuit was filed in the United States District Court for the Southern District of New York by the Self-Insured Schools of California on behalf of itself and all others similarly situated, against the Company Defendants, as well as Hikma Pharmaceuticals plc, Eurohealth (USA) Inc., Hikma Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., Roxane Laboratories, Inc., Amneal Pharmaceuticals LLC, Endo International, plc, Endo Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., Lupin Inc., Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Holdings USA, Inc., Sun Pharmaceutical Industries, Inc., Ranbaxy Laboratories Ltd., Teva Pharmaceutical Industries Ltd., Watson Laboratories, Inc., Wockhardt Ltd., Morton Grove Pharmaceuticals, Inc., Wockhardt USA LLC, Mallinckrodt plc, and Mallinckrodt LLC (hereinafter the Self-Insured Schools Lawsuit).

On September 16, 2020, an additional class action lawsuit was filed in the United States District Court for the Northern District of California, by Ruth Hollman on behalf of herself and all others similarly situated, against the same defendants named in the Self-Insured Schools Lawsuit.

The plaintiffs in certain of the lawsuits are seeking to represent a class of direct purchasers of Xyrem, and the plaintiffs in the remaining lawsuits are seeking to represent a class of indirect purchasers of Xyrem. Each of the lawsuits generally alleges violations of U.S. federal and state antitrust, consumer protection, and unfair competition laws in connection with the Company Defendants' conduct related to Xyrem, including actions leading up to, and entering into, patent litigation settlement agreements with each of the other named defendants. Each of the lawsuits seeks monetary damages, exemplary damages, equitable relief against the alleged unlawful conduct, including disgorgement of profits and restitution, and injunctive relief. It is possible that additional lawsuits will be filed against the Company Defendants making similar or related allegations. If the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

12. Shareholders' Equity

Share Repurchase Program

In November 2016, our board of directors authorized a share repurchase program and as of September 30, 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. During the three months ended September 30, 2020, we did not repurchase any of our ordinary shares. In the nine months ended September 30, 2020, we spent a total of $146.5 million to purchase 1.2 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $121.98 per share. All ordinary shares repurchased were canceled. As of September 30, 2020, the remaining amount authorized under the share repurchase program was $431.2 million.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of September 30, 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 income (loss) before reclassifications	(4,515)	37,879	33,364
Amounts reclassified from accumulated other comprehensive loss	2,228	—	2,228
Other comprehensive income (loss), net	(2,287)	37,879	35,592
Balance at September 30, 2020	$ (3,612)	$ (184,189)	$ (187,801)

During the nine months ended September 30, 2020, other comprehensive income reflects foreign currency translation adjustments, primarily due to the strengthening of the euro against the U.S. dollar, and the net unrealized loss on derivatives that qualify as cash flow hedges.

13. Net Income per Ordinary Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net income	$ 148,234	$ 102,276	$ 105,202	$ 449,375
Denominator:				
Weighted-average ordinary shares used in per share calculations - basic	55,545	56,674	55,637	56,860
Dilutive effect of employee equity incentive and purchase plans	691	764	660	787
Weighted-average ordinary shares used in per share calculations - diluted	56,236	57,438	56,297	57,647
Net income per ordinary share:				
Basic	$ 2.67	$ 1.80	$ 1.89	$ 7.90
Diluted	$ 2.64	$ 1.78	$ 1.87	$ 7.80

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans and the Exchangeable Senior Notes are determined by applying the treasury stock method to the assumed exercise of share options, the assumed vesting of outstanding restricted stock units, or RSUs, the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP, and the assumed issuance of ordinary shares upon exchange of the Exchangeable Senior Notes. The potential issue of ordinary shares issuable upon exchange of the Exchangeable Senior Notes had no effect on diluted net income per ordinary share because the average price of our ordinary shares for the three and nine months ended September 30, 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 per ordinary share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Exchangeable Senior Notes	10,192	5,504	7,390	5,504
Options, RSUs and ESPP	5,023	5,062	5,325	5,084

14. Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Xyrem	$ 447,809	$ 425,644	$ 1,302,492	$ 1,207,173
Defitelio/defibrotide	50,241	37,604	140,387	125,159
Erwinaze/Erwinase	20,145	34,024	90,560	122,545
Vyxeos	30,825	29,581	90,113	89,886
Zepzelca	36,941	—	36,941	—
Sunosi	9,116	987	19,618	987
Other	1,872	4,481	5,246	13,325
Product sales, net	596,949	532,321	1,685,357	1,559,075
Royalties and contract revenues	3,939	5,381	12,693	20,946
Total revenues	$ 600,888	$ 537,702	$ 1,698,050	$ 1,580,021

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
United States	$ 548,410	$ 492,366	$ 1,542,990	$ 1,436,160
Europe	45,778	35,037	125,229	106,956
All other	6,700	10,299	29,831	36,905
Total revenues	$ 600,888	$ 537,702	$ 1,698,050	$ 1,580,021

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
ESSDS	74 %	79 %	77 %	76 %
McKesson	10 %	12 %	11 %	14 %

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 September 30, 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 and $3.5 million during the three and nine months ended September 30, 2020, respectively, 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 nine months ended September 30, 2020 (in thousands):

	Contract Liabilities
Balance as of December 31, 2019	$ 9,581
Amount recognized within royalties and contract revenues	(3,540)
Balance as of September 30, 2020	$ 6,041

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Selling, general and administrative	$ 20,974	$ 20,302	$ 62,590	$ 61,357
Research and development	7,463	6,498	21,511	17,917
Cost of product sales	1,919	1,985	5,513	5,352
Total share-based compensation expense, pre-tax	30,356	28,785	89,614	84,626
Income tax benefit from share-based compensation expense	(3,436)	(4,106)	(10,106)	(12,246)
Total share-based compensation expense, net of tax	$ 26,920	$ 24,679	$ 79,508	$ 72,380

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Shares underlying options granted (in thousands)	159	198	803	1,597
Grant date fair value	$ 37.75	$ 40.62	$ 34.43	$ 42.32
Black-Scholes option pricing model assumption information:				
Volatility	36 %	33 %	33 %	32 %
Expected term (years)	4.6	4.5	4.6	4.5
Range of risk-free rates	0.2-0.3%	1.5-1.7%	0.2-1.6%	1.5-2.5%
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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
RSUs granted (in thousands)	160	80	1,248	642
Grant date fair value	$ 123.79	$ 135.90	$ 114.80	$ 138.50

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 September 30, 2020, compensation cost not yet recognized related to unvested share options and RSUs was $66.8 million and $152.6 million, respectively, which is expected to be recognized over a weighted-average period of 2.5 years and 2.9 years, respectively.

16. Income Taxes

Our income tax provision was $19.3 million in the three months ended September 30, 2020, compared to $10.9 million for the same period in 2019. Our income tax provision was $22.8 million in the nine months ended September 30, 2020 compared to an income tax benefit of $38.6 million for the same period in 2019. The effective tax rate was 11.5% in the three months ended September 30, 2020 compared to 9.5% for the same period in 2019. The increase in the effective tax rate for the three months ended September 30, 2020 compared to the same period in 2019 was primarily due to the release in 2019 of reserves related to unrecognized tax benefits upon expiration of a statute of limitations, partially offset by the impact of tax credits originating in 2020. The effective tax rate was 17.5% in the nine months ended September 30, 2020, compared to (9.3)% for the same period in 2019. The income tax benefit for the nine months ended September 30, 2019 included a discrete tax benefit of $112.3 million resulting from an intra-entity intellectual property asset transfer. The tax benefit, which represents a deferred future benefit, was recorded as a deferred tax asset. The increase in the effective tax rate for the nine months ended September 30, 2020 compared to the same period in 2019 was primarily due to the impact of the intra-entity intellectual property asset transfer. Excluding this effect, the decrease in the effective tax rate for the nine months ended September 30, 2020 compared to the same period in 2019 was primarily due to the impact of the defibrotide acquired IPR&D asset impairment charge, originating tax credits and the impact of the acquired IPR&D expense related to the original PharmaMar transaction, partially offset by the impact of the disallowance of certain interest deductions and a provision for a proposed settlement reached with the French tax authorities. The effective tax rate for the three months ended September 30, 2020 was lower than the Irish statutory rate of 12.5% primarily due to the impact of originating tax credits. The effective tax rate for the nine months ended September 30, 2020 was higher than the Irish statutory rate of 12.5% primarily due to the impact of the disallowance of certain interest deductions and a provision for a proposed settlement reached with the French tax authorities, partially offset by the defibrotide acquired IPR&D asset impairment charge, originating tax credits and the impact of the acquired IPR&D expense related to the original PharmaMar transaction. We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

Our net deferred tax 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. In the period from December 2015 through to December 2019, we received proposed tax assessment notices for each of the years under examination relating to certain transfer pricing adjustments. The notices proposed additional French tax of approximately $43.8 million for 2012 and 2013 and approximately $12.5 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 September 30, 2020. Due to the subjective nature of the transfer pricing issues involved, in May 2020, the Company reached an agreement in principle to settle the audits for all open years with the French tax authorities. The settlement would require the Company to pay incremental taxes, interest and penalties of $18.5 million, translated at the foreign exchange rate as of September 30, 2020. The income tax expense for the nine months ended September 30, 2020 includes the impact of the settlement, which is subject to formal finalization and documentation with the French tax authorities. Certain of our Italian subsidiaries are currently under examination by the Italian tax authorities for the year ended December 31, 2017.

17. Subsequent Event

Asset Acquisition and Exclusive License Agreement

In October 2020, we entered into an asset purchase and exclusive license agreement with SpringWorks Therapeutics, Inc., or SpringWorks, under which we acquired SpringWorks' fatty acid amide hydrolase, or FAAH, inhibitor program. Under the terms of the agreement, SpringWorks has assigned or exclusively licensed all assets relating to its FAAH inhibitor program to us, including assignment of SpringWorks' proprietary FAAH inhibitor PF-04457845, or PF-'845, and its license agreement with Pfizer, Inc., or Pfizer, under which Pfizer exclusively licensed PF-'845 to SpringWorks in 2017. We will initially focus on developing PF-'845 for the potential treatment of post-traumatic stress disorder and associated symptoms. In addition to assuming all milestone and royalty obligations owed by SpringWorks to Pfizer, we made an upfront payment of $35.0 million to SpringWorks, and may make potential milestone payments to SpringWorks of up to $375.0 million upon the achievement of certain clinical, regulatory and commercial milestones, and pay incremental tiered royalties to SpringWorks on future net sales of PF-'845 in the mid- to high-single digit percentages.

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 that transform the lives of patients 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 malignancies and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies.

Our lead marketed products are:

- **Xyrem® (sodium oxybate) oral solution**, a 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 narcolepsy patients seven years of age and older;
- **Xywav™ (calcium, magnesium, potassium, and sodium oxybates) oral solution**, a product that contains 92% less sodium than Xyrem, approved by FDA and launched in the U.S. in November 2020 for the treatment of cataplexy or EDS in narcolepsy patients seven years of age and older;
- **Sunosi® (solriamfetol)**, a product approved by FDA and marketed in the U.S. and in Europe to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea;
- **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;
- **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; and
- **Zepzelca™ (lurbinectedin)**, a product approved by FDA in June 2020 and launched in July 2020 in the U.S. for the treatment of adult patients with metastatic small cell lung cancer, or SCLC, with disease progression on or after platinum-based chemotherapy.

Our strategy to create shareholder value is focused on:

- Strong execution driving revenue growth in our core therapy areas through leveraging our leading market position and expertise in sleep and new high-growth products in oncology that address significant unmet needs;
- Expanding our pipeline with internal and external patient-centric innovation to achieve a balanced portfolio of durable, highly differentiated programs;
- Continuing to build a flexible, efficient, and productive development engine for targeted therapeutic conditions to identify and progress early- and mid-stage assets; and

- Investing in an efficient, scalable operating model and differentiated capabilities to enable successful partnerships and unlock further value through indication expansion and global markets.

Significant Recent Developments Affecting Our Business

In November 2020, we commenced the U.S. launch of Xywav (formerly JZP-258), an oxybate product that contains 92% less sodium than Xyrem, for the treatment of cataplexy or EDS in narcolepsy patients seven years of age and older. FDA approved Xywav for this indication in July 2020. The 92% reduction of sodium 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. When patients start Xywav after sodium oxybate, Xywav treatment is initiated at the same dose and regimen as sodium oxybate (gram for gram) and titrated as needed based on efficacy and tolerability. The label for Xywav, unlike Xyrem, does not include a warning to prescribers to monitor patients sensitive to sodium intake, including patients with heart failure, hypertension or renal impairment. There is a 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. In approving Xywav, FDA approved a risk evaluation and mitigation strategy, or REMS, for Xywav and Xyrem. In an effort to support strong adoption of Xywav, we are focused on providing robust patient access programs and facilitating payer coverage for Xywav, which has been priced at parity with Xyrem.

In October 2020, we announced positive top-line results from a Phase 3 clinical trial evaluating Xywav (JZP-258) in adult patients with idiopathic hypersomnia, a chronic, neurological disorder that is primarily characterized by EDS and that currently has no approved therapies in the U.S. We expect to submit a supplemental new drug application in the first quarter of 2021 with potential approval and launch in the fourth quarter of 2021. FDA granted Fast Track designation for JZP-258 in September 2020.

In October 2020, we entered into an asset purchase and exclusive license agreement with SpringWorks Therapeutics, Inc., or SpringWorks, under which we acquired SpringWorks' fatty acid amide hydrolase, or FAAH, inhibitor program. Under the terms of the agreement, SpringWorks has assigned or exclusively licensed all assets relating to its FAAH inhibitor program to us, including assignment of SpringWorks' proprietary FAAH inhibitor PF-04457845, or PF-'845, and its license agreement with Pfizer, Inc., or Pfizer, under which Pfizer exclusively licensed PF-'845 to SpringWorks in 2017. We will initially focus on developing PF-'845 for the potential treatment of post-traumatic stress disorder and associated symptoms.

In September 2020, FDA granted Rare Pediatric Disease designation for JZP-458 for the treatment of pediatric ALL, and prior to that, in October 2019, FDA granted Fast Track designation 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. Our pivotal Phase 2/3 clinical study (conducted in collaboration with the Children's Oncology Group) for JZP-458 continues to enroll, and we expect to submit our biologics license application, or BLA, to FDA for JZP-458 as early as the end of 2020, with an objective of launching in the U.S. in mid-2021 to ensure that ALL patients have access to a reliable, high-quality recombinant product given the ongoing supply issues with Erwinaze.

In September 2020, we entered into a new research collaboration agreement with Redx Pharma plc, or Redx, to discover and develop drug candidates for two cancer targets in the Ras/Raf/MAP kinase pathway. This research collaboration follows our previously announced purchase of Redx's pre-clinical pan-Raf inhibitor program for the potential treatment of Raf and Ras mutant tumors in July 2019. Under the terms of the research collaboration agreement, we made an upfront payment to Redx of $10.0 million, which will be followed by another $10.0 million in year two, provided research work is continuing. Following delivery of an investigational new drug, or IND,-ready molecule, Redx will be eligible to receive up to a further $200.0 million from us in development, regulatory and commercial milestone payments for each program. The first milestone is payable upon successful IND submission. In addition, Redx is eligible to receive tiered royalties in mid-single digit percentages of any future net sales. Following a successful submission of an IND application, we will be responsible for further development, manufacturing, regulatory activities and commercialization.

In July 2020, we launched Zepzelca in the U.S. and the National Comprehensive Cancer Network added Zepzelca to the clinical practice guidelines in oncology for SCLC as a preferred treatment in patients who relapse in six months or less after prior systemic therapy and as a recommended regimen in patients who relapse more than six months after prior systemic therapy. At launch, all planned contracts with distributors and group purchasing organizations were in place for Zepzelca. In addition, in October 2020, we entered into an amendment and restatement of our license agreement with Pharma Mar, S.A., or PharmaMar, or the amended license agreement, which expanded our exclusive license to include rights to develop and commercialize Zepzelca in Canada.

In July 2020, Defitelio was approved by the Australian Therapeutic Goods Administration for the treatment of VOD.

Continued Emphasis on Research and Development

During the nine months ended September 30, 2020, consistent with our strategy, we continued our focus on research and development activities within our neuroscience and 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- and mid-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, as well as in neuroscience.

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:

Neuroscience

Product Candidates	**Description**
Phase 3	
JZP-258 (oxybate; 92% sodium reduction)	Idiopathic hypersomnia
Phase 2b	
JZP-385	Essential tremor (planned study)
Phase 2	
FAAH inhibitor PF-04457845	Post-traumatic stress disorder (planned study)
Phase 1	
JZP-324	Oxybate extended-release formulation
Preclinical	
Undisclosed targets	Neuroscience

Oncology

Product Candidates	**Description**
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 (Children's Oncology Group cooperative group study)
Zepzelca (lurbinectedin)	Relapsed SCLC (ATLANTIS) (exclusive U.S. license)
Phase 2/3	
JZP-458 (recombinant *Erwinia* asparaginase)	ALL/LBL
Phase 2	
Defitelio	Prevention of Chimeric antigen receptor 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	

Product Candidates	Description
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, which is continuing development)
Undisclosed targets	Ras/Raf/MAP kinase pathway (collaboration with Redx)
Exosome targets (NRAS, STAT3 and 3 others)	Hematological malignancies/solid tumors (collaboration with Codiak BioSciences, Inc., or Codiak)
Defitelio	Exploratory activities

For the remainder of 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.

Operational Excellence

In addition, we remain focused on continuing to build excellence in areas that we believe 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 payors. 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 designed 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. Internationally, we have fully adapted to virtual scientific congresses designed to ensure we can continue to provide promotional and non-promotional interactions and have supported our field-based teams with virtual customer interaction tools, training and content. These initiatives mark a significant operational evolution that is directly linked to our corporate strategy and are designed to better enable our teams to work collaboratively on an aligned and shared agenda. We are leveraging our differentiated operational capabilities this year in achieving three product approvals and executing our ongoing launches of Sunosi in Europe and Zepzelca and Xywav in the U.S.

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. Since the second quarter of 2020, we have been experiencing financial and other impacts of the pandemic, and 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 continue to 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 have developed and are implementing plans to reopen our sites and enable our employees to return to work in our global offices, the field and our manufacturing facilities, which plans take into account applicable public health authority and local government guidelines and which are designed to ensure community and employee safety. However, the effects of the COVID-19 pandemic continue to rapidly evolve and even if our employees more broadly return to work in our global offices, the field and our manufacturing facilities, we may have to resume a more restrictive remote work model, whether as a result of spikes or surges in COVID-19 infection or hospitalization rates or otherwise.

Commercialization

With respect to our commercialization activities, the evolving effects of the COVID-19 pandemic continue to have a negative impact on demand, 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 field-based sales, market access, reimbursement and medical employees out of the field and suspended work-related travel and in-person customer interactions. We utilized technology to continue to engage healthcare professionals and other customers virtually to support patient care. In late June 2020, as clinics and institutions began to allow in-person interactions pursuant to local health authority and government guidelines, our field teams resumed in-person interactions with healthcare professionals and clinics. The level of renewed engagement varies by account, region and country and may be adversely impacted in the future as a result of the continuing impact of the COVID-19 pandemic.

For Xyrem, the closure of sleep labs across the U.S. has resulted in reduced access to sleep testing. Since the end of the first quarter of 2020, we have seen a decline in prescribers' ability to diagnose new narcolepsy patients and a related overall decline in new patients starting on therapy. Although we are starting to see a trend of increasing patient persistence and compliance on Xyrem, we continue to expect that delays in obtaining a narcolepsy diagnosis will have a negative impact on new Xyrem patient enrollments in future quarters. With respect to oxybate-naïve patients, we expect similar impacts on new patient enrollment for Xywav, which we launched in November 2020. For Sunosi, the impact on demand has been primarily related to the reduced ability of our field-based teams to interact with prescribers and patients' inability to meet with healthcare providers during this time. As a result, we have seen slower than expected growth of Sunosi prescribers and new patient starts in the U.S. We also anticipate that pricing and reimbursement reviews by certain European regulatory authorities may take longer in certain countries due to the pandemic, which could delay our rolling Sunosi launch in those European Union, or EU, member states.

Following a decline in demand for Defitelio in the second quarter of 2020, we saw a resurgence in demand in the U.S. and outside the U.S. at the end of the second quarter and into the third quarter due to some hematopoietic stem cell transplants being performed that were previously postponed due to COVID-19 related delays, postponements or suspensions of stem cell transplant procedures. Similarly, following a decline in demand for Vyxeos in the second quarter of 2020, we saw some recovery in demand at the end of the second quarter and into the third quarter for AML treatments previously delayed both in the U.S. and Europe. However, due to the ongoing impacts of the COVID-19 pandemic, we continue to expect a negative impact on utilization of Defitelio and Vyxeos. Since the launch of Zepzelca in July 2020, we are experiencing strong initial physician reception and uptake of Zepzelca across academic and community accounts. Our sales force is actively engaging with target prescribers through virtual and live interactions, and we have been executing a broad multi-channel awareness campaign designed to grow awareness and utilization of Zepzelca.

We have also seen an upward trend in demand for patient financial assistance programs since the end of the first quarter of 2020. Depending on the ultimate duration and severity of 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 an increasing shift from commercial payor coverage to government payor coverage or increasing demand for patient assistance and/or free drug programs, which could adversely affect net revenue.

Supply Chain

We currently expect to have adequate global supply of Xyrem, Sunosi, Defitelio, Vyxeos and Zepzelca for the remainder of 2020, as well as adequate commercial product availability for our new U.S. launch of Xywav. However, the sole manufacturer and licensor of Erwinaze continues to have supply disruptions unrelated to the impact of the COVID-19 pandemic, and we are experiencing supply disruptions of Erwinaze globally and expect these to continue for the remainder of 2020.

Our manufacturing facility in Athlone, Ireland, which produces Xyrem and Xywav, continues to be operational with only office-based staff working remotely. 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 reopened the facility in the second quarter of 2020 taking into account applicable public health authority and local government guidelines as well as employee safety, and the facility has now resumed operations with only office-based staff

working remotely. If the impacts of the COVID-19 pandemic become more severe and begin to impact supply of manufacturing materials or essential distribution systems such as general delivery services, or require us or our suppliers to again cease or restrict operations at our respective manufacturing facilities, 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

With respect to 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 have seen limited COVID-19-related impact to our mid- and late-stage clinical trial activity, despite delays in initiating trial sites. For example, while we temporarily suspended two of our healthy volunteer clinical development programs, JZP-385 and JZP-324, in the interest of volunteer safety, we were able to restart these clinical trials in the third quarter of 2020 with the implementation of appropriate safety protocols. While it has not been the case thus far, we could still 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 continuing impact of the COVID-19 pandemic. If these effects become more severe, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

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 resulted in significant volatility in the 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. The effects of 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 and severity of the pandemic, 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 workforce 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 remainder of the year and into 2021, including with respect to our ability to successfully launch Xywav and continue the launch momentum of Zepzelca.

Corporate Response

The COVID-19 pandemic 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 multiple investigator-sponsored trials, or ISTs, to evaluate the use of defibrotide in COVID-19 patients experiencing respiratory distress. Three of these trials are currently recruiting patients including an IST in Spain for the prevention and treatment of respiratory distress and cytokine release syndrome, a trial in Italy to evaluate the reduction in the rate of respiratory failure in patients with COVID-19 pneumonia and an IST in Michigan evaluating the safety and tolerability of defibrotide for therapy of patients with SARS-CoV2-related acute respiratory distress syndrome.

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 has been substantially dependent on Xyrem. Our future plans assume that our newly launched oxybate product Xywav, with 92% lower sodium compared to Xyrem, absence of a sodium warning and dosing titration option, will become the treatment of choice for patients who can benefit from oxybate treatment, current Xyrem patients, and patients who previously were not prescribed Xyrem, including those patients for whom sodium content is a concern. While we expect that our business will continue to be substantially dependent on oxybate product sales from both Xyrem and Xywav, there is no guarantee that we can maintain oxybate sales at or near historical levels, or that oxybate sales will continue to grow.

Our ability to successfully commercialize Xywav will depend on, among other things, our ability to obtain and maintain adequate coverage and reimbursement for Xywav and acceptance of Xywav by payors, physicians and patients. We are seeking to secure payor coverage for Xywav that is similar to Xyrem and have implemented patient access programs to support patients in obtaining access to Xywav. Moreover, we have increasingly experienced pressure from third party payors to agree to discounts, rebates or restrictive pricing terms for our products, and we cannot guarantee we will be able to agree to commercially reasonable terms with pharmacy benefit managers, or PBMs, and other third party payors, or that we will be able to ensure patient access to our existing and future products and acceptance of our products on institutional formularies. Entering into agreements with PBMs and payors to ensure patient access has and will likely continue to result in higher gross to net deductions for these products. In addition to the COVID-19 related impacts described above, in the future, we expect our oxybate products 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 and Xywav are sold and the number of prescriptions written for Xyrem and Xywav. Xyrem and Xywav may also face increased competition from new branded products for treatment of cataplexy and/or EDS in narcolepsy in the U.S. market.

As for other products in our neuroscience therapeutic area, if we are unable to successfully commercialize Sunosi in the U.S. and EU, or if sales of Sunosi do not reach the levels we expect, our anticipated revenue from Sunosi 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 neuroscience products and product candidates, we are commercializing a portfolio of oncology products, including Defitelio, Erwinaze, Vyxeos and Zepzelca. An inability to effectively commercialize Defitelio, Vyxeos and Zepzelca 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, we cannot compel PBL to work with us on ensuring an orderly transition, or to recognize our continuing rights. 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 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 through 2020 or in 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 continue to 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 with JZP-458 or other products, 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.

Our industry has been, and is expected to continue to be, subject to healthcare cost containment and drug pricing scrutiny by regulatory agencies in the U.S. and internationally. 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. We are also subject to increasing pricing pressure and restrictions on reimbursement imposed by payors. If we fail to obtain and maintain adequate formulary positions and institutional access for newly-launched products such as Sunosi, Xywav, Zepzelca and future approved products such as JZP-458, we will not be able to achieve a return on our investment and our business, financial condition, results of operations and growth prospects would be materially adversely affected.

Finally, business practices by pharmaceutical companies, including product formulation improvements, patent litigation 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 Xywav, our Xyrem patent litigation settlement agreements or otherwise, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. From June to September 2020, a number of class action lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with certain generic companies violate state and federal antitrust and consumer protection laws. For additional information on these class action complaints, see Note 11, Commitments and Contingencies-Legal Proceedings of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits; however, if the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages. Any of the foregoing 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 continues to adversely affect 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 September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2020	2019	(Decrease)	2020	2019	(Decrease)
Product sales, net	$ 596,949	$ 532,321	12 %	$ 1,685,357	$ 1,559,075	8 %
Royalties and contract revenues	3,939	5,381	(27)%	12,693	20,946	(39)%
Cost of product sales (excluding amortization of acquired developed technologies)	42,095	31,400	34 %	98,760	92,582	7 %
Selling, general and administrative	207,255	178,706	16 %	607,061	522,667	16 %
Research and development	78,647	79,855	(2)%	243,676	202,344	20 %
Intangible asset amortization	66,684	62,863	6 %	192,505	181,324	6 %
Impairment charge	—	—	N/A(1)	136,139	—	N/A(1)
Acquired in-process research and development	10,000	51,775	(81)%	215,250	109,975	96 %
Interest expense, net	27,428	17,861	54 %	72,134	54,017	34 %
Foreign exchange loss	639	1,033	(38)%	2,235	3,577	(38)%
Income tax provision (benefit)	19,283	10,903	77 %	22,750	(38,631)	N/A(1)
Equity in loss of investees	623	1,030	(40)%	2,338	2,791	(16)%

(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 September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2020	2019	(Decrease)	2020	2019	(Decrease)
Xyrem	$ 447,809	$ 425,644	5 %	$ 1,302,492	$ 1,207,173	8 %
Defitelio/defibrotide	50,241	37,604	34 %	140,387	125,159	12 %
Erwinaze/Erwinase	20,145	34,024	(41)%	90,560	122,545	(26)%
Vyxeos	30,825	29,581	4 %	90,113	89,886	— %
Zepzelca	36,941	—	N/A(1)	36,941	—	N/A(1)
Sunosi	9,116	987	N/A(1)	19,618	987	N/A(1)
Other	1,872	4,481	(58)%	5,246	13,325	(61)%
Product sales, net	596,949	532,321	12 %	1,685,357	1,559,075	8 %
Royalties and contract revenues	3,939	5,381	(27)%	12,693	20,946	(39)%
Total revenues	$ 600,888	$ 537,702	12 %	$ 1,698,050	$ 1,580,021	7 %

(1) Comparison to prior period not meaningful.

Product Sales, Net

Xyrem product sales increased in the three and nine months ended September 30, 2020 compared to the same periods in 2019 primarily due to a higher average selling price and, to a lesser extent, an increase in sales volume, partially offset by higher gross to net deductions. Price increases were instituted in July 2019 and January 2020. Xyrem product sales volume increased by 4% in the three months ended September 30, 2020 and 5% in the nine months ended September 30, 2020, compared to the same periods in 2019 primarily driven by an increase in the average number of patients on Xyrem. Defitelio/defibrotide product sales increased in the three and nine months ended September 30, 2020 compared to the same periods in 2019 primarily due to higher sales volumes. In the three months ended September 30, 2020, we observed an increase in hematopoietic stem cell transplants that had previously been postponed due to COVID-19. Erwinaze/Erwinase

product sales decreased in the three and nine months ended September 30, 2020 compared to the same periods in 2019 primarily due to limited availability of supply of inventory from the manufacturer. Ongoing supply challenges continue to negatively impact the timing of and our ability to supply Erwinaze to the market. We are experiencing supply disruptions of Erwinaze globally and expect these to continue for the remainder of 2020. Vyxeos product sales increased in the three and nine months ended September 30, 2020 primarily due to an increase in sales volume in Europe. Sunosi product sales were $9.1 million and $19.6 million in the three and nine months ended September 30, 2020, respectively. Sunosi launched in the U.S. in July 2019 and the European rolling launch commenced in May 2020. Zepzelca product sales were $36.9 million in the three and nine months ended September 30, 2020, respectively, following its U.S. launch in July 2020. We expect total product sales for 2020 will be higher than 2019 primarily due to growth in sales of Xyrem and the Sunosi launch, as well as product sales of Zepzelca following launch in July 2020.

Royalties and Contract Revenues

Royalties and contract revenues decreased in the three and nine months ended September 30, 2020 compared to the same periods in 2019 primarily due to lower revenues from out-licensing agreements. 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 increased in the three and nine months ended September 30, 2020 compared to the same periods in 2019 primarily due to changes in product mix. Gross margin as a percentage of net product sales was 92.9% and 94.1% for the three and nine months ended September 30, 2020, respectively, compared to 94.1% for the same periods 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 and nine months ended September 30, 2020 compared to the same periods in 2019 primarily due to increased investment in sales, marketing and launch activities related to certain of our products, 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 launches of Sunosi in the U.S. and in Europe and Zepzelca and Xywav 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Clinical studies and outside services	$ 37,142	$ 33,753	$ 125,036	$ 97,018
Personnel expenses	33,283	24,506	90,331	66,671
Milestone expense	—	11,000	—	11,000
Other	8,222	10,596	28,309	27,655
Total	$ 78,647	$ 79,855	$ 243,676	$ 202,344

Research and development expenses decreased by $1.2 million and increased by $41.3 million in the three and nine months ended September 30, 2020, respectively, compared to the same periods in 2019. Clinical studies and outside services

costs increased by $3.4 million and $28.0 million in the three and nine months ended September 30, 2020, respectively, compared to the same periods in 2019 primarily due to the progress made on our clinical and pre-clinical development programs, including JZP-458 and JZP-385. Personnel expenses increased by $8.8 million and $23.7 million in the three and nine months ended September 30, 2020, respectively, compared to the same periods in 2019 primarily due to increased headcount in support of our development programs. Milestone expense of $11.0 million in the three and nine months ended September 30, 2019 related to a milestone payable under the license and option agreement with Pfenex, which we entered into in July 2016 and amended in December 2017, for worldwide rights to develop and commercialize multiple early-stage hematology product candidates.

For the remainder of 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. A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of and regulatory submissions for our product candidates, and the consequences to our business, financial position and growth prospects can be found in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Intangible Asset Amortization

Intangible asset amortization increased by $3.8 million in the three months ended September 30, 2020 compared to the same period in 2019 primarily due to the commencement of amortization of the Zepzelca intangible asset upon FDA approval in June 2020. Intangible asset amortization increased by $11.2 million in the nine months ended September 30, 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, the commencement of amortization of the Sunosi intangible asset following U.S. Drug Enforcement Agency scheduling in June 2019 and the commencement of the Zepzelca intangible asset amortization. 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 nine months ended September 30, 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 for the prevention of VOD due to a determination that the study is highly unlikely to reach one of its primary endpoints.

Acquired In-Process Research and Development

Acquired IPR&D expense in the nine months ended September 30, 2020 primarily related to an upfront payment of $200.0 million to PharmaMar in connection with our license agreement for Zepzelca. Acquired IPR&D expense in the three months ended September 30, 2019 primarily related to the value attributed to JZP-385 in the acquisition of Cavion, Inc. or Cavion. Acquired IPR&D expense in the nine months ended September 30, 2019 primarily related to an upfront payment of $56.0 million to Codiak in connection with a strategic collaboration agreement and the value attributed to JZP-385 in the acquisition of Cavion.

Interest Expense, Net

Interest expense, net increased by $9.6 million in the three months ended September 30, 2020 compared to the same period in 2019, primarily due to higher non-cash interest expense following the issuance of our 2.00% exchangeable senior notes due 2026, or the 2026 Notes, in June 2020, and lower interest income. Interest expense, net increased by $18.1 million in the nine months ended September 30, 2020, primarily due to higher non-cash interest expense, lower interest income and a loss on extinguishment of debt related to the partial repurchases of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes. We expect interest expense, net will increase in 2020 compared to 2019, primarily due to the increase in our average debt balance following the issuance of the 2026 Notes.

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 provision was $19.3 million in the three months ended September 30, 2020, compared to $10.9 million for the same period in 2019. Our income tax provision was $22.8 million in the nine months ended September 30, 2020 compared to an income tax benefit of $38.6 million for the same period in 2019. The effective tax rate was 11.5% in the three months ended September 30, 2020 compared to 9.5% for the same period in 2019. The increase in the effective tax rate for the three months ended September 30, 2020 compared to the same period in 2019 was primarily due to the release in 2019 of reserves related to unrecognized tax benefits upon expiration of a statute of limitations, partially offset by the impact of tax credits originating in 2020. The effective tax rate was 17.5% in the nine months ended September 30, 2020, compared to (9.3)% for the same period in 2019. The income tax benefit for the nine months ended September 30, 2019 included a discrete tax benefit of $112.3 million resulting from an intra-entity intellectual property asset transfer. The tax benefit, which represents a deferred future benefit, was recorded as a deferred tax asset. The increase in the effective tax rates for the nine months ended September 30, 2020 compared to the same periods in 2019 was primarily due to the impact of the intra-entity intellectual property asset transfer. Excluding this effect, the decrease in the effective tax rate for the nine months ended September 30, 2020 compared to the same period in 2019 was primarily due to the impact of the defibrotide acquired IPR&D asset impairment charge, originating tax credits and the impact of the acquired IPR&D expense related to the original PharmaMar transaction, partially offset by the impact of the disallowance of certain interest deductions and a provision for a proposed settlement reached with the French tax authorities. The effective tax rate for the three months ended September 30, 2020 was lower than the Irish statutory rate of 12.5% primarily due to the impact of originating tax credits. The effective tax rate for the nine months ended September 30, 2020 was higher than the Irish statutory rate of 12.5% primarily due to the impact of the disallowance of certain interest deductions and a provision for a proposed settlement reached with the French tax authorities, partially offset by the impact of the defibrotide acquired IPR&D asset impairment charge, originating tax credits and the impact of the acquired IPR&D expense related to the original PharmaMar transaction. 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 of companies in which we have made investments accounted for under the equity method of accounting.

Liquidity and Capital Resources

As of September 30, 2020, we had cash, cash equivalents and investments of $1.9 billion, borrowing availability under our revolving credit facility of $1.6 billion and long-term debt principal balance of $2.4 billion. Our long-term debt included $592.6 million aggregate principal amount term loan, $218.8 million principal amount of the 2021 Notes, $575.0 million principal amount of our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, and $1.0 billion principal amount of the 2026 Notes. We generated cash flows from operations of $713.4 million during the nine months ended September 30, 2020, and we expect to continue to generate positive cash flows from operations during 2020.

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 resulted in significant volatility in the 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, 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 September 30, 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. During the three months ended September 30, 2020, we did not repurchase any of our ordinary shares. In the nine months ended September 30, 2020, we spent a total of $146.5 million to purchase 1.2 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $121.98 per share. All ordinary shares repurchased were canceled. As of September 30, 2020, the remaining amount authorized under the share repurchase program was $431.2 million.

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

	Nine Months Ended September 30,	
	2020	2019
Net cash provided by operating activities	$ 713,377	$ 688,603
Net cash provided by (used in) investing activities	(1,080,889)	3,753
Net cash provided by (used in) financing activities	472,195	(205,965)
Effect of exchange rates on cash and cash equivalents	(85)	(838)
Net increase in cash and cash equivalents	$ 104,598	$ 485,553

Operating activities

Net cash provided by operating activities increased by $24.8 million in the nine months ended September 30, 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 impact of a $58.6 million payment related to a civil settlement agreement with the U.S. Department of Justice and the Office of the Inspector General of the U.S. Department of Health and Human Services in the nine months ended September 30, 2019, offset by the timing of payments to suppliers.

Investing activities

Net cash provided by (used in) investing activities decreased by $1,084.6 million in the nine months ended September 30, 2020 compared to the same period in 2019, primarily due to the following:

- $975.8 million net increase in the acquisition of investments, primarily time deposits;
- $153.6 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 nine months ended September 30, 2020, compared to the same period in 2019 which included a payment of $56.0 million under our strategic collaboration agreement with Codiak; partially offset by
- The impact of consideration, net of cash acquired of $55.1 million related to our acquisition of Cavion in the nine months ended September 30, 2019.

Financing activities

Net cash provided by (used in) financing activities increased by $678.2 million in the nine months ended September 30, 2020 compared to the same period in 2019, primarily due to:

- An increase of $981.4 million in net proceeds from the issuance of the 2026 Notes, partially offset by $356.2 million of payments for partial repurchases of the 2021 Notes;
- A decrease of $44.6 million in share repurchases; and
- An increase of $8.2 million in proceeds from employee equity incentive and purchase plans.

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. During the nine months ended September 30, 2020, there were no material changes to the amended credit agreement, 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 June 2020, Jazz Investments I Limited, our wholly owned subsidiary, completed a private offering of an aggregate $1,000.0 million principal amount of the 2026 Notes. We used a portion of the net proceeds from the issuance of the 2026 Notes to repurchase for cash $332.9 million aggregate principal amount of the 2021 Notes through individual privately-negotiated transactions concurrently with the offering. In the three months ended September 30, 2020, we repurchased a further $23.3 million aggregate principal amount of the 2021 Notes. The terms of the 2026 Notes are described in Note 9, Debt, of the Notes to Condensed Consolidated Financial Statements included in this report.

In April 2020, 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 in light of the uncertainties and disruption to the global financial markets resulting from the COVID-19 pandemic. We repaid this amount in full in June 2020 following the issuance of the 2026 Notes. As of September 30, 2020, no amounts were outstanding under our revolving credit facility.

Contractual Obligations

The table below presents a summary of our contractual obligations as of September 30, 2020 (in thousands):

	Payments Due by Period				
Contractual Obligations (1)	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 years**
Term loan - principal	$ 592,614	$ 33,387	$ 559,227	$ —	$ —
Term loan - interest (2)	26,991	13,102	13,889	—	—
Exchangeable Senior Notes - principal	1,793,812	218,812	—	575,000	1,000,000
Exchangeable Senior Notes - interest (3)	158,825	32,950	57,250	48,625	20,000
Revolving credit facility - commitment fee (4)	10,878	4,056	6,822	—	—
Commitment to equity method investees	8,325	7,000	1,325	—	—
Purchase and other obligations (5)	105,509	75,413	26,427	3,590	79
Operating lease obligations (6)	198,613	21,730	43,317	42,451	91,115
Total	$ 2,895,567	$ 406,450	$ 708,257	$ 669,666	$ 1,111,194

(1) This table does not include potential future milestone payments or royalty obligations to third parties under asset purchase, product development, license and other agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable. Our contingent obligations to third parties, in the form of development, regulatory and sales-based milestone payments, as of September 30, 2020 included $1,025.0 million across five targets under our strategic collaboration agreement with Codiak, $700.0 million under our license agreement with PharmaMar, $613.0 million under asset purchase and collaboration agreements with Redx, $260.0 million in connection with our acquisition of Cavion, $165.0 million to Aerial BioPharma LLC and SK Biopharmaceuticals Co. Ltd in connection with our acquisition of the rights to Sunosi, $162.5 million under our license agreement with Pfenex and $360.9 million related to other agreements. In October 2020, we entered into an asset purchase and exclusive license agreement with SpringWorks under which we acquired SpringWorks' FAAH inhibitor program. Our potential milestone payments to SpringWorks are up to $375.0 million.

For additional information regarding this asset purchase and exclusive license agreement, see Note 17, Subsequent Event of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

(2) Estimated interest for variable rate debt was calculated based on the interest rates in effect as of September 30, 2020. The interest rate for our term loan borrowing was 1.52% as of September 30, 2020. Interest that is fixed, associated with our interest rate swaps, is calculated based on the fixed interest swap rate as of September 30, 2020.

(3) We used the fixed interest rates of 1.875% on the 2021 Notes, 1.50% on the 2024 Notes and 2.00% on the 2026 Notes to estimate interest owed as of September 30, 2020 until the respective final maturity dates of these notes.

(4) Our revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.25% and assumed undrawn amounts of $1.6 billion as of September 30, 2020 to estimate commitment fees owed.

(5) Consists primarily of noncancelable commitments to our third party manufacturers and to ImmunoGen under our amended collaboration and option agreement.

(6) Consists primarily of the minimum lease payments for our office buildings and automobile lease payments for our sales force. Operating expenses associated with our leased office buildings are not included in table above.

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

Critical Accounting Estimates

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with U.S. 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

Except as set forth below, during the three and nine months ended September 30, 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.

Exchangeable Senior Notes 2026

In the second quarter of 2020, Jazz Investments I Limited, our wholly owned subsidiary, completed a private placement of $1.0 billion aggregate principal amount of the 2026 Notes. The 2026 Notes have a fixed annual interest rate of 2.00% and we, therefore, do not have economic interest rate exposure on the 2026 Notes. However, the fair value of the 2026 Notes is exposed to interest rate risk. Generally, the fair value of the 2026 Notes will increase as interest rates fall and decrease as interest rates rise. The fair value of the 2026 Notes is also affected by volatility in our ordinary share price. As of September 30, 2020, the fair value of the 2026 Notes was estimated to be $1.2 billion.

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 September 30, 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 September 30, 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 1. Legal Proceedings

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

Item 1A. Risk Factors

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

Risks Related to Our Lead Products and Product Candidates

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

Our business has been substantially dependent on Xyrem® (sodium oxybate) oral solution, and our financial results have been significantly influenced by sales of Xyrem. Our future plans assume that our newly launched oxybate product, Xywav™, with 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, absence of a sodium warning and dosing titration option, will become the treatment of choice for patients who can benefit from oxybate treatment, current Xyrem patients, and patients who previously were not prescribed Xyrem, including those patients for whom sodium content is a concern. Our ability to successfully commercialize Xywav will depend on, among other things, our ability to obtain and maintain adequate coverage and reimbursement for Xywav and acceptance of Xywav by payors, physicians and patients. Our ability to maintain or increase oxybate product sales and realize the anticipated benefits from our investment in Xywav is subject to a number of additional 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 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; and challenges to our intellectual property around Xyrem and/or Xywav. While we expect that our business will continue to be substantially dependent on oxybate product sales from both Xyrem and Xywav, there is no guarantee that we can maintain oxybate sales at or near historical levels, or that oxybate sales will continue to grow. A significant decline in oxybate sales 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.

As for other products and product candidates in our 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 continuing COVID-19 pandemic on the successful commercialization in the U.S. and the rolling launch in Europe, which are at an early stage; 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; 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 or the European Commission, or the EC, or other regulatory authority in the future; and our ability to satisfy FDA's post-marketing requirements. If we are unable to successfully commercialize Sunosi in the U.S. and EU, or if sales of Sunosi do not reach the levels we expect, our anticipated revenue from Sunosi will be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 and Xywav are currently the only products 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, new treatment options for EDS in narcolepsy have launched, and in the future, other products may be launched that are competitive with or disrupt the market for our oxybate products.

For example, in the future, we expect Xyrem and Xywav 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 risk evaluation and mitigation strategy, or REMS, as Xyrem and Xywav. 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 a new drug application, or 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 an extended-release formulation of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy. Xyrem may also face increased 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 Xywav will face competition similar to that described above for Xyrem, including from generic or authorized generic sodium oxybate products or new branded entrants in narcolepsy. For example, Avadel has announced that it has obtained an orphan drug designation from FDA for its extended-release sodium oxybate formulation. To obtain approval with orphan drug exclusivity, Avadel will have to show clinical superiority to Xyrem and Xywav. We cannot predict the timing or approvability of Avadel's sodium oxybate product candidate or how FDA will evaluate any clinical superiority arguments that either we or Avadel may make, but in any event, we expect to face competition from Avadel, if its product candidate is approved.

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 Xywav, could have the effect of changing treatment regimens and payor or formulary coverage of Xyrem or Xywav in favor of other products, and indirectly materially and adversely affect sales of Xyrem and Xywav. Examples of such new market entrants include our product, Sunosi, and pitolisant, a drug that was approved by FDA in 2019 for the treatment of EDS in adult patients with narcolepsy and recently approved by FDA in October 2020 pursuant to a complete response resubmission for an adult cataplexy indication in the U.S. 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 Xywav 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 Xywav or Avadel's extended-release 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 patent 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 Xywav.

The active pharmaceutical ingredient, or API, of Xyrem and Xywav, is a form 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 and Xywav 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 and Xywav 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 evolving effects of the COVID-19 pandemic, or a determination by FDA that the REMS is not meeting its goals, could result in enforcement action by FDA, lead to changes in our REMS obligations, negatively affect sales of Xyrem or Xywav, 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.

FDA has stated that it will evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. In July 2020, in connection with the approval of Xywav, FDA approved the Xywav and Xyrem REMS. We cannot predict whether FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xywav and Xyrem REMS, including in connection with the submission of new oxybate products or indications, the introduction of authorized generics, or to accommodate generics, or whether FDA will approve modifications to the Xywav and Xyrem REMS that we consider warranted. Any modifications approved, required or rejected by FDA could change the safety profile of Xywav or Xyrem, and have a significant negative impact in terms of product liability, public acceptance of Xywav or Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xywav or Xyrem, any of which could have a material adverse effect on our oxybate business. Modifications approved, required or rejected by FDA could also make it more difficult or expensive for us to distribute Xywav or Xyrem, make

distribution easier for oxybate competitors, disrupt continuity of care for Xywav or Xyrem patients and/or negatively affect sales of Xywav or Xyrem.

We depend on outside vendors, including Express Scripts Specialty Distribution Services, Inc., or ESSDS, the central certified pharmacy, to distribute Xyrem in the U.S., provide patient support services and implement the requirements of the Xywav and Xyrem REMS. In July 2020, upon expiration of the existing exclusive agreement, we entered into a new agreement with ESSDS for a two-year term. If the central pharmacy fails to meet the requirements of the Xywav and 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 evolving effects of the COVID-19 pandemic or otherwise, the fulfillment of Xywav or 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 Xywav or 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 under the Xywav and Xyrem REMS. Transitioning to a new pharmacy could result in product shortages, which would negatively affect sales of Xywav and 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 Xywav and 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 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 Xywav or Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xywav or Xyrem, any of which could have a material adverse effect on our oxybate business.

We may face pressure to further modify the Xyrem or Xywav REMS or to license or share intellectual property pertinent to that 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 or other governmental authorities 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 premised on a claim that the Xyrem REMS is blocking competition, or the outcome or impact of any such claim. Between June and September 2020, we were served with a number of class action complaints that included allegations that we had used the Xyrem REMS to

delay approval of generic sodium oxybate. For additional information on these class action complaints, see Note 11, Commitments and Contingencies-Legal Proceedings of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits; however, if the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 Xywav and Xyrem REMS provide more extensive information about adverse events experienced by patients taking Xywav and 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 Xywav and Xyrem is regularly reported to FDA and could result in FDA requiring changes to Xywav and/or 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 Xywav and Xyrem. As required by FDA, Xywav's and 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 oxybate product sales and therefore on our business, financial condition, results of operations and growth prospects.

While we expect our oxybate products, Xyrem and our newly approved Xywav, to remain the largest part of our business, our success also depends on our ability to effectively commercialize products in our oncology therapeutic area.

In addition to Xyrem, Xywav and our other neuroscience products and product candidates, we are commercializing a portfolio of products, including our other lead marketed products, Defitelio, Erwinaze, Vyxeos and Zepzelca. An inability to effectively commercialize Defitelio, Vyxeos and Zepzelca and to maximize their potential where possible through successful research and development activities, whether due to the evolving effects of the COVID-19 pandemic or otherwise, and an inability to replace the future product sales we will lose from Erwinaze, 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).

We announced in April 2020 that we stopped enrollment in our Phase 3 trial evaluating defibrotide in the prevention of VOD due to a determination that the study is highly unlikely to reach one of its primary endpoints. Although we do not expect this outcome to impact clinicians' use of Defitelio in the treatment of VOD, it may result in delays in the initiation of treatment for some patients as clinicians wait for definitive signs and symptoms of VOD. Although we saw a resurgence in demand for Defitelio in the U.S. and outside the U.S. beginning in the end of the second quarter of 2020, due to the evolving effects of the COVID-19 pandemic, the reprioritization of healthcare resources and related delays, postponements or suspensions of certain medical procedures such as stem cell transplants, we continue to expect a negative impact on demand for and utilization of 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, we cannot compel PBL to work with us on ensuring an orderly transition, or to recognize our continuing rights. 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 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 through 2020 or in 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 continue to 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 with JZP-458 or other products, 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, which received full FDA approval in October 2020 for 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 the COVID-19 pandemic which is directly negatively impacting, or delaying, the use of Vyxeos, as well as the suspension of in-person interactions with healthcare professionals due to the COVID-19 pandemic; 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. Although we saw some recovery in demand for Vyxeos beginning in the end of the second quarter of 2020, due to the ongoing impacts of the COVID-19 pandemic, we continue to expect a negative impact on demand for and utilization of Vyxeos compared to historical periods. 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.

Zepzelca

Our ability to realize the anticipated benefits from our investment in Zepzelca® (lurbinectedin) is subject to a number of risks and uncertainties, including our ability to successfully commercialize Zepzelca in the U.S.; adequate supply of Zepzelca to meet demand; availability of favorable pricing and adequate coverage and reimbursement; the limited experience of, and need to educate, physicians in the use of Zepzelca for the treatment of metastatic small cell lung cancer, or SCLC; the potential for negative trial data read-outs in ongoing or future Zepzelca clinical trials; and the impact of the evolving effects of the COVID-19 pandemic on the ability of our field teams to access clinicians and prescribers to increase awareness of Zepzelca in the treatment of relapsed SCLC in the U.S.

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 healthcare programs in the U.S. or elsewhere, or 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 evolving effects of the COVID-19 pandemic 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 could adversely affect net revenue.

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 benefit 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 entered into agreements with PBMs and payor accounts to provide rebates to those entities related to 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. We are also seeking to secure payor coverage for Xywav that is similar to Xyrem and have implemented patient access programs for Xywav to support patients in obtaining access to Xywav. However, payors could decide to exclude Xywav from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for Xywav, 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 Xywav and cause some patients to determine not to use Xywav. 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 Xywav. If we are unsuccessful in obtaining broad coverage for Xywav, our anticipated revenue from and growth prospects for Xywav could be negatively affected.

In many countries outside the U.S., procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing authorization. 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, and/or branded products available through parallel import 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. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including those representing the larger markets. The HTA process, which is currently governed by the laws in these countries, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU member states, although a legislative proposal adopted by the EC in January 2018 concerning EU regulation governing HTA procedures may eventually lead to harmonization. If we are unable to maintain favorable pricing and reimbursement status 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 evolving effects of 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 decisions, 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, as governmental oversight and scrutiny of biopharmaceutical companies is increasing. 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 reimbursement for drugs (including under 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 policies that aim to require drug companies to justify their prices through required disclosures. Additionally, proposed legislation and certain executive actions, including a U.S. executive order issued in September 2020, seek to utilize a “most-favored-nation price” or an “international pricing index” as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B

and/or Part D 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. For example, in September 2020, a series of U.S. executive orders were proposed to ban surprise billing if Congress does not act and to require regulatory action to protect patients with pre-existing conditions.

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 and Xywav, 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 make similar price adjustments to Xyrem and Xywav in the future or that price adjustments we have taken or may take in the future will not negatively affect Xyrem or Xywav sales volumes and revenues. We also have made and may in the future make price adjustments on our other products. There is no guarantee that such price adjustments will not negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our products, which could limit the prices that we charge for our products, including Xyrem and Xywav, 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 or equivalent obligation imposed in a European or other foreign country, 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;
- unanticipated serious adverse events;
- 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 clinical superiority and/or advantages over alternative treatments;
- relative convenience and ease of administration;

- with respect to Xyrem and Xywav, physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the Xyrem and Xywav REMS or equivalent obligation imposed in a European or other foreign country;
- 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. Xywav includes the same API as Xyrem, but uses a different mixture of salts. Patients, physicians and regulators may therefore view Xyrem or Xywav 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. The labels for Xyrem and Xywav authorized in the United States include 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 procurement of manufacturing materials, 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 evolving effects of the 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 Xywav, 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 with only office-based staff working remotely. 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 reopened the facility in the second quarter of 2020 taking into account applicable public health authority and local government guidelines as well as employee safety, and the facility has now resumed operations with only office-based staff working remotely. However, the effects of the COVID-19 pandemic continue to rapidly evolve and even if our employees more broadly return to work in our global offices, the field and our manufacturing facilities, we may have to resume a more restrictive remote work model, whether as a result of spikes or surges in COVID-19 infection or hospitalization rates or otherwise.

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 of suitable quality for patients 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 globally and expect these to continue for the remainder of 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 evolving effects of the 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 Medicines and Healthcare Products Regulatory Agency, or MHRA, or other competent authorities in the EU member states or other countries 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.

If the effects of the COVID-19 pandemic become more severe and begin to impact supply of manufacturing materials or essential distribution systems such as general delivery services, or require us or our suppliers to again cease or restrict operations at our respective manufacturing facilities, 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 or other European countries 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 evolving effects of the COVID-19 pandemic, it is possible that we could experience delays in the timing of marketing application review by regulatory authorities 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. It is possible that we could experience delays in regulatory interactions and review of submissions due to COVID-19 impacts described above, such as with respect to our planned BLA submission of JZP-458 or our planned supplemental NDA submission of JZP-258 for idiopathic hypersomnia.

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 or equivalent obligation imposed in a European or other foreign country to ensure that the benefits of the drug outweigh the risks. FDA requires a REMS and a boxed warning for Xyrem and Xywav, and similar restrictions could be imposed on other products in the future. Our receipt of approval for narrower indications than sought, restrictions on marketing through a REMS or equivalent obligation imposed in a European or other foreign country, 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, Sunosi and Zepzelca. 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., the EU, or other European countries, 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 additional 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, Sunosi and Xywav, 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 and/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 effects of the COVID-19 pandemic become more severe, 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 to be submitted to FDA in the planned BLA for JZP-458 or the planned supplemental

NDA for JZP-258 for idiopathic hypersomnia, 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 impacts of the evolving effects of the 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 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 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 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 evolving effects of the 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 have seen limited COVID-19-related impact to our mid- and late-stage clinical trial activity, despite delays in initiating trial sites. For example, while we temporarily suspended two of our healthy volunteer clinical development programs, JZP-385 and JZP-324, in the interest of volunteer safety, we were able to restart these clinical trials in the third quarter of 2020 with the implementation of appropriate safety protocols. While it has not been the case thus far, we could still 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 evolving effects of the COVID-19 pandemic. If these effects become more severe, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects. 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, may 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, or IPR, 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 litigation 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, many pharmaceutical companies have faced extensive litigation over whether patent litigation settlements they have entered into are reasonable and lawful. From June to September 2020, a number of class action lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with Hikma and other ANDA filers violate state and federal antitrust and consumer protection laws. For additional information on these class action complaints, see Note 11, Commitments and Contingencies-Legal Proceedings of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits; however, if the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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 patent 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, 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 evolving effects of the 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.

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 evolving effects of 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.

Continued remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the effects of 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 continue to have a negative impact on demand, 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. Beginning in March 2020, we transitioned our field-based sales, market access, reimbursement and medical employees out of the field and suspended work-related travel and in-person customer interactions. We utilized technology to continue to engage healthcare professionals and other customers virtually to support patient care. In late June 2020, as clinics and institutions began to allow in-person interactions pursuant to local health authority and government guidelines, our field teams resumed in-person interactions with healthcare professionals and clinics. The level of renewed engagement varies by account, region and country and may be adversely impacted in the future as a result of the continuing impact of the COVID-19 pandemic.

For Xyrem, the closure of sleep labs across the U.S. has resulted in reduced access to sleep testing. Since the end of the first quarter of 2020, we have seen a decline in prescribers' ability to diagnose new narcolepsy patients and a related overall decline in new patients starting on therapy. We continue to expect that delays in obtaining a narcolepsy diagnosis will have a negative impact on new Xyrem patient enrollments in future quarters. With respect to oxybate-naïve patients, we expect similar impacts on new patient enrollment for Xywav, which we launched in November 2020. For Sunosi, the impact on demand has been primarily related to the reduced ability of our field-based teams to interact with prescribers and patients' inability to meet with healthcare providers during this time. As a result, we have seen slower than expected growth of Sunosi prescribers and new patient starts in the U.S. We also anticipate that pricing and reimbursement reviews by certain European regulatory authorities may take longer in certain countries due to the pandemic, which could delay our rolling Sunosi launch in those EU member states. In addition, due to the ongoing impacts of the COVID-19 pandemic, we continue to expect a negative impact on utilization of Defitelio and Vyxeos.

We have also seen an upward trend in demand for patient financial assistance programs since the end of the first quarter of 2020. Depending on the ultimate duration and severity of 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 an increasing shift from commercial payor coverage to government payor coverage or increasing demand for patient assistance and/or free drug programs, which could adversely affect net revenue.

In addition, the COVID-19 pandemic continues to rapidly evolve and has resulted in significant volatility in the global financial markets. If this volatility 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, the current recession or additional market corrections resulting from the impact of the evolving effects of the COVID-19 could materially affect our business and the value of our ordinary shares. While we expect these effects 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 and severity of the pandemic, 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 workforce 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 remainder of the year and into 2021, including with respect to our ability to successfully launch Xywav and continue the launch momentum of Zepzelca. 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 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 materially impacts 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, 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 marketing 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 and batch release. 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 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 the COVID-19 pandemic, 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 and Xywav, 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 conduct or 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, the competent authorities of the EU member states on behalf of the EMA, and the competent authorities of other European countries, 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 European countries, 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 whenever possible, and otherwise comply with applicable laws, regulations or guidance, 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 or violations of the federal anti-kickback statute. 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, national sunshine rules, 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, Sunosi and Xywav 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 and Xywav, 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 federal, state and international laws and regulations governing the privacy and security of the personal information we collect and maintain (e.g., Section 5 of the Federal Trade Commission Act, the California Consumer Privacy Act, and the EU's General Data Protection Regulation). These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. Because of the remote work policies we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal information, including health data. 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, and related employment rules, 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. For example, in July 2020, the Court of Justice of the European Union, or the Court of Justice, declared the Privacy Shield Decision (Decision 2018/1250) invalid, which could adversely impact our ability to transfer personal data from the EU to the U.S. The Court of Justice further ruled that in order to transfer data outside of the EU, under the existing mechanism known as the Standard Contractual Clauses, or SCCs, the importing country's level of protection must be adequate. In addition, on September 8, 2020 the Federal Data Protection and Information Commissioner, or FDPIC, of Switzerland issued an opinion concluding that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. The FDPIC also found that SCCs may still be legally adequate at an individual level provided that they can pass a risk assessment conducted by the FDPIC. If the level of protection in the U.S. or any other importing country is called into question under the SCCs, this could further impact our ability to transfer data outside of the EU or Switzerland.

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 the evolving effects of the 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 September 30, 2020, we had total indebtedness of approximately $2.4 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 effects of the 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 for the prevention of VOD due to a determination that the study is highly unlikely to reach one of its primary endpoints.

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 Sunosi, 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 evolving effects of the 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 evolving effects of the 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 evolving effects of the 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

In November 2016, our board of directors authorized a share repurchase program and as of September 30, 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. During the three months ended September 30, 2020, we did not repurchase any of our ordinary shares. In the nine months ended September 30, 2020, we spent a total of $146.5 million to purchase 1.2 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $121.98 per share. All ordinary shares repurchased were canceled. As of September 30, 2020, the remaining amount authorized under the share repurchase program was $431.2 million.

Under our share repurchase program, we are authorized to repurchase shares from time to time through open market repurchases. Such repurchases may be pursuant to Rule 10b-18 or Rule 10b5-1 agreements as determined by our management and in accordance with the requirements of the Securities and Exchange Commission.

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).

4.4A	Indenture, dated as of June 11, 2020 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 June 11, 2020).
4.4B	Form of 2.000% Exchangeable Senior Note due 2026 (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 June 11, 2020).
10.1+	Amended and Restated Non-Employee Director Compensation Policy (approved July 21, 2020).
10.2+	Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan.
10.3+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan.
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: November 2, 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)

JAZZ PHARMACEUTICALS PLC

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Non-employee members of the board of directors (the "***Board***") of Jazz Pharmaceuticals plc (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Policy (this "***Policy***"). The cash compensation and equity grants described in this Policy shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who may be eligible to receive such cash compensation or equity grants, unless such Non-Employee Director declines the receipt of such cash compensation or equity grants by written notice to the Company. This Policy shall remain in effect until it is revised or rescinded by further action of the Board.

1. Cash Compensation.

(a) Subject to Section 1(b) and Section 3 below, each Non-Employee Director shall be eligible to receive an annual retainer of $60,000 for service on the Board. In addition, a Non-Employee Director serving as:

(i) lead independent director of the Board shall be eligible to receive an additional annual retainer of $50,000 for such service;

(ii) chairperson of the Audit Committee shall be eligible to receive an additional annual retainer of $25,000 for such service;

(iii) members (other than the chairperson) of the Audit Committee shall be eligible to receive an additional annual retainer of $15,000 for such service;

(iv) chairperson of the Compensation Committee shall be eligible to receive an additional annual retainer of $22,500 for such service;

(v) members (other than the chairperson) of the Compensation Committee shall be eligible to receive an additional annual retainer of $12,500 for such service;

(vi) chairperson of the Nominating and Corporate Governance Committee shall be eligible to receive an additional annual retainer of $20,000 for such service;

(vii) members (other than the chairperson) of the Nominating and Corporate Governance Committee shall be eligible to receive an additional annual retainer of $10,000 for such service;

(viii) chairperson of the Transaction Committee shall be eligible to receive an additional annual retainer of $22,500 for such service; and

(ix) members (other than the chairperson) of the Transaction Committee shall be eligible to receive an additional annual retainer of $12,500 for such service.

The annual retainers shall be paid in four equal quarterly installments, earned upon the completion of service in each calendar quarter.

(b) Each person who is elected or appointed to be a Non-Employee Director or who is appointed to serve as lead independent director or a member or chairperson of one of the Committees described above, in each case other than on the first day of a calendar quarter, shall be eligible to receive a pro rata amount of the annual retainers described above with respect to the calendar quarter in which such person becomes a Non-Employee Director, lead independent director or a member or chairperson of one

of the Committees, as applicable, which pro rata amount reflects a reduction for each day during the calendar quarter prior to the date of such election or appointment.

(c) Each Non-Employee Director will be entitled to reimbursement from the Company for his or her reasonable travel (including airfare and ground transportation), lodging and meal expenses incidental to meetings of the Board or committees thereof. If any reimbursement payment is subject to tax imposed by the Irish Revenue Commissioners ("***Revenue***"), each Non-Employee Director will be entitled to a payment, up to an amount ("***Gross-Up Payment"***) such that after the deduction of all taxes (including, without limitation, any income taxes calculated at the rate applicable to each Non-Employee Director for the year in which the expenses were incurred) on the Gross-Up Payment, the Non-Employee Director will retain an amount equal to the full reimbursement payment. All taxes due will be paid by the Company to Revenue.

2. Equity Compensation. The stock options and restricted stock unit ("***RSU***") awards described below shall be granted under and shall be subject to the terms and provisions of the Company's Amended and Restated 2007 Non-Employee Directors Stock Award Plan (the "***NEDSAP***").

(a) Initial Grants. A person who is elected or appointed to be a Non-Employee Director for the first time on or following 3 May 2018 automatically shall be granted a nonstatutory stock option to purchase ordinary shares of the Company (an "***Initial Option Grant***") and an RSU award (an "***Initial RSU Grant***"), together equal to a grant date value of approximately $600,000, on the second trading day following the filing date of the Company's next quarterly or annual report filed under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), that occurs after the date of such initial election or appointment. The Initial Option Grant and Initial RSU Grant shall collectively be referred to as an "***Initial Grant***." The Initial Grant will be delivered such that approximately 50% of the value is delivered as an Initial Option Grant and approximately 50% of the value is delivered as an Initial RSU Grant, using the methodology for determining actual share amounts and the stock option to RSU ratio most recently approved by the Compensation Committee.

(b) Continuing Grants. Subject to Section 2(c) below, a person who is a Non-Employee Director on or following 3 May 2018 automatically shall be granted a nonstatutory stock option to purchase ordinary shares of the Company (a "***Continuing Option Grant***") and an RSU award (a "***Continuing RSU Grant***"), together equal to a grant date value of approximately $400,000, on the second trading day following the filing date of the Company's next quarterly or annual report filed under the Exchange Act that occurs after the date of each annual general meeting of the Company's shareholders. The Continuing Option Grant and Continuing RSU Grant shall collectively be referred to as a "***Continuing Grant***." The Continuing Grant will be delivered such that approximately 50% of the value is delivered as a Continuing Option Grant and approximately 50% of the value is delivered as a Continuing RSU grant, using the methodology for determining actual share amounts and the stock option to RSU ratio most recently approved by the Compensation Committee. Notwithstanding the foregoing, each person who is elected or appointed to be a Non-Employee Director for the first time at an annual general meeting of the Company's shareholders shall not be granted a Continuing Grant with respect to such meeting.

(c) Continuing Grants for Certain New Non-Employee Directors. If a person is elected or appointed to be a Non-Employee Director for the first time other than at an annual general meeting of the Company's shareholders, such Non-Employee Director automatically shall be granted a Continuing Grant with respect to the next annual general meeting in accordance with Section 2(b) above, provided that the date of such initial election or appointment is not less than four calendar months prior to the date of the next annual general meeting. If the date of such initial election or appointment is less than four calendar months prior to the date of the next annual general meeting, such Non-Employee Director shall not be granted a Continuing Grant under Section 2(b) above with respect to such next annual general meeting.

(d) Terms of Options Granted to Non-Employee Directors.

(i) Terms and Conditions. The terms and conditions applicable to each Initial Option Grant and Continuing Option Grant granted to Non-Employee Directors pursuant to this Policy shall be subject to the terms and conditions in the forms of stock option notice of grant and option award agreement previously approved by the Board or the Compensation Committee and the NEDSAP.

(ii) Vesting.

(a) Each Initial Option Grant granted to a Non-Employee Director shall vest and become exercisable as to 1/3 of the shares subject to such option on the first anniversary of the date such Non-Employee Director is first elected or appointed to the Board (the "***Initial Grant Vesting Commencement Date***") and as to the remainder of the shares, in 24 equal monthly installments thereafter, subject to the Non-Employee Director's Continuous Service (as defined in the NEDSAP) through such dates.

(b) Each Continuing Option Grant granted to a Non-Employee Director shall vest and become exercisable in full on the first anniversary of the annual general meeting of the Company's shareholders in the year of grant, subject to the Non-Employee Director's Continuous Service (as defined in the NEDSAP) through such date.

(c) Notwithstanding the vesting provisions in clauses (a) and (b) hereof, if a Non-Employee Director does not stand for reelection at an annual general meeting of the Company's shareholders in the year in which his or her term expires or otherwise resigns effective at an annual general meeting of the Company's shareholders and, in either case, the Non-Employee Director's Continuous Service terminates at such annual general meeting, then effective as of the date of such annual general meeting:

(1) the unvested portion, if any, of an Initial Option Grant granted to such Non-Employee Director shall become vested and exercisable with respect to the portion of the Initial Option Grant that would have vested through the anniversary of the Initial Grant Vesting Commencement Date in the year of such annual general meeting; and

(2) the unvested portion, if any, of a Continuing Option Grant granted to such Non-Employee Director shall become vested and exercisable in full.

(e) Terms of RSUs Granted to Non-Employee Directors.

(i) Terms and Conditions. The terms and conditions applicable to each Initial RSU Grant and Continuing RSU Grant granted to Non-Employee Directors pursuant to this Policy shall be subject to the terms and conditions in the forms of RSU notice of grant and RSU award agreement previously approved by the Board or the Compensation Committee, as applicable, and the NEDSAP.

(ii) Vesting.

(a) Each Initial RSU Grant granted to a Non-Employee Director shall vest in three equal annual installments on each of the first three anniversaries of the Initial Grant Vesting Commencement Date, subject to the Non-Employee Director's Continuous Service (as defined in the NEDSAP) through such dates.

(b) Each Continuing RSU Grant granted to a Non-Employee Director shall vest in full on the first anniversary of the annual general meeting of the Company's shareholders in the year of grant, subject to the Non-Employee Director's Continuous Service (as defined in the NEDSAP) through such date.

(c) Notwithstanding the vesting provisions in clauses (a) and (b) hereof, if a Non-Employee Director does not stand for reelection at an annual general meeting of the Company's shareholders in the year in which his or her term expires or otherwise resigns effective at an annual general meeting of the Company's shareholders and, in either case, the Non-Employee Director's Continuous Service terminates at such annual general meeting, then effective as of the date of such annual general meeting:

(1) the unvested portion, if any, of an Initial RSU Grant granted to such Non-Employee Director shall become vested with respect to the portion of the Initial RSU Grant that would have vested on the anniversary of the Initial Grant Vesting Commencement Date in the year of such annual general meeting; and

(2) the unvested portion, if any, of a Continuing RSU Grant granted to such Non-Employee Director shall become vested in full.

3. Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid, as applicable, by the Company to any individual for service as a Non-Employee Director with respect to any period commencing on the date of the annual general meeting of the Company's shareholders for a particular year and ending on the day immediately prior to the date of the annual general meeting of the Company's shareholders for the subsequent year (the "***Annual Period***"), including equity awards granted and cash fees paid by the Company to such Non-Employee Director, will not exceed (i) $750,000 in total value or (ii) in the event such Non-Employee Director is first appointed or elected to the Board during such Annual Period, $1,350,000 in total value, in each case calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes.

*****

Adopted by the Board of Directors of Jazz Pharmaceuticals plc on 2 May 2013.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 1 August 2013.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 1 May 2014.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 30 October 2014.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 30 April 2015.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 4 May 2016.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 3 May 2018.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 21 July 2020.

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

NON-U.S. OPTION GRANT NOTICE

Jazz Pharmaceuticals plc (the "***Company***"), pursuant to its Amended and Restated 2007 Non-Employee Directors Stock Award Plan (the "***Plan***"), hereby grants to Optionholder an option to purchase the number of Ordinary Shares specified and on the terms set forth below. This option is subject to all of the terms and conditions as set forth in this Non-U.S. Option Grant Notice (the "***Grant Notice***") and in the Non-U.S. Option Agreement, including any country-specific Appendix (the "***Agreement***"), and the Plan, both of which are attached hereto and incorporated herein in their entirety.

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

Type of Grant:	Nonstatutory Stock Option
Vesting Schedule:	Subject to Section 1 of the Agreement and any country-specific Appendix to the Agreement, this option will vest as follows: [_____]
Payment:	By one or a combination of the following items (described in the Agreement): ☒ By cash or check ☒ Pursuant to a Regulation T Program if the Ordinary Shares are publicly traded By delivery of already-owned Ordinary Shares if the Ordinary Shares are publicly traded

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

consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

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

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

*** * * * ***

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

ATTACHMENT I

NON-U.S. OPTION AGREEMENT

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

NON-U.S. OPTION AGREEMENT
(Nonstatutory Stock Option)

Pursuant to your Non-U.S. Option Grant Notice (the "***Grant Notice***") and this Non-U.S. Option Agreement, including any country-specific Appendix (the "***Agreement***"), Jazz Pharmaceuticals plc (the "***Company***") has granted you an option under its Amended and Restated 2007 Non-Employee Directors Stock Award Plan (the "***Plan***") to purchase the number of Ordinary Shares indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). Except as otherwise explicitly provided in the Grant Notice or this Agreement, in the event of any conflict between the terms in the Grant Notice or this Agreement and the Plan, the terms of the Plan shall control. Capitalized terms not explicitly defined in the Grant Notice or this Agreement but defined in the Plan shall have the same definitions as in the Plan.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8. Exercise.

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

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

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

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

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

12. Tax Withholding Obligations.

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

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

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

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding amounts or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Ordinary Share equivalent.

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

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

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

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

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

(d) you are voluntarily participating in the Plan;

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

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

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

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

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

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

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

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

For purposes of any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, the parties hereby submit to and consent to the sole

and exclusive jurisdiction of the courts of Santa Clara County, California, or the federal courts for the United States for the Northern District of California, and no other courts, where this grant is made and/or to be performed.

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

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

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

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

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

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

23. Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan, on the option and on any Ordinary Shares purchased upon exercise of the option, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

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

25. Insider Trading / Market Abuse Laws. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Ordinary Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Ordinary Shares, rights to Ordinary Shares (e.g., options) or rights linked to the value of Ordinary Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (a) disclosing the inside information to any third party and (b) "tipping" third parties or causing them otherwise to buy or sell securities (third parties include fellow directors). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under the Company's insider trading policy as may be in effect from time to time. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you should speak to your personal advisor on this matter.

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

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

* * * * *

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

* * * * *

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

APPENDIX
TO THE
NON-U.S. OPTION AGREEMENT

Terms and Conditions

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

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

Notifications

This Appendix contains information regarding exchange controls and certain other issues of which you should be aware with respect to participation in the Plan. The information is based on the securities, exchange control and other laws in effect in the respective countries as of August 2020. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information in this Appendix as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time you exercise the option or sell Ordinary Shares acquired pursuant thereto.

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

HONG KONG

Terms and Conditions

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

Notifications

Securities Law Notification. *WARNING: The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain*

independent professional advice. Neither the grant of the options nor the issuance of Ordinary Shares upon exercise of the options constitutes a public offering of securities under Hong Kong law and the grant is available only to directors of the Company or its Affiliates. The Agreement, the Plan and other incidental communication materials distributed in connection with the options (i) have not been prepared in accordance with and are not intended to constitute a "prospectus" for a public offering of securities under the applicable securities legislation in Hong Kong, and (ii) are intended only for the personal use of each eligible director of the Company or its Affiliates and may not be distributed to any other person.

IRELAND

There are no country-specific provisions.

SWITZERLAND

Notifications

Securities Law Notification. Neither this document nor any other materials relating to the options (i) constitutes a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA"), (ii) may be publicly distributed or otherwise made available in Switzerland to any person other than a director or an employee of the Company or its Affiliates, or (iii) has been or will be filed with, approved or supervised by any Swiss reviewing body according to article 51 of FinSA or any Swiss regulatory authority, including the Swiss Financial Market Supervisory Authority (FINMA).

ATTACHMENT II

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

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

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

Jazz Pharmaceuticals plc (the "***Company***"), pursuant to its Amended and Restated 2007 Non-Employee Directors Stock Award Plan (the "***Plan***"), hereby awards to Participant the number of restricted stock units ("***RSUs***") specified and on the terms set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this Non-U.S. Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and in the Non-U.S. Restricted Stock Unit Award Agreement, including any country-specific Appendix (the "***Agreement***"), and the Plan, both of which are attached hereto and incorporated herein in their entirety.

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

Vesting Schedule: Subject to Section 3 of the Agreement and any country-specific Appendix to the Agreement, the Award will vest as follows:
[_____]

Issuance Schedule: One Ordinary Share will be issuable for each RSU which vests at the time set forth in Section 4 of the Agreement.

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

JAZZ PHARMACEUTICALS PLC

By:_____
Signature

Title: _____

Date: _____

PARTICIPANT

By:_____
Signature

Date: _____

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

* * * * *

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

ATTACHMENT I

NON-U.S. RESTRICTED STOCK UNIT AWARD AGREEMENT

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

NON-U.S. RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to your Non-U.S. Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and this Non-U.S. Restricted Stock Unit Award Agreement, including any country-specific Appendix (the "***Agreement***"), and in consideration of your services, Jazz Pharmaceuticals plc (the "***Company***") has awarded you a Restricted Stock Unit Award (the "***Award***") under its Amended and Restated 2007 Non-Employee Directors Stock Award Plan (the "***Plan***") for the number of restricted stock units (the "***RSUs***") indicated in your Grant Notice. The Award is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). Except as otherwise explicitly provided in the Grant Notice or this Agreement, in the event of any conflict between the terms in the Grant Notice or this Agreement and the Plan, the terms of the Plan shall control. Capitalized terms not explicitly defined in the Grant Notice or this Agreement but defined in the Plan shall have the same definitions as in the Plan.

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

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

2. Number of RSUs and Ordinary Shares.

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

(b) Any additional RSUs that become subject to the Award pursuant to this Section 2 shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other RSUs covered by your Award.

(c) Notwithstanding the provisions of this Section 2, no fractional Ordinary Shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 2. The Board shall, in its discretion, determine an equivalent benefit for any fractional Ordinary Shares or fractional Ordinary Shares that might be created by the adjustments referred to in this Section 2.

3. Vesting. Subject to Section 12 and the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the RSUs credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such RSUs or the Ordinary Shares to be issued in respect of such portion of the Award.

4. Date of Issuance.

(a) To the extent your Award is exempt from application of Section 409A of the Code and any state or foreign law of similar effect (collectively "***Section 409A***"), the Company will deliver to you a number of Ordinary Shares equal to the number of vested RSUs subject to your Award, including any additional RSUs received pursuant to Section 2 above that relate to those vested RSUs on the applicable vesting date(s). However, if a scheduled delivery date falls on a date that is not a U.S. business day, such delivery date shall instead fall on the next following U.S. business day. Notwithstanding the foregoing, in the event that (i) you are subject to the Company's Policy Regarding Stock Trading by Executive Officers, Directors and Other Designated Employees (or any successor policy) (the "***Policy***"), the Company's Policy Against Trading on the Basis of Inside Information, or you are otherwise prohibited from selling Ordinary Shares in the open market and any Ordinary Shares covered by your Award are scheduled to be delivered on a day (the "***Original Distribution Date***") that does not occur during an open "window period" applicable to you or a day on which you are permitted to sell Ordinary Shares pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Exchange Act, as determined by the Company in accordance with the Policy, or does not occur on a date when you are otherwise permitted to sell Ordinary Shares in the open market, and (ii) the Company elects not to satisfy any Tax-Related Items (defined below) by withholding Ordinary Shares from your distribution, then such Ordinary Shares shall not be delivered on such Original Distribution Date and shall instead be delivered on the first U.S. business day of the next occurring open "window period" applicable to you pursuant to the Policy (regardless of whether you are still providing Continuous Service at such time) or the next U.S. business day when you are not prohibited from selling Ordinary Shares in the open market, but in no event later than the fifteenth (15th) day of the third calendar month of the calendar year following the calendar year in which the Ordinary Shares covered by the Award vest. Delivery of the Ordinary Shares pursuant to the provisions of this Section 4(a) is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and

shall be construed and administered in such manner. The form of such delivery of the Ordinary Shares (*e.g.*, a share certificate or electronic entry evidencing such Ordinary Shares) shall be determined by the Company.

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

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

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

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

(c) If you are a U.S. taxpayer and your Award is subject to and not exempt from Section 409A (a "***Non-Exempt Award***"), then the provisions in this Section 4(c) shall apply and supersede anything to the contrary that may be set forth in the Plan, the Grant Notice or in any other section of this Agreement with respect to the permitted treatment of your Non-Exempt Award:

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

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

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

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

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

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

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

8. Transfer Restrictions. Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Ordinary Shares subject to the Award until the Ordinary Shares are issued to you in accordance with Section 4 of this Agreement. After the Ordinary Shares have been issued to you, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such Ordinary Shares provided that any such actions are in compliance with the provisions herein (including the country-specific Appendix hereto) and applicable securities laws.

9. Award Not a Service Contract.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award pursuant to the schedule set forth in Section 3 herein or the issuance of the Ordinary Shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of service or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company or its Affiliates, as applicable, of the right to terminate your service without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the schedule set forth in Section 3 is earned only by providing Continuous Service (not through the act of being elected to the Board, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "reorganization"). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth

herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as a Non-Employee Director for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the right of the Company or its Affiliate, as applicable, to terminate your Continuous Service at any time.

10. Unsecured Obligation. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue Ordinary Shares pursuant to this Agreement. You shall not have voting or any other rights as a shareholder of the Company with respect to the Ordinary Shares to be issued pursuant to this Agreement until such Ordinary Shares are issued to you pursuant to Section 4 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a shareholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

11. Tax Withholding Obligations.

(a) On or before the time you receive a distribution of the Ordinary Shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize the Company to withhold from the Ordinary Shares issuable to you an amount sufficient to satisfy any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items which arise in connection with your Award ("***Tax-Related Items***"), where the Fair Market Value of the Ordinary Shares is measured as of the date the Ordinary Shares are issued pursuant to Section 4. Additionally, the Company may, in its sole discretion, satisfy all or any portion of the Tax-Related Items obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; or (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the Ordinary Shares to be delivered in connection with your Award to satisfy the Tax-Related Items and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax-Related Items directly to the Company and/or its Affiliates. If the obligation for Tax-Related Items is satisfied by withholding from Ordinary Shares otherwise issuable to you, (i) the number of such Ordinary Shares so withheld shall not exceed the minimum statutory withholding rates in connection with the taxes composing the Tax Related-Items, and (ii) for tax purposes, you are deemed to have been issued the full number of Ordinary Shares subject to the vested RSUs, notwithstanding that a number of the Ordinary Shares are held back solely for the purpose of paying the Tax-Related Items. Furthermore, you acknowledge that the Company makes no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award, including, but not limited to, the grant or vesting of the RSUs, the subsequent sale of Ordinary Shares acquired pursuant to such vesting and the receipt of any dividends, and does not commit to and is under no obligation to structure the terms of the grant or any aspect of the Award to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You further acknowledge that if you become subject to tax in more than one jurisdiction

between the Date of Grant and the date of any relevant taxable event, the Company may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

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

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

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

13. Parachute Payments.

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

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

(c) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting

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

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

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

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

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

(d) you are voluntarily participating in the Plan;

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

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

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

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

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

practices, log in to your E*TRADE account to view a copy of the Jazz Pharmaceuticals Privacy Notice.

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

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

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

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

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

21. Headings. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

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

23. Miscellaneous.

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

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

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

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

24. Governing Plan Document. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as expressly provided in this Agreement, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control. In addition, your Award (and any compensation paid or Ordinary Shares issued under your Award) is subject to recoupment in accordance with the Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

25. Severability. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

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

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

28. Insider Trading / Market Abuse Laws. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Ordinary Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Ordinary Shares, rights to Ordinary Shares (e.g., RSUs) or rights linked to the value of Ordinary Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions). Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (a) disclosing the inside information to any third party and (b) "tipping" third parties or causing them otherwise to buy or sell securities (third parties include fellow directors). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under the Company's insider trading policy as may be in effect from time to time. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you should speak to your personal advisor on this matter.

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

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

* * * * *

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

* * * * *

Based on the form of Non-U.S. Restricted Stock Unit Award Agreement for the Amended and Restated 2007 Non-Employee Directors Stock Award Plan as approved by the Board of Directors of Jazz Pharmaceuticals plc on February 14, 2019.

APPENDIX

TO THE

NON-U.S. RESTRICTED STOCK UNIT AWARD AGREEMENT

Terms and Conditions

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

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

Notifications

This Appendix contains information regarding exchange controls and certain other issues of which you should be aware with respect to participation in the Plan. The information is based on the securities, exchange control, and other laws in effect in the respective countries as of August 2020. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information in this Appendix as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time you vest in the RSUs or sell Ordinary Shares acquired pursuant thereto.

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

HONG KONG

Terms and Conditions

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

Notifications

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

IRELAND

Terms and Conditions

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

Notwithstanding the vesting schedule provided in the Grant Notice and Section 4 (a) of the Agreement, (i) if any vesting date set forth in the Grant Notice ("***Vesting Date***") falls on a date when the Company determines that you are not permitted to sell Ordinary Shares in the open market for any reason, including under the Company's Policy Regarding Stock Trading by Executive Officers, Directors and Other Designated Employees (or any successor policy) or the Company's Policy Against Trading on the Basis of Inside Information (or any successor policy), and (ii) the Company elects not to satisfy any Tax-Related Items (defined in Section 11) by withholding Ordinary Shares, then such Vesting Date shall instead be the later of the next U.S. business day of the next occurring open "window period" applicable to you or the next U.S. business day when the Company determines that you are not prohibited from selling Ordinary Shares in the open market (such later date, the "***Actual Vesting Date***").

Notwithstanding the foregoing and Section 3 of the Agreement: (i) if your Continuous Service terminates between the Vesting Date and the Actual Vesting Date, then the vesting of the Ordinary Shares subject to the Award originally scheduled to vest on the Vesting Date will cease and not vest upon termination of your Continuous Service, unless your Continuous Service terminates for a reason other than Cause, in which case they will instead vest in full on the first U.S. business day following the termination of your Continuous Service; and (ii) if you are a Non-Employee Director and you do not stand for reelection at an annual general meeting of the Company's shareholders (an "***Annual Meeting***") in the year in which your term expires or you otherwise resign effective at an Annual Meeting, and, in either case, your Continuous Service terminates at such Annual Meeting, then effective as of the date of such Annual Meeting, the unvested portion, if any, of the Award shall become vested with respect to the portion of the Award that would have vested on the anniversary of the Vesting Commencement Date in the year of such Annual Meeting.

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

SWITZERLAND

Notifications

Securities Law Notification. Neither this document nor any other materials relating to the RSUs (i) constitutes a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("FinSA"), (ii) may be publicly distributed or otherwise made available in Switzerland to any person other than a director or an employee of the Company or its Affiliates, or (iii) has been or will be filed with, approved or supervised by any Swiss reviewing body according to article 51 of FinSA or any Swiss regulatory authority, including the Swiss Financial Market Supervisory Authority (FINMA).

ATTACHMENT II

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

Exhibit 31.1

CERTIFICATION

I, Bruce C. Cozadd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals public limited company;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 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: November 2, 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 September 30, 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: November 2, 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.