

**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 June 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

(State or other jurisdiction of
incorporation or organization)

98-1032470

(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 July 28, 2020, 55,458,631 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 JUNE 30, 2020

INDEX

	Page
<u>PART I – FINANCIAL INFORMATION</u>	
Item 1.	<u>Financial Statements</u> <u>3</u>
	<u>Condensed Consolidated Balance Sheets – June 30, 2020 and December 31, 2019</u> <u>3</u>
	<u>Condensed Consolidated Statements of Income (Loss) – Three and Six Months Ended June 30, 2020 and 2019</u> <u>4</u>
	<u>Condensed Consolidated Statements of Comprehensive Income (Loss) – Three and Six Months Ended June 30, 2020 and 2019</u> <u>5</u>
	<u>Condensed Consolidated Statements of Shareholders’ Equity – Three and Six Months Ended June 30, 2020 and 2019</u> <u>6</u>
	<u>Condensed Consolidated Statements of Cash Flows – Six Months Ended June 30, 2020 and 2019</u> <u>8</u>
	<u>Notes to Condensed Consolidated Financial Statements</u> <u>9</u>
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> <u>28</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u> <u>42</u>
Item 4.	<u>Controls and Procedures</u> <u>42</u>
<u>PART II – OTHER INFORMATION</u>	
Item 1.	<u>Legal Proceedings</u> <u>44</u>
Item 1A.	<u>Risk Factors</u> <u>44</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> <u>72</u>
Item 5.	<u>Other Information</u> <u>73</u>
Item 6.	<u>Exhibits</u> <u>74</u>
	<u>SIGNATURES</u> <u>76</u>

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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 786,082	\$ 637,344
Investments	910,000	440,000
Accounts receivable, net of allowances	351,920	355,987
Inventories	92,534	78,608
Prepaid expenses	49,109	39,434
Other current assets	112,701	78,895
Total current assets	2,302,346	1,630,268
Property, plant and equipment, net	128,259	131,506
Operating lease assets	133,179	139,385
Intangible assets, net	2,286,126	2,440,977
Goodwill	918,021	920,018
Deferred tax assets, net	243,395	221,403
Deferred financing costs	6,347	7,426
Other non-current assets	48,828	47,914
Total assets	\$ 6,066,501	\$ 5,538,897
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 50,043	\$ 45,732
Accrued liabilities	266,918	269,686
Current portion of long-term debt	33,387	33,387
Income taxes payable	55,979	10,965
Deferred revenue	3,633	4,720
Total current liabilities	409,960	364,490
Deferred revenue, non-current	3,588	4,861
Long-term debt, less current portion	2,069,669	1,573,870
Operating lease liabilities, less current portion	144,264	151,226
Deferred tax liabilities, net	162,376	224,095
Other non-current liabilities	134,839	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	2,499,135	2,266,026
Accumulated other comprehensive loss	(236,109)	(223,393)
Retained earnings	878,246	1,067,815
Total shareholders' equity	3,141,805	3,110,981
Total liabilities and shareholders' equity	\$ 6,066,501	\$ 5,538,897

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	\$ 558,203	\$ 523,423	\$ 1,088,408	\$ 1,026,754
Royalties and contract revenues	4,233	10,710	8,754	15,565
Total revenues	562,436	534,133	1,097,162	1,042,319
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	28,008	27,676	56,665	61,182
Selling, general and administrative	191,406	176,014	399,806	343,961
Research and development	78,922	62,384	165,029	122,489
Intangible asset amortization	62,974	61,576	125,821	118,461
Acquired in-process research and development	3,000	2,200	205,250	58,200
Impairment charge	—	—	136,139	—
Total operating expenses	364,310	329,850	1,088,710	704,293
Income from operations	198,126	204,283	8,452	338,026
Interest expense, net	(26,210)	(18,234)	(44,706)	(36,156)
Foreign exchange loss	(464)	(1,933)	(1,596)	(2,544)
Income (loss) before income tax provision (benefit) and equity in loss of investees	171,452	184,116	(37,850)	299,326
Income tax provision (benefit)	54,754	(78,650)	3,467	(49,534)
Equity in loss of investees	1,897	868	1,715	1,761
Net income (loss)	\$ 114,801	\$ 261,898	\$ (43,032)	\$ 347,099
Net income (loss) per ordinary share:				
Basic	\$ 2.07	\$ 4.62	\$ (0.77)	\$ 6.09
Diluted	\$ 2.06	\$ 4.56	\$ (0.77)	\$ 6.01
Weighted-average ordinary shares used in per share calculations - basic	55,413	56,707	55,684	56,955
Weighted-average ordinary shares used in per share calculations - diluted	55,864	57,427	55,684	57,753

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net income (loss)	\$ 114,801	\$ 261,898	\$ (43,032)	\$ 347,099
Other comprehensive income (loss):				
Foreign currency translation adjustments	20,730	13,319	(9,260)	(7,823)
Unrealized gain (loss) on hedging activities, net of income tax provision (benefit) of \$85, (\$440), (\$494) and (\$689), respectively	597	(3,081)	(3,456)	(4,822)
Other comprehensive income (loss)	21,327	10,238	(12,716)	(12,645)
Total comprehensive income (loss)	\$ 136,128	\$ 272,136	\$ (55,748)	\$ 334,454

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

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

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

	Six Months Ended June 30,	
	2020	2019
Operating activities		
Net income (loss)	\$ (43,032)	\$ 347,099
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Intangible asset amortization	125,821	118,461
Share-based compensation	59,258	55,841
Impairment charge	136,139	—
Depreciation	9,266	6,894
Acquired in-process research and development	205,250	58,200
Deferred tax benefit	(82,768)	(151,347)
Provision for losses on accounts receivable and inventory	4,078	2,403
Loss on extinguishment of debt	4,475	—
Amortization of debt discount and deferred financing costs	24,793	22,584
Other non-cash transactions	3,496	(779)
Changes in assets and liabilities:		
Accounts receivable	3,640	(47,574)
Inventories	(18,826)	(18,562)
Prepaid expenses and other current assets	(44,853)	(15,929)
Other non-current assets	1,982	(1,067)
Operating lease assets	6,422	7,399
Accounts payable	5,264	(14,096)
Accrued liabilities	(6,972)	(59,031)
Income taxes payable	45,481	29,050
Deferred revenue	(2,360)	(3,054)
Other non-current liabilities	25,912	14,177
Operating lease liabilities, less current portion	(6,978)	431
Net cash provided by operating activities	455,488	351,100
Investing activities		
Proceeds from maturity of investments	565,000	630,000
Purchases of property, plant and equipment	(7,520)	(21,911)
Acquired in-process research and development	(205,250)	(58,200)
Acquisition of intangible assets	(113,000)	(25,500)
Acquisition of investments	(1,040,475)	(360,975)
Net cash provided by (used in) investing activities	(801,245)	163,414
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	24,251	16,122
Payment of employee withholding taxes related to share-based awards	(14,663)	(14,813)
Repayments of long-term debt	(16,693)	(16,693)
Share repurchases	(146,537)	(171,118)
Payments for partial repurchase of Exchangeable Senior Notes, due 2021	(332,888)	—
Repayments under revolving credit facility	(500,000)	—
Net cash provided by (used in) financing activities	494,851	(186,502)
Effect of exchange rates on cash and cash equivalents	(356)	105
Net increase in cash and cash equivalents	148,738	328,117
Cash and cash equivalents, at beginning of period	637,344	309,622
Cash and cash equivalents, at end of period	\$ 786,082	\$ 637,739

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**, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in both adult and pediatric patients with narcolepsy;
- **Sunosi® (solriamfetol)**, a product approved by FDA and marketed in the U.S. 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 Erwinaze®) 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 recently launched 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.

On July 21, 2020, Xywav™ (formerly JZP-258) was approved in the U.S. for the treatment of cataplexy or EDS in narcolepsy patients seven years of age and older; we expect to launch Xywav in the fourth quarter of 2020. This approval follows multiple significant regulatory approvals and product launches over the last five years. In 2020, we also obtained our European approval of Sunosi, which was launched in Germany in May 2020, and the U.S. approval of Zepzelca, which was launched in July 2020.

Our strategy to create shareholder value is focused on:

- Strong execution driving sales 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 external patient-centric innovation to achieve a balanced portfolio of 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 a scalable operating model and differentiated capabilities to enable successful partnerships and unlock further value through indication expansion and global markets.

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 six months ended June 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 current goodwill impairment test. Goodwill impairment will now be the amount by which the reporting unit’s carrying value exceeds its fair value, limited to the carrying value of the goodwill. We adopted this standard on January 1, 2020 and adoption did not have a material impact on our consolidated financial statements.

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

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 are probable of occurring 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. 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 are having 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 ability to maintain or increase Xyrem product 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, challenges to our intellectual property around Xyrem, and continued acceptance of Xyrem by physicians and patients.

In addition to risks related specifically to Xyrem, we are subject to other challenges and risks related to successfully commercializing a portfolio of oncology products and other neuroscience products, including Sunosi, Defitelio, Erwinaze, Vyxeos, Zepzelca and Xywav, 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 June 30, 2020, we had foreign exchange forward contracts with notional amounts totaling \$283.7 million. As of June 30, 2020, the outstanding foreign exchange forward contracts had a net liability fair value of \$0.3 million. As of June 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 \$5.5 million as of June 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 June 30, 2020 and December 31, 2019, allowances on receivables were not material. As of June 30, 2020, two customers accounted for 87% 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 14% of gross accounts receivable. As of December 31, 2019, two customers accounted for 89% of gross accounts receivable, ESSDS, which accounted for 77% of gross accounts receivable, and McKesson, which accounted for 12% of gross accounts receivable.

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

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes", which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. The amendments are effective for annual reporting periods beginning after December 15, 2020 with early adoption permitted. We are currently evaluating the impact of adopting this new accounting guidance.

2. License Agreement

On December 19, 2019, we entered into an exclusive license agreement with Pharma Mar, S.A., or PharmaMar, for development and U.S. commercialization of 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 this agreement, which became effective in January 2020 upon expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, we paid PharmaMar an upfront payment of \$200.0 million, which was recorded as in-process research and development, or IPR&D expense in our condensed consolidated statements of income (loss) for the six months ended June 30, 2020. In June 2020, we made a milestone payment of \$100.0 million to PharmaMar following FDA 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 full regulatory approval of Zepzelca within certain timelines. PharmaMar is also eligible to receive up to \$550.0 million in potential commercial milestone payments, as well as incremental tiered royalties on future net sales of 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.

3. Cash and Available-for-Sale Securities

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

	June 30, 2020					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	\$ 470,560	\$ —	\$ —	\$ 470,560	\$ 470,560	\$ —
Time deposits	1,100,000	—	—	1,100,000	190,000	910,000
Money market funds	125,522	—	—	125,522	125,522	—
Totals	\$ 1,696,082	\$ —	\$ —	\$ 1,696,082	\$ 786,082	\$ 910,000

	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 (loss). Our investment balances represent time deposits with original maturities of greater than three months and less than one year. Interest income from available-for-sale securities was \$3.1 million and \$7.6 million in three and six months ended June 30, 2020, respectively, and \$5.0 million and \$9.8 million in the three and six months ended June 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 June 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):

	June 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	\$ —	\$ 1,100,000	\$ 1,100,000	\$ —	\$ 460,000	\$ 460,000
Money market funds	125,522	—	125,522	284,172	—	284,172
Foreign exchange forward contracts	—	1,454	1,454	—	2,508	2,508
Totals	\$ 125,522	\$ 1,101,454	\$ 1,226,976	\$ 284,172	\$ 462,508	\$ 746,680
Liabilities:						
Interest rate contracts	\$ —	\$ 5,479	\$ 5,479	\$ —	\$ 1,515	\$ 1,515
Foreign exchange forward contracts	—	1,765	1,765	—	182	182
Totals	\$ —	\$ 7,244	\$ 7,244	\$ —	\$ 1,697	\$ 1,697

As of June 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 June 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 June 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 \$237 million, \$528 million and \$1 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 June 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 six months ended June 30, 2020 and 2019 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Interest Rate Contracts:				
Loss recognized in accumulated other comprehensive loss, net of tax	\$ (324)	\$ (2,698)	\$ (4,524)	\$ (4,039)
Loss (gain) reclassified from accumulated other comprehensive loss to interest expense, net of tax	921	(383)	1,068	(783)

Assuming no change in LIBOR-based interest rates from market rates as of June 30, 2020, \$4.6 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 June 30, 2020 and December 31, 2019, the notional amount of foreign exchange contracts where hedge accounting is not applied was \$283.7 million and \$180.9 million, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Foreign Exchange Forward Contracts:				
Gain (loss) recognized in foreign exchange loss	\$ 3,533	\$ 121	\$ (2,606)	\$ (3,288)

The cash flow effects of our derivative contracts for the six months ended June 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):

	June 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	\$ 5,299
			Other non-current liabilities	180
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	1,454	Accrued liabilities	1,765
Total fair value of derivative instruments		\$ 1,454		\$ 7,244

	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):

Description	June 30, 2020					
	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	Gross Amounts Not Offset in the Consolidated Balance Sheet		
				Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	\$ 1,454	\$ —	\$ 1,454	\$ (1,269)	\$ —	\$ 185
Derivative liabilities	(7,244)	—	(7,244)	1,269	—	(5,975)

Description	December 31, 2019					
	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	Gross Amounts Not Offset 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):

	June 30, 2020	December 31, 2019
Raw materials	\$ 15,856	\$ 13,595
Work in process	42,582	36,658
Finished goods	34,096	28,355
Total inventories	\$ 92,534	\$ 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	(1,997)
Balance at June 30, 2020	\$ 918,021

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

	June 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	12.9	\$ 3,275,569	\$ (989,443)	\$ 2,286,126	\$ 3,166,485	\$ (864,834)	\$ 2,301,651
Manufacturing contracts	—	11,987	(11,987)	—	12,025	(12,025)	—
Trademarks	—	2,889	(2,889)	—	2,890	(2,890)	—
Priority review voucher	—	—	—	—	111,101	(111,101)	—
Total finite-lived intangible assets		3,290,445	(1,004,319)	2,286,126	3,292,501	(990,850)	2,301,651
Acquired IPR&D assets		—	—	—	139,326	—	139,326
Total intangible assets		\$ 3,290,445	\$ (1,004,319)	\$ 2,286,126	\$ 3,431,827	\$ (990,850)	\$ 2,440,977

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

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 June 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):

<u>Year Ending December 31,</u>	<u>Estimated Amortization Expense</u>
2020 (remainder)	\$ 130,647
2021	215,415
2022	170,572
2023	170,572
2024	170,572
Thereafter	1,428,348
Total	\$ 2,286,126

8. Certain Balance Sheet Items

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

	June 30, 2020	December 31, 2019
Leasehold improvements	\$ 53,348	\$ 52,294
Land and buildings	47,112	47,053
Manufacturing equipment and machinery	30,840	28,860
Computer software	22,758	25,680
Computer equipment	17,747	16,577
Furniture and fixtures	11,330	11,152
Construction-in-progress	3,393	5,147
Subtotal	186,528	186,763
Less accumulated depreciation and amortization	(58,269)	(55,257)
Property, plant and equipment, net	\$ 128,259	\$ 131,506

Accrued liabilities consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Rebates and other sales deductions	\$ 122,204	\$ 96,860
Employee compensation and benefits	51,289	80,531
Current portion of operating lease liabilities	12,763	12,728
Inventory-related accruals	12,364	7,816
Sales returns reserve	8,030	3,462
Derivative instrument liabilities	7,064	1,037
Consulting and professional services	6,221	7,665
Accrued interest	6,110	7,540
Royalties	6,031	6,931
Selling and marketing accruals	3,420	10,946
Accrued collaboration expenses	3,161	2,494
Clinical trial accruals	2,965	3,141
Accrued construction-in-progress	442	3,015
Other	24,854	25,520
Total accrued liabilities	\$ 266,918	\$ 269,686

9. Debt

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

	June 30, 2020	December 31, 2019
2021 Notes	\$ 242,112	\$ 575,000
Unamortized discount and debt issuance costs on 2021 Notes	(11,560)	(38,865)
2021 Notes, net	230,552	536,135
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(106,840)	(117,859)
2024 Notes, net	468,160	457,141
2026 Notes	1,000,000	—
Unamortized discount and debt issuance costs on 2026 Notes	(193,498)	—
2026 Notes, net	806,502	—
Term loan	597,842	613,981
Total debt	2,103,056	1,607,257
Less current portion	33,387	33,387
Total long-term debt	\$ 2,069,669	\$ 1,573,870

Exchangeable Senior Notes 2026

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.

As part of the repurchase of \$332.9 million aggregate principal amount of the 2021 Notes concurrently with the offering of the 2026 Notes, we settled a proportionate amount of outstanding interest related to the 2021 Notes of \$2.0 million. We recorded a loss on extinguishment of debt of \$4.5 million 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 \$12.1 million, as a reduction to the equity component. As of June 30, 2020, the principal amount of the 2021 Notes remaining was \$242.1 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 June 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 \$114.8 million, \$149.8 million and \$176.3 million, respectively.

Revolving Credit Facility

In April 2020, we drew down \$500.0 million under the revolving credit facility provided for under the credit agreement that we entered into in June 2015 and subsequently amended, which we refer to as 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.

Maturities

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

<u>Year Ending December 31,</u>	<u>Scheduled Long-Term Debt Maturities</u>
2020 (remainder)	\$ 16,693
2021	275,499
2022	33,387
2023	517,494
2024	575,000
Thereafter	1,000,000
Total	\$ 2,418,073

10. Leases

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

Lease Cost	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease cost	\$ 5,410	\$ 6,056	\$ 10,700	\$ 11,926
Short-term lease cost	890	619	1,760	1,220
Variable lease cost	—	1	1	4
Sublease income	(67)	(158)	(224)	(320)
Net lease cost	\$ 6,233	\$ 6,518	\$ 12,237	\$ 12,830

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

Leases	Classification	June 30, 2020	December 31, 2019
Assets			
Operating lease assets	Operating lease assets	\$ 133,179	\$ 139,385
Liabilities			
Current			
Operating lease liabilities	Accrued liabilities	12,763	12,728
Non-current			
Operating lease liabilities	Operating lease liabilities, less current portion	144,264	151,226
Total operating lease liabilities		\$ 157,027	\$ 163,954

Lease Term and Discount Rate	June 30, 2020	December 31, 2019
Weighted-average remaining lease term - operating leases (years)	9.3	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):

	Six Months Ended June 30,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	\$ 11,404	\$ 8,240
Non-cash operating activities:		
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	\$ 533	\$ 152,142

(1) The June 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):

<u>Year Ending December 31,</u>	<u>Operating leases</u>
2020 (remainder)	\$ 10,078
2021	21,203
2022	21,219
2023	21,489
2024	23,786
Thereafter	104,655
Total lease payments	\$ 202,430
Less imputed interest	(45,403)
Present value of lease liabilities	\$ 157,027

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 June 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 June 30, 2020, we had \$71.7 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 (hereinafter referred to as the Teamsters Lawsuit), 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 (hereinafter referred to as the City of Providence Lawsuit).

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.

The plaintiffs in the BCBS Lawsuit, Teamsters Lawsuit, the GEHA Lawsuit, and the UFCW Lawsuit are seeking to represent a class of direct purchasers, and the plaintiffs in the City of Providence Lawsuit, the UFCW Lawsuit, and the AGL Plan Lawsuit are seeking to represent a class of indirect purchasers of Xyrem. The lawsuits generally allege 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 the BCBS Defendants, including the City of Providence Defendants. The suits seek 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 June 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. In the six months ended June 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 June 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 June 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 loss before reclassifications	(4,524)	(9,260)	(13,784)
Amounts reclassified from accumulated other comprehensive loss	1,068	—	1,068
Other comprehensive loss, net	(3,456)	(9,260)	(12,716)
Balance at June 30, 2020	\$ (4,781)	\$ (231,328)	\$ (236,109)

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

13. Net Income (Loss) per Ordinary Share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net income (loss)	\$ 114,801	\$ 261,898	\$ (43,032)	\$ 347,099
Denominator:				
Weighted-average ordinary shares used in per share calculations - basic	55,413	56,707	55,684	56,955
Dilutive effect of employee equity incentive and purchase plans	451	720	—	798
Weighted-average ordinary shares used in per share calculations - diluted	55,864	57,427	55,684	57,753
Net income (loss) per ordinary share:				
Basic	\$ 2.07	\$ 4.62	\$ (0.77)	\$ 6.09
Diluted	\$ 2.06	\$ 4.56	\$ (0.77)	\$ 6.01

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Exchangeable Senior Notes	6,474	5,504	5,989	5,504
Options, RSUs and ESPP	6,178	5,202	5,895	5,095

14. Revenues

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Xyrem	\$ 446,808	\$ 413,212	\$ 854,683	\$ 781,529
Defitelio/defibrotide	42,714	46,055	90,146	87,555
Erwinaze/Erwinase	32,683	27,622	70,415	88,521
Vyxeos	26,568	31,362	59,288	60,305
Sunosi	8,578	—	10,502	—
Other	852	5,172	3,374	8,844
Product sales, net	558,203	523,423	1,088,408	1,026,754
Royalties and contract revenues	4,233	10,710	8,754	15,565
Total revenues	\$ 562,436	\$ 534,133	\$ 1,097,162	\$ 1,042,319

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
United States	\$ 516,097	\$ 480,932	\$ 994,580	\$ 943,794
Europe	37,895	36,518	79,451	71,919
All other	8,444	16,683	23,131	26,606
Total revenues	\$ 562,436	\$ 534,133	\$ 1,097,162	\$ 1,042,319

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
ESSDS	79%	77%	78%	75%
McKesson	10%	12%	11%	15%

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 June 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 \$2.4 million during the three and six months ended June 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 six months ended June 30, 2020 (in thousands):

	Contract Liabilities
Balance as of December 31, 2019	\$ 9,581
Amount recognized within royalties and contract revenues	(2,360)
Balance as of June 30, 2020	<u>\$ 7,221</u>

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Selling, general and administrative	\$ 21,020	\$ 20,685	\$ 41,616	\$ 41,055
Research and development	7,663	5,896	14,048	11,419
Cost of product sales	1,921	1,708	3,594	3,367
Total share-based compensation expense, pre-tax	30,604	28,289	59,258	55,841
Income tax benefit from share-based compensation expense	(2,924)	(4,473)	(6,670)	(8,140)
Total share-based compensation expense, net of tax	<u>\$ 27,680</u>	<u>\$ 23,816</u>	<u>\$ 52,588</u>	<u>\$ 47,701</u>

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Shares underlying options granted (in thousands)	79	102	644	1,399
Grant date fair value	\$ 33.29	\$ 38.95	\$ 33.61	\$ 42.56
Black-Scholes option pricing model assumption information:				
Volatility	36%	31%	32%	32%
Expected term (years)	4.6	4.5	4.6	4.5
Range of risk-free rates	0.3-0.4%	1.8-2.3%	0.3-1.6%	1.8-2.5%
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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
RSUs granted (in thousands)	129	42	1,088	561
Grant date fair value	\$ 108.20	\$ 132.73	\$ 113.48	\$ 138.87

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 June 30, 2020, compensation cost not yet recognized related to unvested share options and RSUs was \$74.5 million and \$159.4 million, respectively, which is expected to be recognized over a weighted-average period of 2.6 years and 3.0 years, respectively.

16. Income Taxes

Our income tax provision was \$54.8 million and \$3.5 million in the three and six months ended June 30, 2020, respectively, compared to an income tax benefit of \$78.7 million and \$49.5 million for the same periods in 2019. The effective tax rates were 31.9% and (9.2)% in the three and six months ended June 30, 2020, respectively, compared to (42.7)% and (16.5)% for the same periods in 2019. The income tax benefit for the three and six months ended June 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 three and six months ended June 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 increase in the effective tax rate for the three months ended June 30, 2020 compared to the same period in 2019 was primarily due to the impact of the disallowance of certain interest deductions and provision for a proposed settlement reached with the French tax authorities in respect of an ongoing tax audit discussed in more detail below. The decrease in the effective tax rate for the six months ended June 30, 2020 compared to the same period in 2019 was primarily due to the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the PharmaMar transaction, partially offset by the impact of the disallowance of certain interest deductions and provision for the proposed settlement reached with the French tax authorities. The effective tax rate for the three months ended June 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 provision for the proposed settlement reached with the French tax authorities. The effective tax rate for the six months ended June 30, 2020 was lower than the Irish statutory rate of 12.5% primarily due to the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the PharmaMar transaction, partially offset by the impact of certain interest disallowance provision and provision for the proposed settlement reached with the French tax authorities. 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 December 2015, we received proposed tax assessment notices, and, in October 2018 and December 2019, we received revised tax assessment notices from the French tax authorities for 2012 and 2013 and in December 2018 and September 2019, we received a proposed tax assessment notice for 2015, 2016 and 2017, relating to certain transfer pricing adjustments. The notices propose additional French tax of approximately \$41.9 million for 2012 and 2013 and approximately \$12.0 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 June 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 \$17.7 million, translated at the foreign exchange rate as of June 30, 2020. The settlement, which is subject to formal finalization and documentation with the French tax authorities, was accrued as of June 30, 2020 and the income tax expense for the three and six months ended June 30, 2020 includes the impact of the settlement. Certain of our Italian subsidiaries are currently under examination by the Italian tax authorities for the year ended December 31, 2017.

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**, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in both adult and pediatric patients with narcolepsy;
- **Sunosi® (solriamfetol)**, a product approved by FDA and marketed in the U.S. and in Europe to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, or OSA;
- **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 Erwinaze®) 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 recently launched 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.

On July 21, 2020, Xywav™ (formerly JZP-258) was approved in the U.S. for the treatment of cataplexy or EDS in narcolepsy patients seven years of age and older; we expect to launch Xywav in the fourth quarter of 2020. This approval follows multiple significant regulatory approvals and product launches over the last five years. In 2020, we also obtained our European approval of Sunosi, which was launched in Germany in May 2020, and the U.S. approval of Zepzelca, which was launched in July 2020.

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

In addition, we are conducting a Phase 3 clinical trial of Xywav (JZP-258) for the treatment of idiopathic hypersomnia, a chronic neurological disorder that is primarily characterized by EDS that currently has no approved therapies in the U.S. We completed enrollment in this trial in the first quarter of 2020 and expect top-line data in the fourth quarter of 2020 and submission of a supplemental new drug application, or NDA, as early as the first quarter of 2021, with potential approval and launch as early as late 2021.

Our strategy to create shareholder value is focused on:

- Strong execution driving sales 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 external patient-centric innovation to achieve a balanced portfolio of 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 a scalable operating model and differentiated capabilities to enable successful partnerships and unlock further value through indication expansion and global markets.

Significant Developments During the Quarter Affecting Our Business

In June 2020, Jazz Investments I Limited, our wholly owned subsidiary, completed a private offering of an aggregate \$1.0 billion principal amount of 2.00% exchangeable senior notes due 2026, or 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 existing 1.875% exchangeable senior notes due 2021, or the 2021 Notes, through individual privately-negotiated transactions concurrently with the offering. The remaining net proceeds will be used for general corporate purposes, including additional repurchases of 2021 Notes by us from time to time.

In June 2020, Zepzelca received accelerated FDA approval for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy, a product for which we have exclusive U.S. commercialization rights. 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 contracts with distributors and group purchasing organizations were executed for Zepzelca.

In July 2020, FDA approved our NDA for 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. 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. Multiple Xywav dosing options are available for adult and pediatric patients. 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. We developed Xywav to provide a clinically meaningful benefit to patients who are prescribed an oxybate product to treat the chronic condition of narcolepsy. In approving Xywav, FDA approved a risk evaluation and mitigation strategy, or REMS, for Xywav and Xyrem. We plan to launch Xywav in the fourth quarter of 2020, following implementation of the REMS.

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 six months ended June 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

<u>Product Candidates</u>	<u>Description</u>
Phase 3	
Xywav (JZP-258) (oxybate; 92% sodium reduction)	Idiopathic hypersomnia
Phase 2b	
JZP-385	Essential tremor (planned study)
Phase 1	
JZP-324	Oxybate extended-release formulation

Oncology

<u>Product Candidates</u>	<u>Description</u>
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 <i>Erwinia</i> asparaginase)	ALL/LBL
Phase 2	
Defitelio	Prevention of acute Graft versus Host Disease Prevention of CAR T-cell therapy-associated neurotoxicity
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes Cooperative Group cooperative group study) Newly diagnosed older adults with high-risk AML (planned cooperative group study)
Vyxeos + venetoclax	De novo or relapsed/refractory, or R/R, AML (MD Anderson collaboration study)
Phase 1	
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study)
Vyxeos + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study) First-line, fit AML (Phase 1b study) Low intensity therapy for first-line, unfit AML (Phase 1b study)
IMGN632	R/R CD123+ hematological malignancies (Jazz opt-in opportunity with ImmunoGen, Inc., or ImmunoGen) +/- venetoclax/azacitidine in CD123+ AML (Jazz opt-in opportunity with ImmunoGen; Phase 1b/2 study)
Preclinical	
CombiPlex	Hematology/oncology exploratory activities

Product Candidates	Description
JZP-341 (long-acting <i>Erwinia</i> asparaginase)	ALL and other hematological malignancies (collaboration with Pfenex, Inc., or Pfenex)
Recombinant pegaspargase	Hematological malignancies (Jazz opt-in opportunity with Pfenex)
Pan-RAF inhibitor program	RAF and RAS mutant tumors (acquired from Redx Pharma, which is continuing development)
Exosome targets (NRAS, STAT3 and 3 other candidates)	Hematological malignancies/solid tumors (collaboration with Codiak BioSciences, Inc., or Codiak)
Defitelio	Exploratory activities

In April 2020, we announced our 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. This does not impact the approved indication or other ongoing defibrotide development activities. In 2020 and beyond, we expect that our research and development expenses will continue to increase from previous levels, particularly as we prepare for anticipated regulatory submissions and data read-outs from clinical trials, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates.

Operational Excellence

In addition, we remain focused on continuing to build excellence in areas that will give us a competitive advantage, including building an increasingly agile and adaptable commercialization engine and strengthening our customer-focused market expertise across patients, providers and 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 to accelerate our progress, including a more integrated approach to brand planning, a new North American regional business structure, and a new global medical affairs organization. These initiatives mark a significant operational evolution that is directly linked to our corporate strategy and 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 in the U.S. and our planned launch of 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. In the second quarter of 2020, we experienced 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 are having 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. 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. Toward the end of the first quarter of 2020, we saw a decline in prescribers' ability to diagnose new narcolepsy patients and a related decline in new patients starting on therapy. Although new Xyrem patient enrollments trended upward in the latter half of the second quarter of 2020, we continue to expect that delays in obtaining a narcolepsy diagnosis will have a negative impact on new Xyrem patient enrollments in future quarters. Given the long-term impact of the COVID-19 pandemic, we may also potentially see a negative impact on patients' ability to pay for Xyrem prescriptions. For Sunosi, the impact on demand is primarily related to the reduced ability of our field-based teams to interact with prescribers and patients' inability to meet with their 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.

In the second quarter of 2020, demand for Defitelio was impacted by a reduction in the number of hematopoietic stem cell transplants performed due to COVID-19 related impacts, including the reprioritization of healthcare resources and related delays, postponements or suspensions of certain medical procedures such as stem cell transplants. Demand for Vyxeos in the second quarter of 2020 was also impacted by a shift toward oral or less intensive outpatient AML treatments due to COVID-19, which is directly negatively impacting, or delaying, the use of Vyxeos, which prescribers are still primarily utilizing in inpatient settings. While we observed a recovery in demand for Defitelio and Vyxeos toward the end of the second quarter, we continue to expect that the ongoing impacts of the COVID-19 pandemic will have 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, and our sales force is actively engaging with target prescribers through live and virtual interactions.

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 Xywav to support the planned U.S. launch in the fourth quarter of 2020. However, the manufacturer of Erwinaze continues to have supply disruptions unrelated to the impact of the COVID-19 pandemic, and we are experiencing supply disruptions of Erwinaze globally and expect to continue to experience supply disruptions globally 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. We temporarily suspended two of our healthy volunteer clinical development programs, JZP-385 and JZP-324, in the interest of volunteer safety, and expect to restart these clinical trials in August 2020. 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 and our recent issuance of \$1.0 billion principal amount of 2026 Notes, we anticipate having sufficient liquidity to make planned investments in our business in support of our long-term growth strategy. However, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. 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 year, including with respect to our ability to successfully launch Zepzelca and Xywav.

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 investigator-sponsored trials, or ISTs, to evaluate the use of defibrotide in COVID-19 patients experiencing respiratory distress. Currently, two Phase 2 programs are in progress to evaluate the potential use of defibrotide in COVID-19 patients: an IST in Spain for the prevention and treatment of respiratory distress and cytokine release syndrome and a trial in Italy to evaluate the reduction in the rate of respiratory failure in patients with COVID-19 pneumonia.

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

Other Challenges, Risks and Trends Related to Our Business

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

As for other products and product candidates in our neuroscience therapeutic area, we obtained approval of Sunosi in the U.S. and EU, and most recently, Xywav in the U.S. Our future plans assume that Xywav, with its reduction in sodium from

Xyrem, absence of a sodium warning and multiple dosing options, will become the treatment of choice for physicians who have patients who can benefit from oxybate treatment, including current Xyrem patients and patients who previously were not prescribed Xyrem, including those patients for whom sodium content is a concern. If we are unable to successfully commercialize Sunosi or Xywav, or if sales of Sunosi and Xywav do not reach the levels we expect, our anticipated revenue from our neuroscience therapeutic area will be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to our 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 Erwinaze 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, our business, financial condition, results of operations and growth prospects would be materially adversely affected.

A key aspect of our growth strategy is our continued investment in our evolving and expanding research and development activities. If we are not successful in the clinical development of these or other product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. Failure to identify and acquire, in-license or develop additional products or product candidates, successfully manage the risks associated with integrating any products or product candidates into our portfolio or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing, could have a material adverse effect on our business, results of operations and financial condition.

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

Finally, business practices by pharmaceutical companies, including product formulation improvements, patent 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. Any of these risks and uncertainties could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, to the extent the COVID-19 pandemic 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 June 30,		Increase/ (Decrease)	Six Months Ended June 30,		Increase/ (Decrease)
	2020	2019		2020	2019	
Product sales, net	\$ 558,203	\$ 523,423	7 %	\$ 1,088,408	\$ 1,026,754	6 %
Royalties and contract revenues	4,233	10,710	(60)%	8,754	15,565	(44)%
Cost of product sales (excluding amortization of acquired developed technologies)	28,008	27,676	1 %	56,665	61,182	(7)%
Selling, general and administrative	191,406	176,014	9 %	399,806	343,961	16 %
Research and development	78,922	62,384	27 %	165,029	122,489	35 %
Intangible asset amortization	62,974	61,576	2 %	125,821	118,461	6 %
Impairment charge	—	—	N/A(1)	136,139	—	N/A(1)
Acquired in-process research and development	3,000	2,200	36 %	205,250	58,200	253 %
Interest expense, net	26,210	18,234	44 %	44,706	36,156	24 %
Foreign exchange loss	464	1,933	(76)%	1,596	2,544	(37)%
Income tax provision (benefit)	54,754	(78,650)	N/A(1)	3,467	(49,534)	N/A(1)
Equity in loss of investees	1,897	868	119 %	1,715	1,761	(3)%

(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 June 30,		Increase/ (Decrease)	Six Months Ended June 30,		Increase/ (Decrease)
	2020	2019		2020	2019	
Xyrem	446,808	413,212	8 %	854,683	781,529	9 %
Defitelio/defibrotide	42,714	46,055	(7)%	90,146	87,555	3 %
Erwinaze/Erwinase	32,683	27,622	18 %	70,415	88,521	(20)%
Vyxeos	26,568	31,362	(15)%	59,288	60,305	(2)%
Sunosi	8,578	—	N/A(1)	10,502	—	N/A(1)
Other	852	5,172	(84)%	3,374	8,844	(62)%
Product sales, net	558,203	523,423	7 %	1,088,408	1,026,754	6 %
Royalties and contract revenues	4,233	10,710	(60)%	8,754	15,565	(44)%
Total revenues	\$ 562,436	\$ 534,133	5 %	\$ 1,097,162	\$ 1,042,319	5 %

(1) Comparison to prior period not meaningful.

Product Sales, Net

Xyrem product sales increased in the three and six months ended June 30, 2020 compared to the same periods in 2019 primarily due to a higher average net 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 5% in the three and six months ended June 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 decreased in the three months ended June 30, 2020 compared to the same period in 2019 primarily due to lower sales volumes which were negatively impacted by the reduction in the number of hematopoietic stem cell transplants performed due to the COVID-19 pandemic as hospitals managed critical resources including intensive care beds. Defitelio/defibrotide product sales increased in the six months ended June 30, 2020 compared to the same period in 2019 primarily due to higher sales volumes. Erwinaze/Erwinase product sales increased in the three months ended June 30, 2020 compared to the same period in 2019 primarily due to the timing of availability of supply. Erwinaze/Erwinase product sales decreased in the six months ended June 30, 2020 compared to the same period in 2019 primarily due to limited availability of inventory from the manufacturer. Ongoing supply challenges continue to negatively impact the timing of and our ability to supply Erwinaze to the market. We are experiencing supply disruptions of Erwinaze globally and expect to continue to experience supply disruptions globally through the rest of the year. Vyxeos product sales decreased in the three and six months ended June 30, 2020 compared to the same periods in 2019 primarily driven by a decrease in sales volumes in the U.S. which were negatively impacted by recommendations from oncology organizations to treat patients with oral oncolytics when possible to avoid hospitalizations for high risk cancer patients and preserve intensive care beds for patients with COVID-19. Sunosi product sales were \$8.6 million and \$10.5 million in the three and six months ended June 30, 2020, respectively. Sunosi launched in the U.S. in July 2019 and the European rolling launch commenced in Germany in May 2020. We expect total product sales for 2020 will be higher than 2019 primarily due to growth in sales of Xyrem and Sunosi, as well as product sales of Zepzelca.

Royalties and Contract Revenues

Royalties and contract revenues decreased in the three and six months ended June 30, 2020 compared to the same periods in 2019 primarily due to lower milestone 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 months ended June 30, 2020 compared to the same period in 2019 primarily due to changes in product mix. Cost of product sales decreased in the six months ended June 30, 2020 compared to the same period in 2019 primarily due to changes in product mix. Gross margin as a percentage of net product sales was 95.0% and 94.8% for the three and six months ended June 30, 2020, respectively, compared to 94.7% and 94.0% 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 six months ended June 30, 2020 compared to the same periods in 2019 primarily due to increased investment in sales, marketing and launch activities related to our priority products and product candidates, as well as an increase in other expenses related to the expansion of our business. We expect selling, general and administrative expenses in 2020 to increase compared to 2019, primarily due to an increase in expenses related to the continuation of the commercial launch of Sunosi in the U.S. and in Europe, the commercial launch of Zepzelca in the U.S., and the planned commercial launch of 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Clinical studies and outside services	\$ 40,145	\$ 33,034	\$ 87,894	\$ 63,265
Personnel expenses	31,146	20,855	57,048	42,165
Other	7,631	8,495	20,087	17,059
Total	\$ 78,922	\$ 62,384	\$ 165,029	\$ 122,489

Research and development expenses increased by \$16.5 million and \$42.5 million in the three and six months ended June 30, 2020, respectively, compared to the same periods in 2019. Clinical studies and outside services costs increased by \$7.1 million and \$24.6 million in the three and six months ended June 30, 2020, respectively, compared to the same periods in 2019 primarily due to higher clinical trial costs primarily associated with JZP-458, and an increase in expenses related to our ongoing preclinical and clinical development programs and support of partner programs. Personnel expenses increased by \$10.3 million and \$14.9 million in the three and six months ended June 30, 2020, respectively, compared to the same periods in 2019 primarily due to increased headcount in support of our development programs.

In 2020 and beyond, we expect that our research and development expenses will continue to increase from previous levels, particularly as we prepare for anticipated regulatory submissions and data read-outs from clinical trials, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates. 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 in the three months ended June 30, 2020 was in line with the same period in 2019. Intangible asset amortization increased by \$7.4 million in the six months ended June 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. 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 six months ended June 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 six months ended June 30, 2020 primarily related to an upfront payment of \$200.0 million to Pharma Mar, S.A. in connection with our license agreement for Zepzelca. Acquired IPR&D expense in the six months ended June 30, 2019 primarily related to an upfront payment of \$56.0 million to Codiak in connection with a strategic collaboration agreement.

Interest Expense, Net

Interest expense, net increased by \$8.0 million and \$8.6 million in the three and six months ended June 30, 2020 compared to the same periods in 2019, primarily due to a loss on extinguishment of debt of \$4.5 million related to the repurchase of \$332.9 million principal amount of the 2021 Notes due to the write-off of unamortized debt issuance costs and debt discount and, to a lesser extent, lower interest income. 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 in June 2020.

Foreign Exchange Loss

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

Income Tax Provision (Benefit)

Our income tax provision was \$54.8 million and \$3.5 million in the three and six months ended June 30, 2020, respectively, compared to an income tax benefit of \$78.7 million and \$49.5 million for the same periods in 2019. The effective tax rates were 31.9% and (9.2)% in the three and six months ended June 30, 2020, respectively, compared to (42.7)% and (16.5)% for the same periods in 2019. The income tax benefit for the three and six months ended June 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 three and six months ended June 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 increase in the effective tax rate for the three months ended June 30, 2020 compared to the same period in 2019 was primarily due to the impact of the disallowance of certain interest deductions, and provision for a proposed settlement reached with the French tax authorities in respect of an ongoing tax audit, and the decrease in the effective tax rate for the six months ended June 30, 2020 compared to the same period in 2019 was primarily due to the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the PharmaMar transaction, partially offset by the impact of the disallowance of certain interest deductions and provision for the proposed settlement reached with the French tax authorities. The effective tax rate for the three months ended June 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 provision for the proposed settlement reached with the French tax authorities. The effective tax rate for the six months ended June 30, 2020 was lower than the Irish statutory rate of 12.5% primarily due to the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the PharmaMar transaction, partially offset by the impact of the disallowance of certain interest deductions and provision for the proposed settlement reached with the French tax authorities. We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

Equity in Earnings of Investees

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

Liquidity and Capital Resources

As of June 30, 2020, we had cash, cash equivalents and investments of \$1.7 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 \$601.0 million aggregate principal amount term loan, \$242.1 million principal amount of the 2021 Notes, \$575.0 million principal amount of our 1.50% exchangeable senior notes due 2024 and \$1.0 billion principal amount of the 2026 Notes. We generated cash flows from operations of \$455.5 million during the six months ended June 30, 2020, and we expect to continue to generate positive cash flows from operations during 2020.

In April 2020, in an abundance of caution and as a proactive measure, we drew down \$500.0 million under the revolving credit facility provided for under the credit agreement that we entered into in June 2015 and subsequently amended, which we refer to as 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.

We believe that our existing cash, cash equivalents and investments balances, cash we expect to generate from operations and funds available under our revolving credit facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses, as well as the other factors set forth in “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q under the headings “Risks Related to our Lead Products and Product Candidates” and “*To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.*” Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources, and we may not be able to generate sufficient cash to service our debt obligations which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue new operations or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital for corporate development transactions, to expand our operations or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. However, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital 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 June 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. In the six months ended June 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 June 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):

	Six Months Ended June 30,	
	2020	2019
Net cash provided by operating activities	\$ 455,488	\$ 351,100
Net cash provided by (used in) investing activities	(801,245)	163,414
Net cash provided by (used in) financing activities	494,851	(186,502)
Effect of exchange rates on cash and cash equivalents	(356)	105
Net increase in cash and cash equivalents	\$ 148,738	\$ 328,117

Operating activities

Net cash provided by operating activities increased by \$104.4 million in the six months ended June 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 six months ended June 30, 2019 and the timing of receipts from customers.

Investing activities

Net cash provided by (used in) investing activities decreased by \$964.7 million in the six months ended June 30, 2020 compared to the same period in 2019, primarily due to the following:

- \$744.5 million net increase in the acquisition of investments, primarily time deposits;
- \$147.1 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 six months ended June 30, 2020, compared to the same period in 2019 which included a payment of \$56.0 million under our strategic collaboration agreement with Codiak; and
- An increase in acquisition of intangible assets primarily related to the \$100.0 million milestone payment to PharmaMar on FDA approval of Zepzelca.

Financing activities

Net cash provided by (used in) financing activities increased by \$681.4 million in the six months ended June 30, 2020 compared to the same period in 2019, primarily due to:

- An increase of \$981.4 million in net proceeds from issuance of 2026 Notes, partially offset by \$332.9 million of payments for partial repurchase of 2021 Notes;
- A decrease of \$24.6 million in share repurchases; and
- An increase of \$8.1 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 six months ended June 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 \$1.0 billion 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. 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, in an abundance of caution and as a proactive measure, we drew down \$500.0 million under the revolving credit facility provided for under the amended credit agreement to increase our cash position and preserve financial flexibility 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 June 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 June 30, 2020 (in thousands):

Contractual Obligations (1)	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Term loan - principal	\$ 600,961	\$ 33,387	\$ 567,574	\$ —	\$ —
Term loan - interest (2)	31,093	14,490	16,603	—	—
Exchangeable Senior Notes - principal	1,817,112	—	242,112	575,000	1,000,000
Exchangeable Senior Notes - interest (3)	164,382	31,924	59,520	52,938	20,000
Revolving credit facility - commitment fee (4)	11,900	4,056	7,844	—	—
Commitment to equity method investees	9,600	7,000	2,600	—	—
Purchase and other obligations (5)	100,786	71,733	23,320	5,656	77
Operating lease obligations (6)	202,430	21,391	42,483	42,990	95,566
Total	\$ 2,938,264	\$ 183,981	\$ 962,056	\$ 676,584	\$ 1,115,643

(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. In December 2019, we entered into an exclusive license agreement with PharmaMar, for development and U.S. commercialization of Zepzelca. The agreement became effective in January 2020 and we made an upfront payment of \$200.0 million. In June 2020, we made a milestone payment of \$100.0 million to PharmaMar following FDA approval of Zepzelca. PharmaMar is also eligible to receive milestone payments totaling up to \$700.0 million based on regulatory and commercial milestones. PharmaMar is also eligible to receive incremental tiered royalties on future net sales of Zepzelca ranging from the high teens up to 30 percent. In January 2019, we entered into a strategic collaboration agreement with Codiak for an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize potential therapeutic candidates directed at five targets to be developed using Codiak's engEx™

precision engineering platform for exosome therapeutics. Codiak is eligible to receive up to \$20 million in preclinical development milestone payments. Codiak is also eligible to receive milestone payments totaling up to \$200 million per target based on investigational NDA acceptance, clinical and regulatory milestones, including approvals in the U.S., the EU and Japan, and certain sales milestones. Codiak is also eligible to receive tiered royalties on net sales of each approved product. In August 2019, we announced the acquisition of Cavion, for an upfront payment of \$52.5 million with the potential for additional payments of up to \$260.0 million upon the achievement of certain clinical, regulatory and commercial milestones, for a total potential consideration of \$312.5 million. In July 2019, we acquired a pan-RAF inhibitor program for the potential treatment of RAF and RAS mutant tumors from Redx. Redx is eligible to receive up to \$203 million in development, regulatory and commercial milestone payments from us, as well as incremental tiered royalties in mid-single digit percentage based on any future net sales. In 2014, we acquired worldwide development, manufacturing and commercial rights to Sunosi from Aerial (other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights). In January 2020, we received approval of Sunosi by the EC, triggering regulatory milestones of \$10.0 million and \$3.0 million to Aerial and SK, respectively. Aerial and SK are currently eligible to receive milestone payments up to an aggregate of \$165 million based on sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales of Sunosi. In July 2016, we entered into an agreement with Pfenex, which was subsequently amended in December 2017, that granted us worldwide rights to develop and commercialize multiple early-stage hematology product candidates and an option for us to negotiate a license for a recombinant pegaspargase product candidate with Pfenex. Under the amended agreement, Pfenex is eligible to receive future payments of up to \$163 million based on the achievement of development, regulatory and sales milestones. Potential future milestone payments to other third parties under other agreements could be up to an aggregate of \$290 million. These would become due and payable to other third parties upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones, the timing and likelihood of which are not known. We are also obligated under these agreements to pay royalties on net sales of certain products at specified rates, which royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.

- (2) Estimated interest for variable rate debt was calculated based on the interest rates in effect as of June 30, 2020. The interest rate for our term loan borrowing was 1.55% as of June 30, 2020. Interest that is fixed, associated with our interest rate swaps, is calculated based on the fixed interest swap rate as of June 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 June 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 June 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 six months ended June 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 June 30, 2020, the fair value of the 2026 Notes was estimated to be \$1 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 June 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 June 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 current business is substantially dependent on Xyrem[®] (sodium oxybate) oral solution, and our financial results are significantly influenced by sales of Xyrem. A significant decline in sales of Xyrem could cause us to reduce our operating expenses or seek to raise additional funds, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects, including on our ability to acquire, in-license or develop new products to grow our business. There is no guarantee that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties as discussed in greater detail below, including those related to the introduction of authorized generic and generic versions of sodium oxybate and/or new products for treatment of cataplexy and/or excessive daytime sleepiness, or EDS, in narcolepsy in the U.S. market, the current and potential impacts of the COVID-19 pandemic, including the current and expected future negative impact on demand for our products and the uncertainty with respect to our ability to meet commercial demand in the future, increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, challenges to our intellectual property around Xyrem, and continued acceptance of Xyrem by physicians and patients.

In July 2020, FDA approved our NDA for Xywav[™], an oxybate product that contains 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, for the treatment of cataplexy or EDS in narcolepsy patients seven years of age and older. Our ability to realize the anticipated benefits from our investment in Xywav is subject to a number of risks and uncertainties including obtaining and maintaining adequate coverage and reimbursement for Xywav; the introduction of new products in the U.S. market that compete with Xywav in the treatment of cataplexy and/or EDS in narcolepsy, including generic or authorized generic versions of sodium oxybate or new sodium oxybate products; and acceptance of Xywav by payors, physicians and patients.

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 Xywav and/or Sunosi, or if sales of Xywav and Sunosi do not reach the levels we expect, our anticipated revenue from our neuroscience therapeutic area will be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

While Xyrem 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 an NDA approval pathway under Section 505(b)(2) and referencing the safety and efficacy data for Xyrem. In April 2020, Avadel Pharmaceuticals plc, or Avadel, announced positive topline

results from its Phase 3 clinical trial of an extended-release formulation of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy and expects to announce top-line results in the second quarter of 2020. Xyrem may also face 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 that is expected to be submitted to FDA in the third quarter of 2020 pursuant to a complete response resubmission for approval of 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. In June and July 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 Xyrem REMS provide more extensive information about adverse events experienced by patients taking Xyrem, including deaths, than is generally available for other products that are not subject to similar REMS requirements. As required by FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to FDA and could result in FDA requiring changes to Xyrem labeling, including additional warnings or additional boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of Xyrem. As required by FDA, Xyrem's current labeling includes a boxed warning regarding the risk of central nervous system depression and misuse and abuse.

Any failure to demonstrate our substantial compliance with the REMS or any other applicable regulatory requirements to the satisfaction of FDA or another regulatory authority could result in such regulatory authorities taking actions in the future which could have a material adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth prospects.

While 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 recently announced 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. In addition, 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 is resulting in a decrease in demand for Defitelio. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product would be negatively affected and our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, because VOD is an ultra-rare disease, we have experienced inter-quarter variability in our Defitelio sales, which makes Defitelio sales difficult to predict from period to period. As a result, Defitelio sales results or trends in any period may not necessarily be indicative of future performance.

Erwinaze

Erwinaze® (asparaginase *Erwinia chrysanthemi*), which is approved to treat a limited population of patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to *E. coli*-derived asparaginase, is licensed from, and manufactured by, a single source, Porton Biopharma Limited, or PBL, a company that is wholly owned by the UK Department of Health and Social Care. Our license and supply agreement with PBL, which includes an exclusive right to market, sell or distribute Erwinaze, an exclusive license to Erwinaze trademarks, and a non-exclusive license to PBL's manufacturing know-how, will expire on December 31, 2020. In April 2020, PBL announced that it had entered into an agreement with a new

partner to commercialize and distribute Erwinaze after our license and supply agreement expires. As a result, our ability to generate revenue through Erwinaze sales in the future will be adversely impacted. Under our agreement with PBL, we have the right to sell certain Erwinaze inventory for a post-termination sales period of 12 months and retain ownership of certain data, know-how and other property interests, including the biologics license application, or BLA, for Erwinaze in the U.S. and marketing authorizations for Erwinaze 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, our business, financial condition, results of operations and growth prospects would be materially adversely affected.

In addition, a continuing and significant challenge to maintaining sales of Erwinaze and a barrier to increasing sales is PBL's inability to consistently supply product that meets specifications in quantities that are adequate to meet market demand. Other challenges facing Erwinaze include the limited population of patients with ALL, and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population; the development and/or approval of new asparaginase treatments or treatment protocols for ALL that may not include asparaginase-containing regimens and prescribers' use of alternate methods to address hypersensitivity reactions; difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements; and potential competition from future biosimilar products.

Vyxeos

Our ability to realize the anticipated benefits from our investment in Vyxeos[®] (daunorubicin and cytarabine) liposome for injection by successfully and sustainably growing sales is subject to a number of risks and uncertainties, including our ability to differentiate Vyxeos from other liposomal chemotherapies and generically available chemotherapy combinations with which physicians and treatment centers are more familiar; acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries; the increasing complexity of the acute myeloid leukemia, or AML, landscape requiring changes in patient identification and treatment selection, including diagnostic tests and monitoring that clinicians may find challenging to incorporate; the use of new and novel compounds in AML that are either used off-label or are only approved for use in combination with other agents and that have not been tested in combination with Vyxeos; the increasing use of venetoclax, bolstered by the recent announcement of Phase 3 clinical data supporting the use of venetoclax in AML treatment; the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos, particularly as a result of the shift of healthcare resources toward less intensive outpatient AML treatments in the U.S. in light of 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. 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 launch and commercialize Zepzelca in the U.S.; 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.

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. 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. For example, we anticipate that the U.S. Congress, state legislatures, and regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on government-funded reimbursement for drugs (including Medicare, Medicaid) and commercial health plans, new or increased requirements to pay prescription drug rebates and penalties to government health care programs, and additional pharmaceutical cost transparency bills that aim to require drug companies to justify their prices through required disclosures. Additionally, proposals made part of proposed legislation and executive rule-making, including multiple U.S. executive orders released on July 24, 2020, seek to utilize an “international pricing index” as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B to more closely align with international drug prices. If the U.S. were to move to such a pricing system that were to apply to any of our products, our revenues from U.S. sales of such products could decrease.

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

There is also ongoing activity related to the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, together, the Healthcare Reform Act. The Healthcare Reform Act has substantially changed the way healthcare is financed by both governmental and private insurers. These changes have impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment-for-performance initiatives. Certain provisions of the Healthcare Reform Act have been subject to judicial challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. We expect that the Healthcare Reform Act and its implementation, efforts to repeal or replace, or invalidate, the Healthcare Reform Act or portions thereof and other

healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our products.

If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products, including Xyrem, may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. We have periodically increased the price of Xyrem, most recently in January 2020, and there is no guarantee that we will make similar price adjustments in the future or that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes and revenues. 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, 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 pharmaceutical products in some countries could contribute to similar downward trends elsewhere.

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

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

- the clinical indications for which a product is approved and any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and its diagnosis;
- the severity of side effects and other risks in relation to the benefits of our products;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand, particularly with respect to Erwinaze;
- physicians’ decisions relating to treatment practices based on availability of product, particularly with respect to Erwinaze;
- perceived clinical superiority and 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;
- 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 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 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 to continue to experience supply disruptions globally in 2020. In addition, FDA has issued a warning letter and FDA Forms 483 to PBL citing, among other things, significant violations of cGMP for finished pharmaceuticals and significant deviations from cGMP for APIs. We cannot predict whether the required remediation activities by PBL in connection with its prior warning letter and FDA Forms 483 will further strain PBL's manufacturing capacity or otherwise further adversely affect

Erwinaze supply. We also cannot predict whether a delay in the ability of FDA to conduct inspections as a result of COVID-19 impacts could result in a delay in obtaining regulatory discretion required for release of Erwinaze supply in the U.S.

As capacity constraints and supply disruptions continue, whether as a result of continued quality or manufacturing challenges at PBL, the 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 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 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.

Even if we receive approval of a product, regulatory authorities may impose significant labeling restrictions or requirements, including limitations on the dosing of the product, requirements around the naming or strength of a product, restrictions on indicated uses for which we may market the product, the imposition of a boxed warning or other warnings and precautions, and/or the requirement for a REMS to ensure that the benefits of the drug outweigh the risks. FDA requires a REMS and a boxed warning for Xyrem and 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 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. or EU, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of and revenues from our products could be materially adversely affected.

We are pursuing activities related to the development of 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, 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. We temporarily suspended two of our healthy volunteer clinical development programs, JZP-385 and JZP-324, in the interest of volunteer safety, and expect to restart these clinical trials in August 2020. 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 and adversely impact our clinical trial operations.

Risks Related to Our Intellectual Property

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

Our commercial success depends in part on obtaining, maintaining and defending intellectual property protection for our products and product candidates, including protection of their use and methods of manufacturing and distribution. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents or have adequately protected trade secrets that cover these activities.

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

- our patent applications, or those of our licensors or partners, may not result in issued patents;
- others may independently develop similar or therapeutically equivalent products without infringing our patents, or those of our licensors, such as products that are not covered by the claims of our patents, or for which we do not have adequate exclusive rights under our license agreements;
- our issued patents, or those of our licensors or partners, may be held invalid or unenforceable as a result of legal challenges by third parties or may be vulnerable to legal challenges as a result of changes in applicable law;
- we or our licensors or partners might not have been the first to invent or file, as appropriate, subject matters covered by our issued patents or pending patent applications or those of our licensors or partners;
- competitors may manufacture products in countries where we have not applied for patent protection or that have a different scope of patent protection or that do not respect our patents; or

- others may be issued patents that prevent the sale of our products or require licensing and the payment of significant fees or royalties.

Patent enforcement generally must be sought on a country-by-country basis, and issues of patent validity and infringement may be judged differently in different countries. For example, in the EU, approval of a generic pharmaceutical product can occur independently of whether the reference brand product is covered by patents, and enforcement of such patents generally must await approval and an indication that the generic product is being offered for sale.

Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property portfolio. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, and potentially invalidated or held unenforceable, including through patent litigation or through patent office procedures that permit challenges to patent validity. Patents can also be circumvented, potentially including by FDA approval of an ANDA or Section 505(b)(2) application that avoids infringement of our intellectual property.

We have settled patent litigation with nine companies seeking to introduce generic versions of Xyrem in the U.S. by granting those companies licenses to launch their generic products (and in certain cases, an authorized generic version of Xyrem) in advance of the expiration of the last of our patents. Notwithstanding our Xyrem patents and settlement agreements, additional third parties may also attempt to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy that design around our patents or assert that our patents are invalid or otherwise unenforceable. Such third parties could launch a generic or 505(b)(2) product referencing Xyrem before the dates provided in our patents or settlement agreements. For example, we have several method of use patents listed in FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book, that expire in 2033 that cover treatment methods included in the Xyrem label related to a drug-drug interaction, or DDI, with divalproex sodium. Although FDA has stated, in granting a Citizen Petition we submitted in 2016, that it would not approve any sodium oxybate ANDA referencing Xyrem that does not include the portions of the currently approved Xyrem label related to the DDI patents, we cannot predict whether a future ANDA filer, or a company that files a Section 505(b)(2) application for a drug referencing Xyrem, may pursue regulatory strategies to avoid infringing our DDI patents notwithstanding FDA's response to the Citizen Petition, or whether any such strategy would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of these patents or will otherwise obtain a judicial determination that a generic or other sodium oxybate product, its package insert or the generic sodium oxybate REMS or another separate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents a future ANDA filer or other company introducing a different sodium oxybate product from marketing its product, or instead require that party to pay damages in the form of lost profits or a reasonable royalty.

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

We also currently rely on trade secret protection for several of our products, including Erwinaze and Defitelio. Trade secret protection does not protect information or inventions if another party develops that information or invention independently, and establishing that a competitor developed a product through trade secret misappropriation rather than through legitimate means may be difficult to prove. Trade secret protection also requires that information be secret and subject to reasonable efforts to maintain secrecy, and this requirement may come into conflict with requirements to provide information to employees, consultants, business partners, and regulatory bodies. We seek to protect our trade secrets and other unpatented proprietary information in part through confidentiality and invention agreements with our employees, consultants, advisors and partners. Nevertheless, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. Moreover, if a dispute arises with our employees, consultants, advisors or partners over the ownership of rights to inventions, including jointly developed intellectual property, we could lose patent protection or the confidentiality of our proprietary information, and possibly also lose the ability to pursue the development of certain new products or product candidates.

We have incurred and may in the future incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products.

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. If we choose to go to court to stop a third party from infringing our patents, our licensed patents or our partners' patents, that third party has the right to ask the court or an administrative agency to rule that these patents are invalid and/or should not be enforced. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, the inter partes review process, 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. In June and July 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 and revenues from our approved products, our supply chain, regulatory, clinical development and corporate development activities. With respect to our commercialization activities, the evolving effects of the COVID-19 pandemic are having a negative impact on demand, 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. Toward the end of the first quarter of 2020, we saw a decline in prescribers' ability to diagnose new narcolepsy patients and a related decline in new patients starting on therapy. Although new Xyrem patient enrollments trended upward in the latter half of the second quarter of 2020, we continue to expect that delays in obtaining a narcolepsy diagnosis will have a negative impact on new Xyrem patient enrollments in future quarters. Given the long-term impact of the COVID-19 pandemic, we may also potentially see a negative impact on patients' ability to pay for Xyrem prescriptions. For Sunosi, the impact on demand is primarily related to the reduced ability of our field-based teams to interact with prescribers and patients' inability to meet with their 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 the second quarter of 2020, demand for Defitelio was impacted by a reduction in the number of hematopoietic stem cell transplants performed due to COVID-19 related impacts, including the reprioritization of healthcare resources and related delays, postponements or suspensions of certain medical procedures such as stem cell transplants. Demand for Vyxeos in the second quarter of 2020 was also impacted by a shift toward less intensive outpatient AML treatments due to COVID-19, which is directly negatively impacting, or delaying, the use of Vyxeos, which prescribers are still primarily utilizing in inpatient settings. While we observed a recovery in demand for Defitelio and Vyxeos toward the end of the second quarter, we continue to expect that the ongoing impacts of the COVID-19 pandemic will have a negative impact on utilization of Defitelio and Vyxeos. In the first month of Zepzelca's launch, we experienced relatively strong initial physician reception and uptake of Zepzelca, in spite of the reduced ability of our field-based teams to interact with healthcare providers due to COVID-19.

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 already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital or an impact on liquidity, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, a recession or market correction resulting from the impact of 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 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 year, including with respect to our ability to successfully launch Zepzelca.

and Xywav. 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 could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, there is a risk that the scope of a marketing authorization for a medicinal product granted by the EC or by the competent authorities of EU member states will not encompass the UK. In these circumstances, a separate 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. 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 and the competent authorities of the EU member states on behalf of the EMA, also periodically inspect our records related to safety reporting. The EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that the marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended or revoked. Failure to adequately and promptly correct the observation(s) can result in further regulatory enforcement action, which could include the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

Erwinaze, defibrotide and Vyxeos are available on a named patient basis or through a compassionate use process in many countries where they are not commercially available. If any such country's regulatory authorities determine that we are promoting such products without proper authorization, we could be found to be in violation of pharmaceutical advertising laws or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties. Any failure to maintain revenues from sales of Erwinaze, defibrotide and/or Vyxeos on a named patient basis and/or to generate revenues from commercial sales of these products exceeding historical sales on a named patient basis could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

FDA, the competent authorities of the EU member states and other governmental authorities require advertising and promotional materials to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. Regulatory authorities actively investigate allegations of off-label promotion in order to enforce regulations prohibiting these types of activities. A determination that we have promoted an approved product for off-label uses could subject us to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties, other sanctions and imprisonment. Even if we are not determined to have engaged in off-label promotion, an allegation that we have engaged in such activities could have a significant impact on our sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. Failure to maintain a comprehensive and effective compliance program, and to integrate the operations of acquired businesses into a combined comprehensive and effective compliance program on a timely basis, could subject us to a range of regulatory actions and/or civil or criminal penalties that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products.

Other Regulatory Authorities

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

We are subject to numerous fraud and abuse laws and regulations globally and our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws and regulations. These laws are described in "Business—Government Regulation" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2019. While we maintain a comprehensive compliance program to try to ensure that our practices and the activities of our third-party contractors and employees fall within the scope of available statutory exceptions and regulatory safe harbors 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, 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 data protection and privacy laws and regulations governing the processing of personal data. 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, 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, the importing country's level of protection must be adequate. If the level of protection in the U.S. or any other importing country is called into question under the Standard Contractual Clauses, this could further impact our ability to transfer data outside of the EU.

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 June 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**

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our “affiliated purchasers” as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934, as amended, during each fiscal month during the three-month period ended June 30, 2020:

	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (3)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (4)
April 1 - April 30, 2020	52,500	\$ 105.66	52,500	\$ 433,156,902
May 1 - May 31, 2020	17,500	\$ 110.72	17,500	\$ 431,219,240
June 1 - June 30, 2020	—	\$ —	—	\$ 431,219,240
Total	70,000	\$ —	70,000	

- (1) This table does not include ordinary shares that we withheld in order to satisfy minimum tax withholding requirements in connection with the vesting and release of restricted stock units.
- (2) Average price paid per ordinary share includes brokerage commissions.
- (3) The ordinary shares reported in this column above were purchased pursuant to our publicly announced share repurchase program. In November 2016, we announced that our board of directors authorized the use of up to \$300 million to repurchase our ordinary shares. In November 2018, December 2018, and October 2019, our board of directors increased the existing share repurchase program authorization by \$320.0 million, \$400.0 million, and \$500.0 million respectively thereby increasing the total amount authorized for repurchase to \$1.5 billion.
- (4) The dollar amount shown represents, as of the end of each fiscal month, the approximate dollar value of ordinary shares that may yet be purchased under our publicly announced share repurchase program, exclusive of any brokerage commissions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under our credit agreement, corporate and regulatory requirements and market conditions, and may be modified, suspended or otherwise discontinued at any time without prior notice.

Item 5. Other Information**Results of Matters Presented at the 2020 Annual General Meeting of Shareholders**

On July 30, 2020, we held our 2020 annual general meeting of shareholders, or the annual meeting, at our corporate headquarters in Dublin, Ireland. At the annual meeting, our shareholders voted on three proposals, each of which is described in more detail in our definitive proxy statement on Schedule 14A as filed with the U.S. Securities and Exchange Commission on June 12, 2020, or the Proxy Statement. The results of the matters presented at the annual meeting, based on the presence in person or by proxy of holders of 48,172,091 of the 55,346,861 ordinary shares entitled to vote, are described below.

Proposal 1

Proposal 1 was to elect by separate resolutions each of the four nominees for director named below to hold office until our 2023 annual general meeting of shareholders. Each of the four nominees for director was elected as follows:

Director Nominees	For	Against	Abstain	Broker Non-Votes
Bruce C. Cozadd	41,147,508	4,233,454	343,787	2,447,342
Heather Ann McSharry	43,716,632	1,988,273	19,844	2,447,342
Anne O’Riordan	45,123,421	582,111	19,217	2,447,342
Rick E Winningham	43,477,704	2,221,356	25,689	2,447,342

Proposal 2

Proposal 2 was to ratify, on a non-binding advisory basis, the appointment of KPMG, Dublin as the independent auditors of the company for the fiscal year ending December 31, 2020 and to authorize, in a binding vote, the board of directors, acting through the audit committee, to determine the auditors’ remuneration. This proposal was approved as follows:

For	Against	Abstain	Broker Non-Votes
47,258,687	900,811	12,593	—

Proposal 3

Proposal 3 was to approve, on an advisory basis, the compensation of our named executive officers as disclosed in the Proxy Statement. This proposal was approved as follows:

For	Against	Abstain	Broker Non-Votes
40,033,236	5,669,898	21,615	2,447,342

Proposal 4

Proposal 4 was to approve an amendment and restatement of our Amended and Restated 2007 Non-Employee Directors Stock Award Plan, as disclosed in the Proxy Statement. This proposal was approved as follows:

For	Against	Abstain	Broker Non-Votes
27,736,377	17,972,113	16,259	2,447,342

Proposal 5

Proposal 5 was to approve a capital reduction and creation of distributable reserves under Irish Law, as disclosed in the Proxy Statement. This proposal was approved as follows:

For	Against	Abstain	Broker Non-Votes
48,004,256	96,664	71,171	—

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).

[Table of Contents](#)

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+	Offer Letter, dated as of May 2, 2020, by and between Jazz Pharmaceuticals, Inc. and Kim Sablich.
10.2†	Pharmacy Master Services Agreement, dated as of July 1, 2020, by and between Jazz Pharmaceuticals, Inc. and Express Scripts Specialty Distribution Services, Inc.
10.3+	Amended and Restated 2007 Non-Employee Directors Stock Award Plan (approved July 30, 2020).
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: August 4, 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 Letterhead]

April 25, 2020

Kim Sablich
[address on file]

Re: Offer of employment with Jazz Pharmaceuticals

Dear Kim,

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

1. Position, Duties and Responsibilities. Your initial assignment will be as Executive Vice President, General Manager North America (EVP, GM North America), reporting to me. This offer is for a full time position, based in Jazz Pharmaceuticals’ offices in Palo Alto, California. In this position, you will be a member of the Executive Committee. This position will require domestic and international business travel from time to time. As part of your employment relationship, you agree to comply with Jazz Pharmaceuticals’ policies and procedures in effect from time to time during your employment.

2. Base Salary, Annual Bonus, Signing Bonus. Your initial annual base salary rate will be \$550,000, less all applicable deductions and withholdings and payable in accordance with Jazz Pharmaceuticals’ customary payroll practices. As an exempt employee, you will be paid on a salaried basis and you will be expected to work the number of hours required to do your job well and you are not eligible for overtime compensation. Salary is subject to periodic review and adjustment by Jazz Pharmaceuticals, in accordance with its normal practices; we have a Company- wide performance review process that takes place early in each calendar year.

You will be eligible for consideration of an annual bonus, and in this position, your annual target bonus will be 55%. The amount of your bonus will be based on the Company’s level of achievement of its annual objectives, and on your level of achievement of your objectives. Bonuses are not guaranteed, and whether there will be a bonus in any year, and the amount of any bonus, is within the discretion of the Board of Directors of Jazz Pharmaceuticals plc. Your bonus for 2020 will be prorated due to your partial year of employment.

In addition, Jazz Pharmaceuticals will pay you a signing bonus in the total amount of \$300,000, less all applicable deductions and withholdings, paid to you in two equal installments. The first payment of \$150,000 is payable on the first regular pay date occurring 30 days after your employment start date, and the second payment of \$150,000 is payable on the first regular pay date occurring six (6) months after your employment start date, subject to your continued employment in good standing with Jazz Pharmaceuticals through each applicable date. You will be required to repay the signing bonus in full if you resign from your employment with Jazz Pharmaceuticals

within one year of your employment start date; in such case, you will be expected to repay the full amount of the signing bonus on your last day of employment or within 30 days thereafter.

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

4. Equity Awards. Your offer includes a grant of options to purchase 42,000 Jazz Pharmaceuticals plc ordinary shares and a grant of 16,800 restricted stock units ("RSUs") giving you a right to receive Jazz Pharmaceuticals plc ordinary shares at a future date, subject to approval by the Compensation Committee, the terms and conditions of the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan, and the terms and conditions of the applicable award agreements, which will be provided to you as soon as practicable after the grant date. Subject to your continued employment on each vesting date, the options will vest 1/4th on the first annual anniversary of your start date and 1/48th of the total granted per month thereafter, and the RSUs will vest 1/4th annually over four years. The options will have an exercise price that equals the fair market value of Jazz Pharmaceuticals plc ordinary shares on the date of grant. The RSUs will have no exercise price. The options and RSUs will be granted on the second trading day following the filing date of the Company's next quarterly or annual report filed with the U.S. Securities and Exchange Commission following your start date in accordance with the Company's Equity Incentive Grant Policy.

5. Confidential Information and Inventions Agreement, Outside Employment. To enable Jazz Pharmaceuticals to safeguard its proprietary and confidential information, it is a condition of employment that you sign and comply with Jazz Pharmaceuticals' standard form of "Employee Confidential Information and Inventions Agreement." We understand that you are likely to have signed similar agreements with prior employers, and wish to impress upon you that Jazz Pharmaceuticals does not want to receive the confidential or proprietary information of others, and does not want you to use such information in the course of your employment with us, and Jazz Pharmaceuticals will support you in respecting your lawful obligations to prior employers. By accepting this offer, you are representing to Jazz Pharmaceuticals that your performance of your duties will not violate any agreements you may have with, or trade secrets of, any third parties. You agree that, during your employment with Jazz Pharmaceuticals, you will not engage in any business activity that competes with Jazz Pharmaceuticals, and you will notify your manager if you are considering accepting outside work, including self-employment, consulting arrangements, or any roles on any corporate Boards of Directors.

6. Code of Conduct. Jazz Pharmaceuticals is committed to integrity and the pursuit of excellence in all we do. We fulfill these commitments while upholding a high level of ethical conduct. The Code of Conduct is one element of Jazz Pharmaceuticals' efforts to ensure lawful and ethical conduct by the Company and its subsidiaries and their employees, officers and directors. It is a condition of employment that you read, agree to and sign Jazz Pharmaceuticals' Code of Conduct in the first week of employment. If you have questions about the Code of

April 25, 2020
Kim Sablich

Conduct, please let Human Resources know and we will ensure that you receive answers to your inquiries as quickly as possible.

7. At-Will Employment Status. Should you decide to accept our offer, you will be an “at-will” employee of Jazz Pharmaceuticals. This means that either you or Jazz Pharmaceuticals may terminate the employment relationship at any time, with or without cause, and with or without advance notice. Due to your at-will employment status, Jazz Pharmaceuticals also retains the discretion to modify the terms and conditions of your employment, including but not limited to your salary, incentive compensation and benefits, as well as your job title, location, duties, responsibilities, assignments and reporting relationships. Participation in any benefit, compensation or bonus program does not change the nature of the employment relationship, which remains “at-will”. Your at-will employment status can only be changed in a writing signed by you and the Chief Executive Officer of Jazz Pharmaceuticals.

8. Authorization To Work. Federal government regulations require that all employees present documentation verifying their identity and demonstrating that they are authorized to work in the United States. Your employment is contingent on your ability to prove your identity and authorization to work in the United States, and your compliance with the government’s employment verification requirements.

9. Offer Contingencies. This offer is contingent upon satisfactory completion (as determined by the Company) of your background and reference checks, including but not limited to verification of previous employment record, academic achievement and criminal background. Accordingly, we strongly suggest that you not resign from your current employment or make any other arrangements that you would not otherwise make until we advise you that the background and reference checks have been completed to our satisfaction.

10. Complete Offer and Agreement. This letter, including the Employee Confidential Information and Inventions Agreement referenced herein, contains our complete understanding and agreement regarding the terms of your employment with Jazz Pharmaceuticals, and it is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. There are no other, different or prior agreements or understandings on this or related subjects.

11. Start Date, Acceptance of Offer. Your start date will be mutually agreed between you and Jazz Pharmaceuticals. To accept our offer of employment, please sign the enclosed copy of this letter in the space indicated below, and then return the completed letter to me by the close of business on Friday, May 1, 2020. If we do not receive the fully signed letter back from you by this date, this offer of employment will terminate.

April 25, 2020
Kim Sablich

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

If you have any questions about this letter, please let me know or feel free to contact Heidi Manna, our Chief Human Resources Officer.

Sincerely,

/s/ Dan Swisher

Daniel Swisher
President & Chief Operating Officer

ACCEPTANCE OF EMPLOYMENT OFFER:

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

/s/ Kim Sablich

Kim Sablich

Date: 02-May-2020

[***] = CERTAIN PORTIONS OF THIS AGREEMENT HAVE BEEN OMITTED BECAUSE THE OMITTED PORTIONS ARE BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

CONFIDENTIAL

Pharmacy Master Services Agreement

This Pharmacy Services Agreement (the “Agreement”) is made effective as of 1 July 2020 (the “Effective Date”) by and between **Jazz Pharmaceuticals, Inc.** with a principal place of business at 3170 Porter Drive, Palo Alto, CA 94304 (“Jazz Pharmaceuticals”) and **Express Scripts Specialty Distribution Services, Inc.** with a principal place of business at One Express Way, St. Louis, MO 63121 (“ESSDS”). Jazz Pharmaceuticals and ESSDS may be referred to herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, Jazz Pharmaceuticals and ESSDS are parties to that certain Master Services Agreement, dated as of July 1, 2017, as amended, (the “Prior Master Services Agreement”) through which ESSDS provides dispensing, distribution, and other services for the Product (as defined below);

WHEREAS, the Parties desire to terminate the Prior Master Services Agreement and enter into a new agreement through which ESSDS will continue to provide certain services performed under the Prior Master Services Agreement, and undertake certain additional services associated herewith; and

WHEREAS, ESSDS has experience in providing the services desired by Jazz Pharmaceuticals and is willing to provide such services under the terms set forth in this Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants, representations and warranties set forth in this Agreement, the Parties agree as follows:

ARTICLE I

DEFINITIONS

As used in this Agreement, each of the following terms (and the plural or singular thereof, when appropriate) shall have the meaning set forth herein:

- 1.1 “Adverse Drug Experience” shall have the meaning assigned to it in 21 CFR 310.305 and 21 CFR 314.80, as such provision may be amended from time to time.
- 1.2 “Affiliate” of an entity shall mean any person or entity controlling, controlled by, or under common control with such entity for so long as such control exists. As used herein, “control” means ownership, directly or indirectly, of at least fifty percent (50%) of the common stock or voting ownership interests of the entity in question.

- 1.3“Applicable Laws” shall mean all federal, state, and local laws and governmental agency regulations and requirements applicable to the Services, including without limitation HIPAA, Medicare and Medicaid laws under Title XVIII and XIX of the Social Security Act, and relevant State and Federal pharmacy licensure requirements and pharmacy regulations.
- 1.4“Average Daily Sales” shall mean the average number of commercial bottles of the Product sold per day over the previous six (6) months, excluding all sales of Product (i) for dispensing to VA, and (ii) to Puerto Rico.
- 1.5“Bridge Benefit” shall mean the Jazz Pharmaceuticals’ sponsored program that provides Product at no cost to eligible patients who are at risk of an interruption in therapy due to a change in the their insurance circumstances.
- 1.6“Certified Pharmacy” shall mean the facility or facilities licensed and operated by ESSDS in compliance with the REMS Program and utilized by ESSDS in connection with the performance of this Agreement.
- 1.7“Confidential Information” shall have the meaning assigned to it in Section 8.2.
- 1.8“Data” shall mean the data specified in a Work Order, including but not limited to physician and patient data and required data elements for the REMS Program Central Database, and such other data as the Parties agree shall be provided by ESSDS to Jazz Pharmaceuticals under this Agreement.
- 1.9“DEA” shall mean the United States Drug Enforcement Administration, or any successor thereto.
- 1.10“Deliverables” shall mean those items to be delivered to Jazz Pharmaceuticals by ESSDS hereunder and as may be specified in a Work Order.
- 1.11“FDA” shall mean the United States Food and Drug Administration or any successor thereto.
- 1.12“Full Time Employee” or “FTE” shall mean a full time ESSDS employee working a forty (40) hour week who is dedicated exclusively to performing Pharmacy Services pursuant to the Agreement or any applicable Work Order.
- 1.13“HIPAA” means the Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations promulgated pursuant thereto in the United States Code of Federal Regulations (45 CFR Parts 160 and 164).
- 1.14“Information Technology” shall have the meaning assigned to it in Section 8.8 herein.

- 1.15“Inspection” shall have the meaning assigned to it in Section 5.2 herein
- 1.16“Intellectual Property” means any and all patents, trade secrets, inventions, know-how, copyrights, trademarks, service marks and trade dress, applications for the same, and registrations and applications for registration or renewals thereof in the United States and all other nations throughout the world, including without limitation all derivative works, renewals, extensions, reversions or restorations associated with such copyrights, now or hereafter provided by applicable law, regardless of the medium of fixation or means of expression.
- 1.17“Non-PAP Order” shall mean each shipment of Product by ESSDS to any Non-PAP Patient in accordance with this Agreement.
- 1.18“Non-PAP Patient” shall mean any Patient other than a PAP Patient.
- 1.19“Patient Assistance Program” or “PAP” shall mean the Jazz Pharmaceuticals' sponsored program that provides Product at no cost to eligible patients. Jazz Pharmaceuticals has sole discretion over the eligibility criteria and operation of the PAP. “PAP Patient” shall mean a Patient who has been approved as eligible to participate in the PAP.
- 1.20“PAP Order” shall mean each shipment of Product by ESSDS to any PAP Patient in accordance with this Agreement.
- 1.21“Patient” shall mean an individual who has been prescribed the Product.
- 1.22“Patient Data” shall include data about a Patient including information about a Patient’s health, medical insurance claims, and payment information obtained from the Patient or the Patient’s prescribing physician.
- 1.23“Pharmacy Services” shall have the meaning assigned to it in Section 2.1 herein.
- 1.24“Physician Confidential Information” shall mean information pertaining to a physician that is protected from use or disclosure pursuant to applicable law.
- 1.25“Product” shall mean Xyrem[®] (sodium oxybate) oral solution and dosing kit, and/or the branded version of an oxybate formulation, if approved, filed under NDA 021196.
- 1.26“Product Complaint” shall mean notification relating to product quality, purity, identity, potency, packaging, tampering, and/or quality aspects of the Product.
- 1.27“Records” shall have the meaning assigned to it in Section 7.1 herein.

- 1.28“REMS Documents” shall mean the approved XYREM REMS Documents, including both the XYREM REMS Document and the XYREM REMS Supporting Document, as well as any modifications or successor documents thereto as approved by the FDA.
- 1.29“REMS Pharmacy Services” shall have the meaning assigned to it in Section 2.1 herein.
- 1.30“REMS Program” shall mean the XYREM REMS Program, as approved by the FDA, or any successor entity thereto as approved by FDA, including successor entities including additional oxybate formulations, and as described in the REMS Documents.
- 1.31“REMS Program Items” shall mean materials required in connection with the performance of REMS Pharmacy Services by ESSDS hereunder, including, but not limited to, REMS Program enrollment forms and materials to be distributed to prescribers and patients. REMS Program Items shall not include any Product.
- 1.32“Services” shall mean the Pharmacy Services and REMS Pharmacy Services collectively, as defined in Section 2.1.
- 1.33“Service Level Agreements” or “SLAs” shall mean the service levels required for certain Services in order to support the Product, and are defined in Exhibit D.
- 1.34“SOPs” shall mean the written standard operating procedures of ESSDS, as of the Effective Date, or any others mutually agreed to be the Parties after the Effective Date, which describe the REMS Program-specific operation processes of ESSDS.
- 1.35“Territory” shall mean the United States of America, including its territories where ESSDS is allowed to legally distribute and ship the Product.
- 1.36“Trademarks” shall mean the Jazz Pharmaceuticals trademarks set forth in Exhibit B.
- 1.37“Veteran’s Administration” or “VA” shall mean the U.S. Department of Veteran’s Affairs, which provides a prescription benefit to VA healthcare system enrollees.
- 1.38“VA FSS” shall mean the Veteran’s Administration Federal Supply Schedule pricing contract provided to Jazz Pharmaceuticals for the Product.
- 1.39“Voucher Program Services” shall mean those voucher program services set forth in any applicable Work Order.
- 1.40“WAC” shall mean the current wholesale acquisition cost of Product as provided by Jazz Pharmaceuticals. WAC does not include discounts, rebates or chargebacks. WAC may not be the actual acquisition cost.
- 1.41“Work Order” shall have the meaning assigned to it in Section 2.1.

1.42 “Work Instructions” or “WIs” shall mean written work instructions of ESSDS, as of the Effective Date, or any others mutually agreed to by the Parties after the Effective Date, which provide detailed descriptions of the performance of certain tasks at ESSDS specifically required for Product.

ARTICLE II

PHARMACY AND REMS PHARMACY SERVICES

2.1 **Services.** During the term of the Agreement, all commercial, non-clinical trial Product sold by Jazz Pharmaceuticals, or made available through the PAP, in the Territory will be dispensed exclusively through ESSDS pursuant to the terms of this Agreement. ESSDS agrees to provide those pharmacy and REMS services described in this Agreement and written Work Orders hereunder (the “Pharmacy Services”), including but not limited to pharmacy dispensing services, safety and support services, ancillary supply services, certain education services, and data reporting.

During the term of the Agreement, ESSDS agrees to provide other REMS services described in this Agreement and written Work Orders hereunder (the “REMS Pharmacy Services”), including but not limited to activities directed towards ensuring Jazz Pharmaceuticals’ compliance with the requirements of the REMS Program.

The Pharmacy and REMS Pharmacy Services (collectively, the “Services”) to be provided as of the Effective Date are described in written Work Orders hereunder. These Services may be amended from time to time through the addition of a Work Order. Each Work Order will be numbered in consecutive order. Each Work Order will be deemed incorporated into this Agreement. In the event of a conflict between the terms of this Agreement and the terms of the Work Order, the terms of this Agreement will govern, unless the Parties have expressly agreed in the Work Order that the Work Order shall amend a specified section of this Agreement, in which case such amendment will only apply to such Work Order.

In addition to the Services set forth in the following, fully executed Work Orders to the Prior Master Services Agreement between the Parties, and for which services are ongoing, shall henceforth be considered Work Orders under this Agreement. Each of these Work Orders shall be subject to the terms and conditions set forth in this Agreement as if they were originally executed hereunder, except that the fees associated with these Work Orders are subject to the annual adjustment specified in Section 3.1, meaning that the fees charged at execution will be those fees agreed upon for calendar year 2020, [***].

Pharmacy Master Services Agreement

For the avoidance of doubt, Jazz Pharmaceuticals' commercial function shall have responsibility for Jazz's oversight of Pharmacy Services, and decisions related to changes to Pharmacy Services shall be directed by personnel in that function.

For the avoidance of doubt, Jazz Pharmaceuticals' non-commercial function of Pharmacovigilance, Quality and Safety shall have responsibility for Jazz's oversight of the REMS Pharmacy Services, and decisions related to changes to REMS Pharmacy Services shall be directed by personnel in that function.

2.2 Modifications in Services. Jazz Pharmaceuticals may propose changes (such as a change in process) to Services through a Work Order by submitting a request in writing setting forth the proposed modifications to such Services (a "Modification Request"). In the event of any Modification Request, or if ESSDS receives a technical direction from Jazz Pharmaceuticals that is reasonably viewed by ESSDS as a Modification Request, ESSDS shall notify Jazz Pharmaceuticals in writing of the anticipated cost impact of such Modification Request. The Parties agree to negotiate in good faith any adjustments to the fees payable under this Agreement that are necessitated by a Modification Request and recognize that ESSDS shall have no obligation to perform modified or additional Services until the parties have agreed on the associated fees. A Modification Request must be signed by the Parties.

2.3 Exclusive Pharmacy. During the term of this Agreement, all commercial, non-clinical trial Product sold by Jazz Pharmaceuticals, or made available through the PAP, in the Territory will be dispensed exclusively through ESSDS pursuant to this Agreement. [***] Notwithstanding the foregoing, Jazz Pharmaceuticals may establish a third party pharmacy to make available commercial, non-clinical trial Product in the Territory if ESSDS does not, or cannot, meet Jazz Pharmaceuticals requirements for dispensing the Product in the Territory in accordance with the terms and conditions of the Agreement.

2.4 Data and Data Reports. ESSDS will provide to Jazz Pharmaceuticals or third parties authorized by Jazz Pharmaceuticals, the Data and Data Reports as set forth in any Work Order. Data will be transferred with the content and in the formats defined in the Work Order, and will be provided in the manner and frequency defined in the Work Order.

[***]

2.5 Warehousing. All commercial, non-clinical trial Product sold, or made available pursuant to this Agreement in the Territory shall be warehoused at ESSDS at the Certified Pharmacy in accordance with any related Work Orders or SOPs, and Work Instructions, and with due care in accordance with the standards and practices which are generally accepted in the industry and exercised by other persons engaged in performing similar services in the local areas and in accordance with Applicable Law.

2.6 Quality of Services; Compliance with Law. ESSDS agrees to perform the Services in a professional and timely manner in accordance with the terms and conditions of this Agreement, the applicable Work Orders or any mutually agreed Modification Requests, Work Instructions and SOPs and in compliance with Applicable Laws and currently recognized and accepted industry standards. The SOPs and Work Instructions shall not be modified without notice to Jazz Pharmaceuticals unless required by law and Jazz Pharmaceuticals shall have the right in the event of a change to notify ESSDS of any change it believes will be required to the Work Instructions as a result of the change to such SOPs. In such event the Parties will work together in good faith to determine whether a Modification Request is required. ESSDS shall provide the Services through personnel, who are appropriately skilled, qualified, properly licensed where applicable, and trained to provide Services. ESSDS shall perform the Services at the designated ESSDS locations listed in Exhibit D, ESSDS Locations. The Certified Pharmacy shall maintain all relevant State and Federal licenses required by Applicable Law.

ESSDS shall monitor developments in Applicable Laws and shall promptly notify Jazz Pharmaceuticals of any relevant developments of which it becomes aware, and the Parties shall work together in good faith to determine whether a Modification Request is required.

2.7 Personnel. ESSDS shall provide the REMS Pharmacy Services through personnel who are qualified and appropriately trained to provide the REMS Pharmacy Services (the "Personnel"). ESSDS shall have sole discretion over the management and oversight of its Personnel working on the REMS Pharmacy Services, but will reasonably consult with Jazz Pharmaceuticals with respect to Jazz Pharmaceuticals' personnel recommendations to help to ensure Jazz Pharmaceuticals' satisfaction with the REMS Pharmacy Services. ESSDS shall provide opportunities to review and make recommendation on job descriptions prior to such job descriptions being used in the Personnel recruitment process for open positions. Prior to assigning any individual to work on the REMS Pharmacy Services on a full-time basis, Jazz Pharmaceuticals shall be given an opportunity to confirm that it is satisfied with such person's training and qualifications. ESSDS shall ensure that all employees assigned to support the REMS Pharmacy Services are qualified and competent in their respective roles and responsibilities and have reasonable experience performing the tasks they will perform in connection with the REMS Pharmacy Services, consistent with industry standards. In addition, ESSDS will ensure that its Personnel participate in any instruction and training as required by Jazz Pharmaceuticals, including training directly from Jazz Pharmaceuticals.

[***]

Specific roles are or will be described in more detail in the applicable Work Order(s). In the event that Jazz Pharmaceuticals is dissatisfied with any individual performing REMS Pharmacy Services, it may notify ESSDS of its concerns and ESSDS will take such concerns under advisement and take corrective action as appropriate.

It is understood that ESSDS and its employees will be serving under this Agreement as an independent contractor, and will not be eligible to participate in any benefits extended by Jazz Pharmaceuticals to its employees.

ESSDS will maintain in full force and effect throughout the performance of this Agreement insurance related to Worker's Compensation for its employees who perform REMS Pharmacy Services under this Agreement and will provide Jazz Pharmaceuticals a certificate of insurance evidencing such coverage if requested in writing by Jazz Pharmaceuticals.

2.8 Handling of the Product. In connection with the provision of Services, ESSDS shall at all times handle, maintain, store, transport and deliver the Product in accordance with all Applicable Laws and SOPs. ESSDS will prepare the Product under conditions that are consistent with currently accepted standards of care including relevant requirements specified in the applicable SOPs and Work Instructions, the REMS Program, and Product Prescribing Information.

2.9 Subcontracting. ESSDS may not subcontract or otherwise delegate any of its obligations with respect to the Services, except to an Affiliate, without Jazz Pharmaceuticals' prior written consent, which will not be unreasonably withheld, including by agreeing to a Work Order specifying the subcontractor. Upon receipt of such consent, before allowing any subcontractor to be performing services, ESSDS shall enter into a binding written agreement with such subcontractor that protects Jazz Pharmaceuticals' rights and interests to at least the same degree as this Agreement. ESSDS shall be responsible for any permitted subcontractors' compliance with the terms hereof. Jazz Pharmaceuticals shall have no obligation to pay any such subcontractors for any Services.

2.10 Privacy.

(a) Notwithstanding anything to the contrary herein (including the Exhibits hereto), ESSDS shall only provide information to Jazz Pharmaceuticals in a manner consistent with HIPAA. Accordingly, the Parties agree that ESSDS shall only provide Jazz Pharmaceuticals information that is de-identified in accordance with HIPAA's de-identification provision, 45 C.F.R. § 164.514(b), unless ESSDS: (i) has on file a valid, unrevoked, HIPAA-compliant authorization for each patient whose protected health information ("PHI") is sought to be disclosed; or (ii) authorization is not required under Applicable Law in order to disclose the PHI. Jazz Pharmaceuticals represents and warrants that it cannot and will not attempt to identify the individual who is the subject of any de-identified information. To the extent that Jazz Pharmaceuticals, or a contractor of Jazz Pharmaceuticals (e.g., a Hub), maintains the relevant HIPAA authorization, Jazz Pharmaceuticals agrees to, or to require its contractor to, appropriately communicate to ESSDS any expiration, revocation, or restriction requested by a patient related to the HIPAA authorization or the patient's PHI.

(b) If Jazz Pharmaceuticals seeks PHI from ESSDS for Jazz Pharmaceuticals' public health activities purposes (e.g., REMS, adverse event reporting), Jazz Pharmaceuticals represents and warrants that the disclosure of such PHI by ESSDS to Jazz Pharmaceuticals, either directly to Jazz Pharmaceuticals or to Jazz Pharmaceuticals' data collection agent, satisfies the conditions of 45 C.F.R. § 164.512(b) in that: (i) if Jazz Pharmaceuticals uses a third party to collect data for Jazz Pharmaceuticals, such third party is serving in the capacity as Jazz Pharmaceuticals' agent for the purpose of, among other things, collecting data on behalf of Jazz Pharmaceuticals; (ii) the data to be collected is to be used and/or disclosed by Jazz Pharmaceuticals, or its data collection agent, solely for public health activities purposes and for no other purpose; (iii) de-identified data (as described in 45 C.F.R. § 164.514(b)) is not sufficient under the circumstances to enable Jazz Pharmaceuticals to satisfy its public health activities purposes; and (iv) the data to be collected includes the minimal amount of PHI required in order for Jazz Pharmaceuticals to conduct its public health activities purposes.

2.11 REMS Program Items

(a) REMS Program Items. From the Effective Date of this Agreement, Jazz Pharmaceuticals shall provide REMS Program Items to ESSDS of the type and quantities to be reasonably determined by Jazz Pharmaceuticals for performance of REMS Pharmacy Services. ESSDS shall not utilize or distribute REMS Program Items for any purpose other than as set forth in this Agreement and the Work Orders hereunder. ESSDS is strictly prohibited from selling, utilizing, or transferring REMS Program Items to any third-party under any circumstances not contemplated by this Agreement.

(b) Title; Storage. REMS Program Items shall be marked as property of Jazz Pharmaceuticals. ESSDS shall furnish and maintain a suitable place for storage of REMS Program Items. Legal title to all REMS Program Items shall remain with Jazz Pharmaceuticals.

ARTICLE III

COMPENSATION, INVOICING AND PAYMENT

3.1 Services Fees. The full and complete compensation by Jazz Pharmaceuticals for ESSDS' performance of the Services and for assumption of its obligations hereunder shall be as set forth in the applicable Work Order, which shall be inclusive of all taxes applicable to the performance of Services. The fees for Services may only be modified by written agreement of the Parties via an amendment to the applicable Work Order in accordance with Section 2.1. All expenses, including shipping costs, reimbursed hereunder shall be at cost, without markup. Unless otherwise set forth in a Work Order, ESSDS shall be responsible for all costs and expenses associated with fulfilling its obligations hereunder. On the first anniversary of the Effective Date, and each anniversary thereafter, [***]. ESSDS shall notify Jazz Pharmaceuticals in writing before the effective time of any such increase in fees.

3.2 Invoices for Services Fees. ESSDS will issue invoices to Jazz Pharmaceuticals for payment and reimbursement of the fees and expenses for the Services as set forth in the applicable Work Order hereunder. ESSDS will provide reasonable detailed invoices, together with adequate supporting documentation. All fees shall be paid in United States dollars and payable in the same. Invoices will be sent to:

Jazz Pharmaceuticals, Inc.
3170 Porter Drive
Palo Alto, CA 94304
Attention Accounts Payable
Or via email to: ap@jazzpharma.com

3.3 Payment. Jazz Pharmaceuticals will pay all undisputed amounts invoiced in accordance with the terms hereof within thirty (30) days of receipt. In the event that Jazz Pharmaceuticals disputes any portion of an invoice, Jazz Pharmaceuticals will pay the undisputed portion in the ordinary course and will notify ESSDS within ten (10) business days of the disputed portion and will request information from ESSDS reasonably necessary to substantiate the invoiced amount. ESSDS will provide the requested information within ten (10) business days. If Jazz Pharmaceuticals continues to question the invoiced amounts following such information request and response, it shall promptly notify ESSDS and the Parties shall, within ten (10) business days, meet (in person or by phone) to resolve any dispute. The finally resolved amount shall be payable within thirty (30) days of the original invoice date or within ten (10) business days of the dispute resolution, whichever is later. In the event that Jazz Pharmaceuticals has prepaid any amounts and the actual fees or expenses are less than estimated, then ESSDS will promptly (and in all cases within thirty (30) days) reimburse the amount of any overpayment to Jazz Pharmaceuticals or at Jazz Pharmaceuticals' request credit the amount of such overpayment to other invoices.

3.4 Fair Market Value. ESSDS agrees with Jazz Pharmaceuticals that the compensation payable to ESSDS for the Services to be performed by it (a) are for bona fide series provided by ESSDS to Jazz Pharmaceuticals, (b) have been determined through good faith and negotiated at arm's length and as such represent the fair market value for such Services, and (c) does not take into account the volume or value of referrals or business otherwise generated between the Parties or their Affiliates for which payment may be made, in whole or in part, under Medicare, Medicaid or other federal or state health care programs. ESSDS also confirms to Jazz

Pharmaceuticals that it will retain the Services fees provided by Jazz Pharmaceuticals under this Agreement and that such Services fees will not be passed on to any of ESSDS' customers. No provision of this Agreement shall be applied or construed in a manner inconsistent with applicable state or federal laws or regulations.

ARTICLE IV

SUPPLY OF PRODUCT

4.1 Non-PAP Orders

(a) General. Jazz Pharmaceuticals shall deliver to ESSDS at the Certified Pharmacy sufficient quantities of Product to fulfill Non-PAP orders. ESSDS maintains a reasonable quantity of components on-site or nearby to allow product disbursements to occur in a timely and efficient manner. The Product to be shipped pursuant to Non-PAP Orders shall be furnished to, and held by, ESSDS on a consignment basis at a Certified Pharmacy at all times. The consignment of Product hereunder shall at no time be construed as a loan or other debt financing or secured transaction arrangement between the Parties, and title to consigned Product shall remain with Jazz Pharmaceuticals until transferred pursuant to Section 3.1(b).

(b) Transfer of Title. Upon removal of the consigned Product by ESSDS from the product storage area to fulfill a Non-PAP Order, title to such Product shall pass to ESSDS and ESSDS shall be deemed to have purchased from Jazz Pharmaceuticals such Product. ESSDS shall confirm all such purchases and shipments of Product in writing to Jazz Pharmaceuticals on a weekly basis via a confirmation of Product Shipped, which will document all purchases of Product by ESSDS in the previous week. If a month ends in the beginning or middle of a week, ESSDS shall send an additional purchase order to Jazz Pharmaceuticals to confirm purchases made as of the last day of each month. This transfer of title process applies only to Product that has not already been purchased as part of a Buy In option, as described in Section 4.2, where title transfers upon submission of a relevant purchase order.

(c) Pricing of Non-PAP Orders. Subject to the restrictions set forth in Section 6.2 of this Agreement and any FDA requirement or other Applicable Law, ESSDS shall have the sole authority to determine pricing to Patients for Non-PAP Orders.

4.2 Buy In. ESSDS shall be offered [***] Manufacturer's Product [***]

4.3 PAP Orders. Subject to available space as determined by ESSDS, Jazz Pharmaceuticals will deliver to ESSDS at the Certified Pharmacy, at Jazz Pharmaceuticals own expense, sufficient quantities of Product to fulfill PAP orders. ESSDS will maintain a reasonable quantity of components on-site or nearby to allow product disbursements to occur in a timely and efficient manner. The Product shipped pursuant to PAP Orders shall be for the account of Jazz Pharmaceuticals, and title to such Product shall remain with Jazz Pharmaceuticals until confirmation of the PAP Order in ESSDS' internal order processing system, at which time title will pass to the PAP Patient. ESSDS will fulfill PAP Orders as set forth in the applicable SOP and Business Rules.

4.4 Risk of Loss. All risk of Product loss or damage during the time that such Product is at the Certified Pharmacy prior to the transfer of title to ESSDS pursuant to Section 3.1(b) shall be borne by Jazz Pharmaceuticals, except to the extent caused by the negligence or willful misconduct of ESSDS or its affiliates. Payment to Jazz Pharmaceuticals by ESSDS for Product lost or damaged while at the Certified Pharmacy (i) after title to such Product has transferred to ESSDS pursuant to Section 3.1(b); or (ii) that is the result of ESSDS or its affiliates negligence or willful misconduct shall be based on Jazz Pharmaceuticals' actual replacement costs, as reasonably determined and documented by Jazz Pharmaceuticals.

4.5 Returns and Replacement. In the event that (a) Product is damaged or destroyed after the transfer of title pursuant to Section 3.1(a) and (b) such damage or destruction [***] ESSDS shall replace the Product to the Patient free of charge once the damaged Product is returned to ESSDS. ESSDS shall monitor all reports of lost Product for the potential for abuse or diversion in compliance with relevant SOPs and WIs. ESSDS will cooperate with state and federal authorities fully in any investigations of lost Product, and will promptly provide reports of such loss to Jazz Pharmaceuticals within one (1) week from ESSDS' conclusion of its investigation. Where abuse or diversion is not suspected and the damage or destruction is the direct result of a defect [***] ESSDS will promptly replace the Product at no charge to the Patient once approved by the pharmacy. Jazz Pharmaceuticals shall reimburse ESSDS for an amount equal to the replacement cost of such Product.

All Return or Replacement activities will be conducted in accordance with applicable SOPs, Work Instructions, and the REMS Documents. Applicable fees will apply to the processing and shipping of replacement Product and WAC price will be applied to the replacement Product, and record of the shipment will be kept in the Patient file. Upon receipt of damaged Product, ESSDS will keep damaged Product in a secure locked area in compliance with applicable SOPs, and will dispose of it using Jazz Pharmaceuticals' reverse distributor vendor in compliance with applicable SOP and Applicable Law. ESSDS will be responsible for covering any shipping costs associated with getting the Product to the reverse distributor for destruction. All other costs associated with the utilization of Jazz Pharmaceuticals' reverse distributor vendor will be covered by Jazz Pharmaceuticals.

4.6 Expired Product. Jazz Pharmaceuticals will, at its cost, replace Product that expires prior to the purchase thereof by ESSDS. Jazz Pharmaceuticals will not replace expired Product once it has been purchased by ESSDS. ESSDS will dispose of or return expired Product as reasonably directed by Jazz Pharmaceuticals, in accordance with Applicable Law and applicable SOPs and WIs, and Jazz Pharmaceuticals shall promptly reimburse ESSDS for all reasonable out-of-pocket expenses incurred in complying with this Section.

4.7 Territory. ESSDS shall use commercially reasonable efforts to obtain and maintain all necessary licenses and approvals to dispense Product in the Territory.

4.8 Recall or Market Withdrawal. Jazz Pharmaceuticals may elect to recall or withdraw the Product from the market as a result of (i) a request, instruction, or other action of a government entity; (ii) a determination for reasons associated with safety, quality, technical or other issues directly affecting the Product.

4.8.1 In the event of such recall or withdrawal, Jazz Pharmaceuticals shall provide as much written notice to ESSDS as reasonably possible of such recall or withdrawal (such notice to include the reasons for the recall or withdrawal and any notices or other communication from any government entity in relation thereto). ESSDS shall reasonably cooperate in effecting such recall in accordance with the applicable SOP.

4.8.2 If Jazz Pharmaceuticals is required to recall, or, on its own initiative, recalls or withdraws any Product sold in the Territory, ESSDS shall reasonably assist Jazz Pharmaceuticals in such recall in accordance with the Applicable Laws. For such purposes, ESSDS shall maintain a complete and current list of Patients who ESSDS reasonably believes could have been exposed to product covered by the recall or withdrawal. Jazz Pharmaceuticals shall pay for all reasonable documented out of pocket costs and expenses of ESSDS solely as a result of any such recall, unless the recall results from ESSDS' negligence, recklessness, or willful misconduct. ESSDS shall provide to Jazz Pharmaceuticals, at Jazz Pharmaceutical's request, any information reasonably requested by Jazz Pharmaceuticals in connection with Jazz Pharmaceuticals' investigations relating to recalled Product, subject to the confidentiality constraints imposed by Applicable Law.

ARTICLE V

AUDITS; REGULATORY INQUIRIES; DEBARMENT; OTHER REGULATORY MATTERS

5.1 Audit. During the Term and for a period of eighteen (18) months thereafter, ESSDS shall make Records available for Jazz Pharmaceuticals or its designee's inspection during regular business hours and upon at least forty-eight (48) hours' advance notice. In addition, Jazz Pharmaceuticals shall have the right, during the Term, (i) to one time annually inspect (or more frequently and without notice if Jazz Pharmaceuticals has reasonable cause to perform such an inspection) any of ESSDS' facilities from which the Services are performed and equipment used to perform the Services (including computers, call centers, software programs and any other systems) during normal business hours and upon 30 day prior written notice, accompanied by a detailed audit scope (ii) to be present when Services are being performed by ESSDS or ESSDS' permitted subcontractors, and (iii) to monitor by telephone the performance of any call center or telephone-related ESSDS Services provided under this Agreement. ESSDS will cooperate in any audits at ESSDS' expense. If any audit results in findings that require follow-up or action, ESSDS will address such findings within a commercially reasonable timeframe at ESSDS' expense. Audits will be excluded during the months of December and January, unless the request is related to an inspection and timing stipulated by a government regulator that impacts the services defined in this agreement. If a third party is used to conduct any audit, such third party will sign a confidentiality agreement with ESSDS.

5.2 Regulatory Inquiries and Inspections. To the extent practicable and permitted under Applicable Law, ESSDS shall notify Jazz Pharmaceuticals immediately (with a copy of all associated notices and correspondence) of its receipt of any notice of an inspection, audit or regulatory action relating to the Product by, any regulatory authority, including without limitation, the United States Department of Health and Human Services, the FDA or any other government agency or any state board of pharmacy or any national accrediting body (an "Inspection"). Jazz Pharmaceuticals shall have the right to be present at and to participate in any such Inspection or regulatory action with respect to the Product or the Services. In the event that ESSDS does not receive prior notice of such regulatory inspection, ESSDS shall notify Jazz Pharmaceuticals as soon as practicable after such inspection begins.

5.3 No Debarment.

5.3.1 ESSDS represents and warrants to Jazz Pharmaceuticals that it (i) is not currently excluded, debarred, suspended or otherwise ineligible to participate in Federal health care programs or in Federal procurement or nonprocurement programs or proposed for exclusion under such programs, and (ii) has not been convicted of a criminal offense that falls with 42 USC §1320a-7(a) or §1320a-7(b)(1)-(3) but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in Federal health care programs or in federal procurement or nonprocurement programs. ESSDS agrees that it will immediately notify Jazz Pharmaceuticals in writing if any of the representations and warranties made by ESSDS in this Section ceases to be true at any time during the term of the Agreement.

5.3.2 Jazz Pharmaceuticals represents and warrants to ESSDS that it (i) is not currently excluded, debarred, suspended or otherwise ineligible to participate in Federal health care programs or in Federal procurement or nonprocurement programs or proposed for exclusion under such programs, and (ii) has not been convicted of a criminal offense that falls under 42 USC §1320a-7(a) or §1320a-7(b)(1)-(3) but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in Federal health care programs or in federal procurement or nonprocurement programs. Jazz Pharmaceuticals agrees that it will immediately notify ESSDS in writing if any of the representations and warranties made by Jazz Pharmaceuticals in this Section cease to be true at any time during the term of the Agreement.

ARTICLE VI

PURCHASE PRICE OF PRODUCTS

6.1 Purchase Price of Products. With respect to all Product purchased by ESSDS pursuant to Section 3.1, ESSDS shall pay a purchase price to Jazz Pharmaceuticals [***]. Notwithstanding, ESSDS shall pay Jazz Pharmaceuticals [***].

6.2 Payment Terms. ESSDS shall have the right to establish the price at which it resells Product to Non-PAP Patients, and shall have all right title and interest in and to any amounts that ESSDS receives from third parties in connection with Product dispensed or distributed pursuant to Non-PAP Orders; provided, however, that the price at which ESSDS sells Product shall not exceed [***]. This limitation is intended solely to create an upper limit, and is not intended by either party to indicate a desire, intent, or belief that the practice of pricing at, or near, this upper limit is sufficient to meet current marketplace demands. The parties acknowledge the vast complexities of pricing within the pharmaceutical marketplace, and ESSDS represents that typical pricing conventions will apply (example: larger customers typically receive better pricing). ESSDS shall make best efforts in all cases to negotiate in good faith with any Third Party Payer in connection with the purchase of Product on terms that are commercially reasonable. The parties have a shared desire to ensure Patients receive drug in a timely manner. From time to time Jazz Pharmaceuticals may become aware of specific Third Party Payer issues that could impact patients. In the event that Jazz Pharmaceuticals becomes aware of such issues, Jazz Pharmaceuticals may escalate those concerns through the Jazz Pharmaceuticals' Head of US Market Access, directly to the ESSDS VP of Commercial Activity. ESSDS agrees to use best efforts to ensure such issues are quickly resolved. Nothing in this section shall be interpreted as Jazz Pharmaceuticals setting pharmacy pricing or taking any action inconsistent with provisions contained in Article 4.1(c), titled "Pricing of Non-PAP Orders".

ARTICLE VII

RECORDS AND NOTIFICATIONS

7.1 **Records.** ESSDS shall at all times keep and maintain complete, timely and accurate written records relating to the performance of the Services as provided for under this Agreement (collectively, the “Records”). ESSDS shall maintain the Records in compliance with Applicable Laws and ESSDS’s record retention policies.

7.2 **Adverse Event Reporting.** ESSDS shall comply with the agreed Potential Adverse Event Reporting SOP and WIs and report any potential Adverse Drug Experiences that it receives to Jazz Pharmaceuticals in compliance with those SOPs and WIs.

7.3 **Product Complaints.** ESSDS shall comply with the agreed Product Complaint SOP and properly report any technical complaints (e.g., reports about potential production issues such as packaging irregularities that are not a result of shipping damage) or Product Complaints (e.g. reports regarding contamination, discoloration, improper labeling, adulteration) that it receives to Jazz Pharmaceuticals.

7.4 **Other Notifications.** Other Notifications. ESSDS shall notify Jazz Pharmaceuticals within one (1) business day if the Product or the REMS Program is within the scope of a FDA or DEA inspection.

ARTICLE VIII

CONFIDENTIALITY

8.1 **Confidentiality of Agreement.** The Parties agree that the terms and conditions of the Agreement are Confidential Information (as defined in Section 8.2 below) and shall not be disclosed to anyone for any purpose without the prior written consent of the other Party, except as expressly permitted by this Agreement.

8.2 **Confidential Information.** Each Party acknowledges that in connection with this Agreement, it may receive information, including and without limitation, trade secrets and innovations, information regarding the Product and planned products, the Program and the Services and planned services, contractors, customers, prospective customers, financial data, computer software processes, ideas, marketing information, strategies, forecasts, development programs, data, know-how, improvements and other valuable business information from or on behalf of the other Party (the “Disclosing Party”) which the Disclosing Party considers to be proprietary and confidential and the value of which might be lost if the confidentiality of such information is not maintained (collectively, the “Confidential Information”). The Party receiving such Confidential Information (the “Receiving Party”) agrees, at all times during the term of this Agreement, and subject to the limitations set forth herein, (i) to treat as confidential all Confidential Information received from the Disclosing Party with at least the same degree of care with which the Receiving Party treats its own confidential information, (ii) to disclose Confidential Information to only those of its employees, agents, consultants and permitted subcontractors who have a need to know such Confidential Information in order to accomplish the purposes of this Agreement and who are subject to obligations of confidentiality at least as restrictive as those obligations of confidentiality in this

Section, and (iii) to not use the Disclosing Party's Confidential Information for any purpose except those purposes permitted by this Agreement. Unless otherwise expressly set forth herein to the contrary, each Party hereby acknowledges and agrees that, as between the Parties, the Disclosing Party owns all right, title, and interest in and to the Confidential Information disclosed to the Receiving Party.

8.3. Exceptions. The obligations of confidentiality and nonuse set forth herein shall not apply to information that the Receiving Party can demonstrate by competent written evidence: (i) is or becomes generally available to the public other than as a result of a disclosure by the Receiving Party in breach this Agreement, (ii) was within the Receiving Party's possession prior to the date of the Prior Agreement and had become known to the Receiving Party from the Receiving Party's own sources without restriction, (iii) becomes available to the Receiving Party on a non-confidential basis from a third Party not acting on behalf of the Disclosing Party and not under any obligation to keep such information confidential, and (iv) was or is independently developed by the Receiving Party without the use of or access to any Confidential Information. Any combination of features or disclosures will not be deemed to fall within the foregoing exclusions merely because certain individual features fall within such foregoing exclusions unless the combination as a whole falls within any of the above exclusions.

8.4. Authorized Disclosure. The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent such disclosure is required by Applicable Law, a valid order of a court or other governmental body having jurisdiction, or rules of a securities exchange; *provided, however,* that the Receiving Party both: (a) gives prompt notice to the Disclosing Party of the disclosure requirement in order to allow the Disclosing Party to obtain any available limitation on or exemptions from such disclosure requirement, where reasonably practicable, and (b) reasonably cooperates in such efforts by the Disclosing Party, where not prohibited by Applicable Law, court order, or securities exchange rules.

8.5. Permitted Uses and Disclosures. The Receiving Party may use Confidential Information in the performance of its obligations or exercise of its rights under this Agreement or any Work Order.

8.6. Data. ESSDS agrees to maintain the security and confidentiality of all Data, including any Personal Data, in accordance with all Applicable Laws, applicable agreements, patient release forms, consents, and the provisions of this Agreement, the SOPs and all Work Orders. For the purposes of this Section, "Personal Data" shall mean computerized or electronic records as well as paper-based files in any medium or format collected by ESSDS in connection with the performance of Services, including by not limited to information received from any patient, health care professional, and other business-to-business customers or vendors that specifically identifies, or when used together with other available information identifies, a particular individual. Personal Data includes name, address, telephone number, fax number, Social Security number, DEA number, other government issued identifier, credit card information, insurance identification number, IP addresses, email address and information relating to the past, present or future health or condition (physical or mental) of an individual, but does not include information that is deidentified, encoded or made anonymous. The parties agree that Jazz Pharmaceuticals will not have any ownership in Personal Data created, collected or recorded by ESSDS in connection with the Services. ESSDS agreed that it will not utilize Personal Data outside the scope of this Agreement, provided however, that ESSDS

and/or its affiliates may use Personal Data in the aggregate or on a deidentified basis with other drug-use data, to the extent permitted by law, without charge, for research, cost analysis and other internal business purposes of ESSDS, provided that said use does not in any way compete with the business of Jazz Pharmaceuticals. ESSDS will establish commercially reasonable controls to ensure the confidentiality of Confidential Information and Data and to ensure that Data is not disclosed contrary to the provisions of this Agreement; provided, further, without limiting the foregoing, that ESSDS shall implement and/or maintain a comprehensive written information privacy and security program that includes appropriate administrative, technical and physical safeguards and other security measures appropriate to the size and complexity of ESSDS' operations and the nature and scope its activities that are designed to (a) ensure the security and confidentiality of Data; (b) protect against any anticipated threats or hazards to the security, confidentiality and integrity of Data; and (c) protect against unauthorized access to or use of Data that could result in the destruction, use, modification or unauthorized disclosure of Data.

8.7 Return of Confidential Information. Upon expiration or earlier termination of this Agreement, or upon the Disclosing Party's earlier request, the Receiving Party (a) shall return to the Disclosing Party all documents, papers, and other materials in the Receiving Party's possession or under the Receiving Party's control containing the Disclosing Party's Confidential Information, or (b) shall destroy any or all such documents, papers and other materials items, thereafter sending the Disclosing Party a signed certification of destruction covering the applicable items. Notwithstanding the foregoing, each Party may retain a single archival copy of the other Party's Confidential Information for the sole purpose of facilitating compliance with the surviving provisions of this Agreement.

8.8 Access to Information Technology.

(a) Jazz Pharmaceuticals may provide ESSDS with access to the Jazz Pharmaceuticals network, system, and/or a specific application, as Jazz Pharmaceuticals may decide in its sole discretion (the "Information Technology") for use under this Agreement. This Information Technology will be used solely for purposes of, and in connection with, the Services provided under this Agreement and for no other purpose whatsoever. Access to such Information Technology will be strictly limited to those ESSDS agents, employees and consultants (the "IT Access Recipients") who are required to use such Information Technology for the performance of the Services. The Information Technology may not be copied, modified or distributed, or provided to or used by any third party. ESSDS will be liable for any unauthorized use of Jazz Pharmaceuticals' Information Technology by any IT Access Recipients.

(b) ESSDS will notify Jazz Pharmaceuticals within forty eight (48) hours in the event that any IT Access Recipient has terminated its relationship with ESSDS, including but not limited to (i) ESSDS employees that have left employment with the ESSDS for any reason whatsoever; and (ii) ESSDS agents or contractors that are no longer under contractual obligations with ESSDS relating to the Services provided hereunder.

(c) ESSDS will notify Jazz Pharmaceuticals within forty eight (48) hours in the event that the duties of any IT Access Recipient have been reassigned such that the recipient no longer requires access to Information Technology.

(d) ESSDS will take all reasonable precautions to prevent the unauthorized access to Jazz Pharmaceuticals' Information Technology by ESSDS Personnel. ESSDS will notify Jazz Pharmaceuticals immediately (and in all cases within three days) of becoming aware of any actual or suspected unauthorized access to the Information Technology.

8.9 Injunctive Relief. Each Party acknowledges that the disclosure or use of the other

Party's Confidential Information, other than as expressly permitted herein, without such Party's prior written permission may cause the Disclosing Party irreparable harm and that any material breach or threatened material breach of the obligations of confidentiality and non-use by the

Receiving Party will entitle the Disclosing Party to seek injunctive relief, in addition to any other legal remedies available to it, in any court of competent jurisdiction.

ARTICLE IX

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 General. Each Party hereby represents, warrants, and covenants to the other that: (i) it has all requisite corporate power and authority to enter into this Agreement and perform and observe all obligations and conditions required to be performed or observed by that Party under this Agreement, (ii) neither the execution and delivery of this Agreement nor the performance by that Party of its respective obligations under this Agreement will conflict with or result in a breach of any covenant or agreement between that Party and any third party, (iii) this Agreement represents the legal, valid, and binding obligation of that Party, and (iv) as of the Effective Date, such Party has (or will have at such time as performance of its obligations under this Agreement may require) obtained all of the local, state, and federal permits, licenses, or other regulatory registrations or approvals necessary, if any, for the performance of its obligations under this Agreement.

9.2 ESSDS Representations and Warranties.

9.2.1 ESSDS represents and warrants that, to the best of its knowledge, it owns and possesses all right, title and interest in and to, or has valid licenses to use all the proprietary rights necessary to perform its obligations under this Agreement.

9.2.2 ESSDS warrants that any computer systems used in connection with the Services shall operate substantially in accordance with any descriptions or the specifications set forth in this Agreement or any applicable Work Orders. A business continuity plan, as set forth in the applicable SOP, will be implemented by ESSDS to assure that this warranty will be met.

9.2.3 ESSDS represents, warrants, and covenants that ESSDS's contracted work with pharmaceutical/medical device manufacturers is independent from its parent company's clinical and formulary decisions. There is a firewall between ESSDS's pharmaceutical/medical device services business and the pharmacy benefit management ("PBM") business. ESSDS will not be influenced by any PBM rebate or other related agreements with pharmaceutical/medical device manufacturers. Similarly, transactions between pharmaceutical/medical device manufacturers and ESSDS will not affect PBM clinical and formulary decisions.

9.2.4 ESSDS shall:

(a) provide all Services and Deliverables to Jazz Pharmaceuticals pursuant to this Agreement in compliance with Applicable Laws and in a good, workmanlike, and timely manner, consistent with standards for the industry;

(b) comply with the descriptions, specifications and representations as to the Services and Deliverables (including performance, capabilities, accuracy, completeness, characteristics, specifications, configurations, standards, functions, and requirements) as set forth in this Agreement or in a Work Order, including, without limitation, the Performance Standards and Measures included in the applicable Work Order and the specifications contained within the REMS Documents.

(c) maintain all licenses, certifications, permits and authorizations pertinent to the practice of pharmacy and required by all Applicable Laws, the REMS Documents, rules and regulations and this Agreement.

(d) make no representation, guarantee, or warranty about the Product, whether orally or in writing, except as contained in written materials delivered to ESSDS by Jazz Pharmaceuticals for use in connection with the Services; and (i) avoid deceptive, misleading or unethical practices that are or might be detrimental to Jazz Pharmaceuticals, the Product, or the public; and (ii) make no false or misleading representations with regard to Jazz Pharmaceuticals or the Product.

(e) use commercially reasonable technical measures to (i) detect and eliminate computer viruses and other destructive code introduced to any computer systems used in connection with the Services, (ii) correct any error reproducible by ESSDS in any computer systems used in connection with the Services, and (iii) ensure that any computer systems used in connection with the Services are available without interruption, except as contemplated by the business continuity plan, included as an Appendix to JPP-0002 – Inventory Control SOP.

9.3 Jazz Pharmaceuticals Representations and Warranties

9.3.1 Jazz Pharmaceuticals represents and warrants that, to the best of its knowledge, it owns and possesses all right, title and interest in and to, or has valid licenses to use all of the proprietary rights necessary to perform its obligations under this Agreement.

9.3.2 Jazz Pharmaceuticals warrants that, as of the delivery to ESSDS, the Product will (a) conform to Jazz Pharmaceuticals' stated Product specifications, (b) not be adulterated or misbranded within the meaning of the federal Food, Drug and Cosmetic Act of 1938, Title 21, as amended (the "Act"), and (c) not be articles which may not, under the provisions of the Act, be introduced into interstate commerce. THE WARRANTY SET FORTH IN THIS SECTION IS THE SOLE AND EXCLUSIVE WARRANTY GIVEN BY JAZZ PHARMACEUTICALS WITH RESPECT TO THE PRODUCT. JAZZ PHARMACEUTICALS EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES RELATED TO THE PRODUCT, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

9.3.3 Jazz Pharmaceuticals represents and warrants that: (i) it is engaging ESSDS to perform bona fide, legitimate, reasonable, and necessary Services; (ii) the Services are not intended to serve, either directly or indirectly, as a means of marketing the Product or as remuneration for steering patients or prescribers to the Product; (iii) the Services are not intended to diminish the objectivity or professional judgment of ESSDS; (iv) any service requirements imposed by Jazz Pharmaceuticals, including through SOPs, Work Instructions, and Business Rules, are reasonably limited to what is necessary to ensure compliance with Jazz Pharmaceuticals' obligations under Applicable Law, including with respect to the REMS Program; (v) the Services do not involve counseling or promotion of any off-label use of Product; and (vi) the Services do not involve the counseling or promotion of a business arrangement or other activity that violates Applicable Law.

9.3.4 Jazz Pharmaceuticals represents and warrants that: (i) all programs initiated by Jazz Pharmaceuticals and included as part of the Services, including any eligibility criteria for participation in any such programs, shall be structured in accordance with Applicable Law; and (ii) Jazz Pharmaceuticals is responsible for the content of all materials provided by Jazz Pharmaceuticals for use or distribution in connection with the Services, including REMS Program Items, and Jazz Pharmaceuticals shall ensure that all such materials have received any required regulatory approvals, are educational and not promotional with respect to the Product or providing Product-related or REMS Program-related information.

ARTICLE X

OWNERSHIP AND INTELLECTUAL PROPERTY

10.1 Intellectual Property of Jazz Pharmaceuticals. All Intellectual Property (including patents, copyrights, trademarks, trade secrets, ideas, improvements, discoveries, enhancements,

modifications, know-how, data, and information of every kind and description) either (a) conceived, generated, made, fixed in a tangible medium of expression or reduced to practice, as the case may be, by ESSDS within the scope and course of providing the Services to Jazz Pharmaceuticals under this Agreement, either alone or jointly with others or (b) owned or controlled by Jazz Pharmaceuticals on the Effective Date and/or otherwise independently of ESSDS and this Agreement which arise out of or relate to this Agreement, the Services, or the Jazz Pharmaceuticals Confidential Information (the "Jazz Intellectual Property") will be the sole and exclusive property of Jazz Pharmaceuticals. ESSDS will disclose Jazz Intellectual Property under subpart (a) of this paragraph promptly to Jazz Pharmaceuticals, and hereby assigns all of ESSDS's right, title and interest in and to any such Jazz Intellectual Property to Jazz Pharmaceuticals without royalty or any other consideration (other than compensation for the Services as provided by this Agreement or an applicable Work Order). For the avoidance of doubt, this includes, but may not be limited to, all Records, Deliverables, Program Items, and Data. Jazz Pharmaceuticals shall also own all right, title, and interest in any telephone numbers, fax numbers, web, and email domains established by ESSDS solely in connection with the Services hereunder and all such Intellectual Property rights therein, and the Parties will take all actions necessary so that any such numbers and domains will be registered with Jazz Pharmaceuticals following the expiration or termination of this Agreement for any reason, at Jazz Pharmaceuticals' sole cost and expense. ESSDS will cooperate fully with Jazz Pharmaceuticals in the process of securing and enforcing Jazz Pharmaceuticals' rights to such Jazz Intellectual Property, which may include executing applications, assignments or other instruments, and Jazz Pharmaceuticals will compensate ESSDS for ESSDS's reasonable time devoted to such activities at Jazz Pharmaceuticals' request and reimburse ESSDS for reasonable expenses incurred in connection therewith. If any part of the Jazz Intellectual Property under subpart (a) of this paragraph is based on, incorporates or is an improvement or derivative of, or cannot be reasonably and fully made, used, reproduced, modified, distributed or otherwise exploited without using, any technology or intellectual property rights owned or licensed by ESSDS and not assigned hereunder, then ESSDS hereby grants to Jazz Pharmaceuticals and its Affiliates a nonexclusive, either (i) perpetual and irrevocable (with respect to Records, Deliverables, Program Items, and Data supplied by ESSDS that incorporate such technology or intellectual property) or (ii) term-based (with respect to Jazz Pharmaceuticals' receipt of Services, as provided in Section 10.3), worldwide, royalty-free, sublicensable (other than for receipt of Services) right and license to exploit and exercise all such technology and intellectual property rights in support of Jazz Pharmaceuticals' receipt of the Services (as provided in Section 10.3) and exercise or exploitation of the Jazz Intellectual Property or any rights to the foregoing assigned to Jazz Pharmaceuticals (including, without limitation, any modifications, improvements and derivatives of any of them). Any copyrightable work, whether published or unpublished, created by ESSDS in connection with or during the performance of any Services will be considered a work made for hire to the fullest extent permitted by law. If any such copyrightable work is not classified as a work made for hire, then ESSDS assigns all worldwide rights in the work to Jazz Pharmaceuticals without royalty or any other consideration. No third party has or will have any claim of ownership for Intellectual Property assigned by ESSDS to Jazz Pharmaceuticals under this Agreement.

10.2 Intellectual Property of ESSDS. Notwithstanding anything to the contrary in Section 10.1 or otherwise, the Jazz Intellectual Property does not include, and ESSDS shall retain all right, title and interest in and to, the ESSDS IP. "ESSDS IP" shall mean (a) all Intellectual Property (including trade secrets, trademarks, patents, copyrights and other non-registered intellectual property) owned or control by ESSDS on the Effective Date and/or otherwise independently of Jazz Pharmaceuticals and this Agreement, including but not limited to, all Intellectual Property embodied in the ESSDS

Software and all ESSDS Prior Works that ESSDS shall use in connection with performing the Services under this Agreement. The term “ESSDS Prior Works” shall mean any and all Intellectual Property or other products developed, owned, controlled or acquired by ESSDS prior to the Effective Date of this Agreement and/or otherwise independently of Jazz Pharmaceuticals and this Agreement, including, but not limited to (i) computer software, technology, patient-centric services and analytics for pharmaceutical, biotechnology, medical device, vaccine and diagnostic manufacturers (“ESSDS Software”), (ii) specialty pharmacy industry knowledge, (iii) specialty pharmacy distribution and services software, and (iv) specialty pharmacy data reporting to payers and manufacturers, subject to any data reporting restrictions set forth elsewhere in this Agreement.

10.3 Licenses to Jazz Pharmaceuticals. ESSDS hereby grants to Jazz Pharmaceuticals a limited, non-transferable, non-exclusive, royalty-free right and license to the ESSDS IP, including the ESSDS Software, ESSDS Portal, and ESSDS Prior Works, solely as reasonably necessary in Jazz Pharmaceuticals’ normal course of receiving and using the Services during the term of this Agreement.

ARTICLE XI

TERM AND TERMINATION

11.1 Term; Renewal. Unless otherwise terminated in accordance with the terms hereof, this Agreement will remain in effect for a period of two (2) years from the Effective Date. If no such notice of termination is given, this Agreement can be renewed for one (1) additional one (1) year term at the discretion of Jazz Pharmaceuticals by a written amendment hereto, subject to the right of termination as otherwise provided herein.

11.2 Termination Without Cause. Either Party may terminate this Agreement or any Work Order at any time without cause on one hundred eighty (180) days’ prior written notice to the other Party.

11.3 Termination for Cause. Either Party may terminate this Agreement immediately upon written notice to the other Party if such other Party materially breaches this Agreement and, after receiving written notice identifying such breach, fails to cure such material breach within thirty (30) days after receipt of such notice. Such notice will include the effective date of termination.

11.4 Termination for Legal Necessity. Either Party may terminate this Agreement immediately upon written notice to the other Party in the event that (1) any Applicable Law, court decision, or the like is enacted, promulgated, published, or otherwise made effective, which would make ESSDS’ performance of the Pharmacy Services illegal or otherwise commercially impracticable or Jazz Pharmaceuticals’ development or commercialization of the Product commercially, medically, or technically impracticable or (2) Jazz Pharmaceuticals receives notice of regulatory action by the FDA that results in the termination or suspension of its rights to manufacture or distribute the Product in the United States.

11.5 Bankruptcy or Insolvency. Either Party may terminate this Agreement immediately upon written notice to the other Party, if such other Party makes an assignment for the benefit of creditors, files a petition in bankruptcy, is adjudicated insolvent or bankrupt, a receiver or trustee is appointed with respect to a substantial part of such other Party's property, or a proceeding is commenced against it which will substantially impair its ability to perform hereunder.

11.6 Partial Termination. A Party shall have the option and right to terminate (i) all of the Services or (ii) one or more specific services that may be part of the Services (collectively or individually referred to as "Specified Service") as provided for in this Article X with one hundred eighty (180) days' prior written notice to the other Party.

11.7 Effect of Termination. Upon expiration or earlier termination of this Agreement:

11.7.1 ESSDS shall deliver to Jazz Pharmaceutical, at Jazz Pharmaceuticals' expense, all tangible materials in ESSDS' possession or control belonging to Jazz Pharmaceuticals.

11.7.2 ESSDS shall notify any person or entity who contacts ESSDS in connection with any matter related to the Services that ESSDS is no longer providing those Services and direct them as requested by Jazz Pharmaceuticals.

11.7.3 ESSDS shall invoice Jazz Pharmaceuticals for any payments due for the applicable Services through the date of termination, pursuant to Section 2.8 and Jazz Pharmaceuticals shall pay such invoice(s) in accordance with Section 2.7.

11.7.4 ESSDS shall otherwise provide all other cooperation reasonably requested by Jazz Pharmaceuticals to ensure a smooth transition and the uninterrupted operation of the Specified Service.

11.8 Transition of Services. Upon termination or expiration of this Agreement or any Specified Service, the Parties shall mutually agree on an expeditious schedule of transition of the applicable Services.

11.9 Transition of Patient Information. In connection with any of the Services, Jazz Pharmaceuticals may request that ESSDS transfer all prescriptions, all patient and prescriber data required to administer and maintain compliance with the REMS Program, SOPs and Business Rules at Jazz Pharmaceutical's request to a pharmacy assuming responsibility for such services for the purpose of continuing "treatment" (as that term is defined by HIPAA) of affected Patients, and ESSDS shall expeditiously honor that request to the extent disclosure of such Patient Data by ESSDS is permitted under Applicable Law, including, but not limited to, HIPAA. All such Patient Data shall be transferred in standard NCPDP format. The purpose of any transfer of Patient Data is to assure, to the extent possible, as smooth transition for Patients.

11.10 Survival. Termination or expiration of the Agreement for any reason shall not affect the continuing rights and obligations of the Parties under Articles III; VII; VIII; X; XII; and XIV; and Sections 2.3; 2.4.1; 5.1; 5.2; 9.1; 11.7; 11.8; 11.9; 11.10; and 13.4 of this Agreement.

ARTICLE XII

INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

12.1 Indemnification by Jazz Pharmaceuticals. Subject to the terms hereof, Jazz Pharmaceuticals shall indemnify and defend ESSDS, its Affiliates, and their respective directors, officers, employees, agents, successors and permitted assigns, from and against any liabilities, damages, loss, judgments, settlements or expense (including reasonable attorneys' fees) (collectively, "Losses") as a result of any third-party claim, demand, or action (collectively, "Claims") to the extent arising from (a) the manufacture, sale or use, of the Product; (b) the negligence, recklessness, or willful misconduct of Jazz Pharmaceuticals or any of its employees, or (c) Jazz Pharmaceuticals' failure to comply with its obligations under this Agreement. Such obligation to indemnify, defend, and hold harmless shall not apply to the extent Losses and Claims are caused by ESSDS' breach hereof, negligence, recklessness, or willful misconduct.

12.2 Indemnification by ESSDS. Subject to the terms hereof, ESSDS shall indemnify and defend Jazz Pharmaceuticals, its Affiliates, and their respective directors, officers, employees, agents, successors and permitted assigns, from and against any Losses as a result of any third-party Claims, to the extent arising from (a) the negligence, recklessness or willful misconduct of ESSDS or any of its employees, or (b) ESSDS' breach of any representation, warranty, or obligation under this Agreement. Such obligation to indemnify, defend, and hold harmless shall not apply to the extent Losses and Claims are caused by Jazz Pharmaceuticals' breach hereof, negligence, recklessness or willful misconduct.

12.3 Indemnification Conditions and Procedures. The Party seeking indemnification (the "Requesting Party") shall (a) promptly notify the other Party (the "Indemnifying Party") in writing upon receipt of oral or written notice of any actual or alleged Claim, (b) allow the Indemnifying Party, at its discretion and cost, to undertake and control the defense of such Claim, (c) diligently assist the Indemnifying Party and cooperate in defending against such Claim; and (d) not, except at its own cost, voluntarily make or agree to make any payment or incur any expense in connection with any such Claim without the prior written consent of the Indemnifying Party.

12.4 Limitation of Liability. EXCEPT WITH RESPECT TO BREACHES OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE VIII, INTELLECTUAL PROPERTY INFRINGEMENT CLAIMS, AND THE PARTIES' INDEMNIFICATION OBLIGATIONS UNDER SECTIONS 11.1 AND 11.2, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR LOST PROFITS OR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SIMILAR DAMAGES, HOWEVER CAUSED AND ON ANY LEGAL THEORY, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

12.5 Insurance. Each Party will maintain at least [***] of commercial general liability insurance and [***] of product liability insurance. ESSDS will maintain Workers' Compensation coverage (or its equivalent) in compliance with Applicable Law, automotive liability insurance of at least [***] and professional liability insurance of at least [***]. As evidence of the coverage required by this Agreement, either Party may, in lieu of actual policies, accept Certificates of Insurance setting forth the nature of the coverage, the limits of liability, the name of the insurance carrier, policy number and the date of expiration, which shall be furnished on demand.

ARTICLE XIII

COLLABORATION

13.1 Annual Review. No less than one hundred-eighty (180) days prior to each anniversary of the Effective Date of this Agreement, ESSDS and Jazz Pharmaceuticals will meet to review the Services to be performed during the next twelve (12) months (each such meeting, an "Annual Review"). The purpose of each Annual Review is to assess the operational program(s), identify any areas of improvement, and discuss any additional or revised services. The Annual Review is not intended to take the place of regular and ongoing communications between the Parties pursuant to Section 13.2. The Annual Review will take place at a time, location, and method (i.e., in-person or teleconference) mutually determined by the Parties.

13.2 Regular Meetings and Communication. Jazz Pharmaceuticals and ESSDS agree to meet (whether in-person or by teleconference) as necessary, for ESSDS to effectively perform the Services specified in each Work Order hereunder. Jazz Pharmaceuticals and ESSDS agree to meet formally on at least a quarterly basis during the Term to, among other things, discuss performance under the Agreement, strategic planning, and to evaluate the progress being made against objectives established in this Agreement or Work Orders and any enhancements that might be made to the processes set forth herein.

13.3 Non-Disparagement; No Disadvantaging. Neither Party will disparage the other Party or the Product or Services. Notwithstanding the foregoing, the following actions shall not be considered disparaging: (i) the action taken is related to drug interactions with other prescription or over-the-counter drug products, (ii) the action taken is related to contraindications for such Product; (iii) the action taken involves displaying or communicating relative Patient costs or coverage, (iv) or as otherwise may be consistent with ESSDS's independent exercise of the practice of pharmacy in accordance with all Applicable Law.

13.4 Exclusivity and Non-Competition. From the effective date until twelve (12) months after the termination of this agreement, ESSDS will not accept or participate in Services related to products related to oxybate and oxybate salts and their derivatives with any other party without the prior written consent of Jazz Pharmaceuticals. From the effective date until the termination or expiration of the Agreement, ESSDS will not accept or participate in Services related to products indicated for the treatment of cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy.

ARTICLE XIV

GENERAL PROVISIONS

14.1 Amendment. This Agreement may not be amended or modified except by a written instrument signed by both Parties.

14.2 Waiver. A failure by either Party to insist upon strict compliance with any term of this Agreement, to exercise any option, to enforce any right, or to seek any remedy upon any default of the other Party shall not affect, or constitute a waiver of, such Party's right to insist upon strict compliance with that term, to exercise that option, to enforce that right, or to seek that remedy with respect to that default or any prior, contemporaneous, or subsequent default. No custom or practice of the Parties at variance with any provision of this Agreement shall affect, or constitute a waiver of, a Party's right to demand strict compliance with all provisions of this Agreement.

14.3 Assignment. Jazz Pharmaceuticals may assign this Agreement, in whole or in part, to any Affiliate or to a third-party successor to substantially all of the business to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. ESSDS may assign this Agreement, in whole or in part, upon consent of Jazz Pharmaceuticals, such consent not to be unreasonably withheld.

14.4 No Implied Licenses. Except as expressly provided in this Agreement, nothing contained herein shall be deemed to grant either Party any rights or licenses under any Intellectual Property rights of the other Party.

14.5 Entire Agreement. This Agreement (together with all Exhibits and Work Orders hereto incorporated by reference) constitutes the entire agreement between the Parties with respect to the Services and supersedes all prior negotiations, representations or agreements, written or oral, regarding the subject matter hereof, which will remain in full force and effect in accordance with its terms with respect to disclosures made prior to the date hereof. Jazz Pharmaceuticals specifically rejects and will not be bound by any other terms and conditions.

14.6 Tax Liability. ESSDS will be solely responsible for meeting its corporation tax and any applicable social security (or equivalent in any other country, e.g., national insurance obligations) and for enabling that its employees meet their respective income tax and applicable social security obligations (or equivalent in any other country) and all other applicable social insurances. ESSDS shall indemnify and hold harmless Jazz Pharmaceuticals for all taxes, social security or its equivalent and other contributions, costs, claims, penalties, interest, expenses or proceedings which Jazz Pharmaceuticals may incur arising from or in connection with the failure of ESSDS or its employees to meet their respective responsibilities under this Section.

14.7 Relationship of the Parties. ESSDS will be an independent contractor of Jazz Pharmaceuticals, and nothing in this Agreement will be construed to create any partnership, joint venture, agency, or employment relationship between the Parties or between Jazz Pharmaceuticals and the Personnel of ESSDS. ESSDS is and will remain responsible for its respective Personnel and will make no claim against Jazz Pharmaceuticals or its Affiliates for eligibility to participate in any benefits extended by Jazz Pharmaceuticals to its employees. ESSDS will have no authority to act for, bind or commit Jazz Pharmaceuticals or its Affiliates in any way.

14.8 Force Majeure. If the performance of any part of this Agreement by either party shall be affected for any length of time by fire or other casualty, government restrictions, war, riots, strikes, or labor disputes, lock outs, transportation delays, and acts of God, or any such similar causes which are beyond the reasonable control of such Party, such Party shall not be responsible for delay or failure of the performance of this Agreement for such length of time; provided, however, that the obligation of the Parties to pay amounts then due shall not be suspended or delayed; and provided, further, that if ESSDS is precluded from rendering Services for a continuous period in excess of ten (10) business days, Jazz Pharmaceuticals shall be entitled to terminate this agreement upon five (5) days' notice.

14.9 Severability. If any of the provisions or any portion of any provision of this Agreement is held to be unenforceable or invalid by a court or arbitration panel of competent jurisdiction, the validity and enforceability of the enforceable portion of any such provision and/or the remaining provisions will not be affected.

14.10 Governing Law. This Agreement, and any dispute related hereto, will be governed and construed in accordance with the laws of the State of Delaware, excluding any choice of law rules which may direct the application of the laws of another jurisdiction. In the event of any dispute between the Parties, prior to any Party commencing an action for damages, each Party will designate a representative and the representatives will meet in person or telephonically in a good-faith attempt to resolve their differences. Prior to such meeting, the complaining Party will provide a written explanation of the dispute.

14.11 Notices. Any notice delivered to a Party pursuant to this Agreement must be in writing and may be delivered: personally (effective upon receipt); by depositing with a nationally-recognized overnight courier (effective one business day after deposit); or by depositing in the United States Mail, postage prepaid, registered or certified mail, return receipt requested (effective five days after deposit). All notices hereunder will be addressed to the Party at the address indicated below, or at such other address that may have been specified by written notice delivered in accordance with this Section:

If to ESSDS:

Express Scripts, Inc.
c/o Express Scripts Specialty Distribution Services, Inc.
One Express Way,
St. Louis, MO 63121
Attn: Legal Department

with a copy to: Express Scripts Specialty Distribution Services, Inc.
One Express Way,
St. Louis, MO 63121
Attn: General Manager

If to Jazz Pharmaceuticals:

Jazz Pharmaceuticals, Inc.
Attention: Legal Department
3170 Porter Drive
Palo Alto, CA 94304
Email: Jazz_Notices@jazzpharma.com

14.12 Counterparts. This Agreement, any Work Order, and any amendments hereto or thereto, may be executed in counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Facsimile and pdf signatures will be considered original signatures.

14.13 Compliance with Laws. Each Party shall, in its respective performance of this Agreement, take all actions necessary and appropriate to assure that it complies with all applicable federal, state, and local laws and regulations, including, without limitation, the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Public Contracts Anti-Kickback Act (41 U.S.C. § 51 et seq.) and the Stark Law (42 U.S.C. § 1395nn).

14.14 Publicity. Neither Party shall cause or permit the oral or written release of any statement, advertisement, information or publicity referring to the other Party or any of its personnel without such Party's prior written consent.

(Signature Page to Follow)

Intending to be bound by the provisions hereof, each of the parties hereto have caused this Agreement to be executed personally or by its duly authorized representative, to be effective as of the Effective Date.

AGREED TO:

Jazz Pharmaceuticals, Inc.

/s/ Debra S. Feldman

Name: Debra S. Feldman

Title: VP, Pharmacovigilance

Date: 25-Jun-2020

/s/ Ernie Ross

Name: Ernie Ross

Title: VP, U.S. Market Access

Date: 25-Jun-2020

AGREED TO:

Express Scripts Specialty Distribution Services, Inc.

/s/ Joshua B. Parker

Name: Joshua B. Parker

Title: VP

Date: 06/23/2020 | 2:52 PM CDT

Approved as to Legal Form
RPM for JD
6-23-20
Legal Dept.

EXHIBIT A

Trademarks

XYREM® (sodium oxybate)

XYREM REMS Program®

866-XYREM88®

Jazz Pharmaceuticals, Inc.®

Pharmacy Master Services Agreement

EXHIBIT B

ESSDS LOCATIONS

**Express Scripts Building 5
8931 Springdale Ave. Ste. A St. Louis, MO 63134**

**Express Scripts Building 6
4700 North Hanley Rd. St. Louis, MO 63134**

EXHIBIT C

WORK ORDER NO. _____
TO PHARMACY MASTER SERVICES AGREEMENT

This Work Order No. __ (“Work Order __”), dated as of the last date signed below, is made effective _____, 20__ (“Work Order Effective Date”), pursuant to the terms of the Pharmacy Master Services Agreement (“Master Agreement”) effective as of July 1, 2017 between Jazz Pharmaceuticals, Inc. (“Jazz Pharmaceuticals”) and Express Scripts Specialty Distribution Services, Inc. (“ESSDS”), (individually, “Party” and collectively, “Parties”), the terms of which are incorporated herein by reference.

No modification of this Work Order __ will be deemed effective unless in writing and signed by the Parties via a Work Order Modification in accordance with Article II, Section 2 of the Master Agreement. No waiver under this Work Order __ will be effective unless in writing and signed by the Party to be bound and then only to the extent expressly waived in such signed writing.

A. SCOPE OF SERVICES

B. PROGRAM FEES and PASS THROUGH EXPENSES

Accepted and Agreed:

EXPRESS SCRIPTS SPECIALTY DISTRIBUTION SERVICES, INC.

JAZZ PHARMACEUTICALS, INC.

By: _____

By: _____

Signature: _____

Signature: _____

Title: _____

Title: _____

Date: _____

Date: _____

Exhibit A

Scope of Service

Exhibit B

Fees

EXHIBIT D

Service Level Agreements (“SLA”)

This document identifies the expected level of service for certain Services during the Term of the Agreement. The purpose of this SLA is to specify the requirements of certain Services with regards to:

Function	Activity	Measurement	Service Level Commitment
Operations	Inbound Calls to the Call Center across all departments	Average Speed to Answer (ASA)	Monthly ¹ ASA ≤ 40 Seconds for RPH; ≤ 30 Seconds for PSC, RN and Reimbursement
Operations	Inbound Calls to the Call Center across all departments	Inbound call Service Level (SL)	80% of all inbound calls are answered in ≤ 20 seconds Monthly ¹
Operations	Inbound Calls to the Call Center across all departments	Maximum wait time	≥ 99% of all inbound calls will be answered in less than 5 minutes unless caller is proactively offered an automated, or manual, option to receive a returned call without losing his/her place in queue
Operations	Inbound Calls to the Call Center	Inbound Call Abandon Rate	≤ 4% abandon rate Monthly ¹
Customer Experience	Patient Feedback among patients who received shipment	Patient Satisfaction Percentage ²	Greater than or equal to 90% Monthly ¹

¹Excludes the month of January. ESSDS will make commercially reasonable efforts to achieve SLAs for the month of January.

²Patient Satisfaction Percentage is measured by a patient responding with 3, 4, or 5 to the question “*On a scale from 1 - 5 where 1 is Very Dissatisfied and 5 is Very Satisfied, how would you rate your overall experience with your specialty pharmacy?*”

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

1. GENERAL.

The Company, by means of the Plan, seeks to retain the services of its Non-Employee Directors, to secure and retain the services of new Non-Employee Directors and to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate by giving them an opportunity to benefit from increases in value of the Ordinary Shares through the grant of Stock Awards. The Plan is also intended to provide a source of Ordinary Shares to be used to pay distributions under the Company's Directors Deferred Compensation Plan, but only to the extent such Ordinary Shares were credited prior to August 15, 2010 to a Non-Employee Director's stock account pursuant to the Company's Directors Deferred Compensation Plan.

2. ADMINISTRATION.

(a) Administration by Board. The Board shall administer the Plan. The Board may not delegate administration of the Plan.

(b) Powers of Board. The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time (A) which of the Non-Employee Directors eligible under the Plan shall be granted Stock Awards; (B) when and how each Stock Award shall be granted; (C) what type or combination of types of Stock Award shall be granted; (D) the provisions of each Stock Award granted (which need not be identical); (E) the number of Ordinary Shares with respect to which each Stock Award shall be granted; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To determine the provisions of each Stock Award to the extent not specified in the Plan.

(iii) To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.

(iv) To amend the Plan or a Stock Award as provided in Section 10.

(v) To terminate or suspend the Plan as provided in Section 11.

(vi) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan.

(c) **Effect of Board's Decision.** All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

(d) **Cancellation and Re-Grant of Stock Awards.** The Board shall not have the authority to (i) reduce the exercise or strike price of any outstanding Option or SAR or (ii) cancel any outstanding Option or SAR that has an exercise or strike price (per share) greater than the then-current Fair Market Value of the Ordinary Shares in exchange for cash or other Stock Awards under the Plan, unless the shareholders of the Company have approved such an action within 12 months prior to such an event.

3. SHARES SUBJECT TO THE PLAN.

(a) **Share Reserve.** Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate number of Ordinary Shares that may be issued under the Plan shall not exceed the sum of the following:

(i) two hundred thousand (200,000) Ordinary Shares (which were approved as of the Effective Date);

(ii) an automatic annual increase beginning on January 1, 2008 and ending on (and including) January 1, 2016, in an amount equal to the sum of (A) the excess of (x) the number of Ordinary Shares subject to Options granted during the preceding calendar year, over (y) the number of Ordinary Shares added back to the share reserve during the preceding calendar year pursuant to the provisions of Section 3(b), plus (B) for the automatic annual increases occurring on or prior to January 1, 2010 only, the aggregate number of Ordinary Shares credited to the Non-Employee Directors' stock accounts pursuant to the Company's Directors Deferred Compensation Plan during the applicable preceding calendar year; *provided, however*, that such automatic annual increase shall not exceed two hundred thousand (200,000) Ordinary Shares; and

(iii) five hundred thousand (500,000) Ordinary Shares (which were approved at the Company's 2020 annual general meeting of shareholders).

For the avoidance of doubt, no Ordinary Shares credited to the Non-Employee Directors' stock accounts pursuant to the Company's Directors Deferred Compensation Plan on or after August 15, 2010 shall act to increase the share reserve under this Section 3(a). Notwithstanding the foregoing, for purposes of Section 3(a)(ii), the Board may act prior to the first day of any calendar year, to provide that there shall be no increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year shall be a lesser number of Ordinary Shares than would otherwise occur pursuant to Section 3(a)(ii).

(b) Reversion of Shares to the Share Reserve. If a Stock Award shall for any reason expire or otherwise terminate, in whole or in part, without all of the Ordinary Shares covered by such Stock Award having been issued, the Ordinary Shares not acquired under such Stock Award shall revert to and again become available for issuance under the Plan. If any Ordinary Shares subject to a Stock Award are not delivered to an Awardholder because such Ordinary Shares are withheld for the payment of taxes, the number of Ordinary Shares that are not delivered to the Awardholder shall remain available for issuance under the Plan. If the exercise price of a Stock Award is satisfied by tendering Ordinary Shares held by the Awardholder (either by actual delivery or attestation), then the number of Ordinary Shares so tendered shall remain available for issuance under the Plan.

(c) Payment Shares. Subject to the overall limitation in Section 3(a) on the number of Ordinary Shares that may be issued pursuant to Stock Awards, Ordinary Shares may be used as the form of payment for distributions under the Company's Directors Deferred Compensation Plan but only to the extent such Ordinary Shares were credited prior to August 15, 2010 to a Non-Employee Director's stock account pursuant to the Company's Directors Deferred Compensation Plan.

(d) Source of Shares. The shares issuable under the Plan shall be authorized but unissued or reacquired Ordinary Shares, including Ordinary Shares repurchased by the Company or any Affiliate on the open market or otherwise.

4. ELIGIBILITY.

The persons eligible to receive Stock Awards are the Non-Employee Directors of the Company.

5. OPTION AND SAR PROVISIONS.

Each Option or SAR shall be in such form and shall contain such terms and conditions as required by the Plan. Each Option and SAR shall contain such additional terms and conditions, not inconsistent with the Plan, as the Board shall deem appropriate. Each Option and SAR shall include (through incorporation of provisions hereof by reference in the applicable Stock Award or otherwise) the substance of each of the following provisions:

(a) Term. No Option or SAR shall be exercisable after the expiration of ten (10) years from the date it was granted.

(b) Exercise Price. The exercise price (or strike price) of each Option or SAR shall be one hundred percent (100%) of the Fair Market Value of the Ordinary Shares subject to the Option or SAR on the date the Option or SAR is granted, provided that in all cases the exercise price (or strike price) is not less than the nominal value of an Ordinary Share. Each SAR will be denominated in Ordinary Share equivalents.

(c) Consideration for Options. The purchase price of Ordinary Shares acquired pursuant to an Option may be paid, to the extent permitted by applicable law, in any combination

of the following; *provided, however*, that where Ordinary Shares are issued pursuant to the exercise of an Option the nominal value of each newly issued Ordinary Share is fully paid up: (i) cash or check, (ii) delivery to the Company (either by actual delivery or attestation) of Ordinary Shares, or (iii) to the extent permitted by law, pursuant to a program developed under Regulation T as promulgated by the 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.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Awardholder must provide written notice of exercise to the Company in compliance with the provisions of the Award Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of Ordinary Shares equal to the number of Ordinary Share equivalents in which the Awardholder is vested under such SAR, and with respect to which the Awardholder is exercising the SAR on such date, over (B) the strike price that will be determined by the Board at the time of grant of the SAR. The appreciation distribution in respect to a SAR may be paid in Ordinary Shares, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR; *provided, however*, that where Ordinary Shares are issued pursuant to a SAR the nominal value of each newly issued Ordinary Share is fully paid up.

(e) Transferability. Except as otherwise provided for in this Section 5(e), an Option or SAR shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable only by the Awardholder during the life of the Awardholder. However, an Option or SAR may be transferred for no consideration upon written consent of the Board if (i) at the time of transfer, a Form S-8 registration statement under the Securities Act is available for the issuance of Ordinary Shares by the Company upon the exercise of such transferred Option or SAR, or (ii) the transfer is to the Awardholder's employer at the time of transfer or an affiliate of the Awardholder's employer at the time of transfer. Any such transfer is subject to such limits as the Board may establish, and subject to the transferee agreeing to remain subject to all the terms and conditions applicable to the Option or SAR prior to such transfer. The forgoing right to transfer the Option or SAR shall apply to the right to consent to amendments to the Award Agreement for such Option or SAR. In addition, until the Awardholder transfers the Option or SAR, an Awardholder may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the death of the Awardholder, shall thereafter be entitled to exercise the Option or SAR.

(f) Vesting. The total number of Ordinary Shares subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of Ordinary Shares as to which an Option or SAR may be exercised.

(g) Early Exercise. The Option may, but need not, include a provision whereby the Optionholder may elect at any time before the Optionholder's Continuous Service terminates to exercise the Option as to any part or all of the Ordinary Shares subject to the Option prior to the full vesting of the Option. Any unvested Ordinary Shares so purchased may be subject to a repurchase option in favor of the Company or any Affiliate or to any other restriction the Board determines to be appropriate. The Company or Affiliate will not exercise its repurchase option until at least six (6) months (or such longer or shorter period of time required to avoid classification of the Option as a liability for financial accounting purposes) have elapsed following exercise of the Option unless the Board otherwise specifically provides in the Option.

(h) Termination of Continuous Service. In the event that an Awardholder's Continuous Service terminates (other than upon the Awardholder's death or Disability or upon a Change in Control), the Awardholder may exercise his or her Option or SAR (to the extent that the Awardholder was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Awardholder's Continuous Service, or (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Awardholder does not exercise his or her Option or SAR within the time specified herein or in the Award Agreement (as applicable), the Option or SAR shall terminate.

(i) Extension of Termination Date. If the exercise of an Option or SAR following the termination of the Awardholder's Continuous Service (other than upon the Awardholder's death or Disability or upon a Change in Control) would be prohibited at any time solely because the issuance of Ordinary Shares would violate the registration requirements under the Securities Act, then the Option or SAR shall terminate on the earlier of (i) the expiration of a period of three (3) months after the termination of the Awardholder's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement.

(j) Disability of Awardholder. In the event that an Awardholder's Continuous Service terminates as a result of the Awardholder's Disability, the Awardholder may exercise his or her Option or SAR (to the extent that the Awardholder was entitled to exercise it as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service, or (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination, the Awardholder does not exercise his or her Option or SAR within the time specified herein or in the Award Agreement, the Option or SAR shall terminate.

(k) Death of Awardholder. In the event that (i) an Awardholder's Continuous Service terminates as a result of the Awardholder's death, or (ii) the Awardholder dies within the three (3)-month period after the termination of the Awardholder's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Awardholder was entitled to exercise such Option or SAR as of the date of death) by the Awardholder's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance, or

by a person designated to exercise the Option or SAR upon the Awardholder's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death, or (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Awardholder's death, the Option or SAR is not exercised within the time specified herein, the Option or SAR shall terminate.

(l) Termination Upon Change in Control. In the event that an Awardholder's Continuous Service terminates as of, or within twelve (12) months following a Change in Control, the Awardholder may exercise his or her Option or SAR (to the extent that the Awardholder was entitled to exercise such Option or SAR as of the date of termination of Continuous Service) within such period of time ending on the earlier of (i) the date twelve (12) months following the effective date of the Change in Control, or (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Awardholder does not exercise his or her Option or SAR within the time specified herein or in the Award Agreement (as applicable), the Option or SAR shall terminate.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARs.

(a) Restricted Stock Awards. Each Award Agreement evidencing a Restricted Stock Award shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. To the extent consistent with the Company's Bylaws, at the Board's election, Ordinary Shares may be (i) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (ii) evidenced by a certificate, which certificate shall be held in such form and manner as determined by the Board. The terms and conditions of such Award Agreements may change from time to time, and the terms and conditions of separate Award Agreements need not be identical; *provided, however*, that each Award Agreement for a Restricted Stock Award shall conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law; *provided, however*, that where Ordinary Shares are issued pursuant to a Restricted Stock Award the nominal value of each newly issued Ordinary Share is fully paid up.

(ii) Vesting. Ordinary Shares awarded under an Award Agreement for a Restricted Stock Award may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Continuous Service. If an Awardholder's Continuous Service terminates, the Company or any Affiliate may receive through a forfeiture condition or a repurchase right any or all of the Ordinary Shares held by the Awardholder that have not vested as of the date of termination of Continuous Service under the terms of the Award Agreement for a Restricted Stock Award.

(iv) Transferability. Rights to acquire Ordinary Shares under the Award Agreement for a Restricted Stock Award shall be transferable by the Awardholder only upon such terms and conditions as are set forth in the Award Agreement for such Restricted Stock Award, as the Board shall determine in its sole discretion, so long as the Ordinary Shares awarded under the Award Agreement remain subject to the terms of the Award Agreement.

(v) Dividends. An Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the Ordinary Shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Award Agreement for a Restricted Stock Unit Award shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of such Award Agreements may change from time to time, and the terms and conditions of separate Award Agreements need not be identical; *provided, however*, that each Award Agreement for a Restricted Stock Unit Award shall conform to (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid upon delivery of each Ordinary Share subject to the Restricted Stock Unit Award. The consideration to be paid (if any) for each Ordinary Share subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law; *provided, however*, that where Ordinary Shares are issued pursuant to a Restricted Stock Unit Award the nominal value of each newly issued Ordinary Share is fully paid up.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of Ordinary Shares, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Award Agreement for such Restricted Stock Unit Award.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the Ordinary Shares (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of Ordinary Shares covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional Ordinary Shares covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional Ordinary Shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will

be subject to all of the same terms and conditions of the underlying Award Agreement to which they relate.

(vi) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Awardholder's termination of Continuous Service.

(c) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Ordinary Shares, including the appreciation in value thereof (e.g., options or share rights with an exercise price or strike price less than 100% of the Fair Market Value of the Ordinary Shares at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of Ordinary Shares (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards; *provided, however*, that where Ordinary Shares are issued pursuant to an Other Stock Award the nominal value of each newly issued Ordinary Share is fully paid up.

7. COVENANTS OF THE COMPANY.

(a) Availability of Shares. During the terms of the Stock Awards, the Company shall keep available at all times the number of Ordinary Shares required to satisfy such Stock Awards.

(b) Securities Law Compliance. The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell Ordinary Shares upon exercise of the Stock Awards; *provided, however*, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Ordinary Shares issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Ordinary Shares under the Plan, the Company shall be relieved from any liability for failure to issue and sell Ordinary Shares upon exercise of such Stock Awards unless and until such authority is obtained. A Non-Employee Director shall not be eligible for the grant of a Stock Award or the subsequent issuance of Ordinary Shares pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.

8. MISCELLANEOUS.

(a) Use of Proceeds. Proceeds from the sale of Ordinary Shares pursuant to Stock Awards shall constitute general funds of the Company.

(b) Shareholder Rights. No Awardholder shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any Ordinary Shares subject to such Stock Award unless and until (i) such Awardholder has satisfied all requirements for exercise of the

Stock Award pursuant to its terms, if applicable, and (ii) the issuance of the Ordinary Shares subject to such Stock Award has been entered into the books and records of the Company.

(c) No Service Rights. Nothing in the Plan, any instrument executed, or Stock Award granted pursuant thereto shall confer upon any Awardholder any right to continue to serve the Company as a Non-Employee Director or shall affect the right of the Company or an Affiliate to terminate the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(d) Investment Assurances. The Company may require an Awardholder, as a condition of exercising or acquiring Ordinary Shares under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Awardholder's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Awardholder is acquiring the Ordinary Shares subject to the Stock Award for the Awardholder's own account and not with any present intention of selling or otherwise distributing the Ordinary Shares. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (i) the issuance of the Ordinary Shares upon the exercise or acquisition of Ordinary Shares under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (ii) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on share certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Ordinary Shares.

(e) Withholding Obligations. The Awardholder may satisfy any federal, state, local or foreign tax withholding obligation relating to the exercise or acquisition of Ordinary Shares under a Stock Award by any of the following means (in addition to the Company's right to withhold from any compensation paid to the Awardholder by the Company) or by a combination of such means: (i) tendering a cash payment; (ii) authorizing the Company to withhold Ordinary Shares from the Ordinary Shares otherwise issuable to the Awardholder as a result of the exercise or acquisition of Ordinary Shares under the Stock Award; *provided, however*, that no Ordinary Shares are withheld with a value exceeding the maximum amount of tax that may be required to be withheld by law (or such other amount as may be permitted while still avoiding classification of the Stock Award as a liability for financial accounting purposes); (iii) delivering to the Company owned and unencumbered Ordinary Shares; or (iv) by such other method as may be set forth in the Award Agreement.

(f) Electronic Delivery. Any reference herein to a “written” agreement or document shall include any agreement or document delivered electronically or posted on the Company’s intranet.

9. ADJUSTMENTS UPON CHANGES IN ORDINARY SHARES; CORPORATE TRANSACTIONS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall proportionately and appropriately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities by which the share reserve is to increase automatically each year pursuant to Section 3(a), and (iii) the class(es) and number of securities and price per Ordinary Share subject to outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

(b) Dissolution or Liquidation. In the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding Ordinary Shares not subject to a forfeiture condition or the Company’s right of repurchase) shall terminate immediately prior to the completion of such dissolution or liquidation, and any Ordinary Shares subject to the Company’s repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service.

(c) Corporate Transaction.

(i) Stock Awards May Be Assumed. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation’s parent company) may assume or continue any or all Stock Awards outstanding under the Plan or may substitute similar stock awards for Stock Awards outstanding under the Plan (including but not limited to, stock awards to acquire the same consideration paid to the shareholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company or any Affiliate in respect of Ordinary Shares issued pursuant to Stock Awards may be assigned by the Company to the successor of the Company (or the successor’s parent company, if any), in connection with such Corporate Transaction. A surviving corporation or acquiring corporation may choose to assume or continue only a portion of a Stock Award or substitute a similar stock award for only a portion of a Stock Award.

(ii) Stock Awards Held by Active Awardholders. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Stock Awards or substitute similar stock awards for such outstanding Stock Awards, then with respect to Stock Awards that have not been assumed, continued or substituted and that are held by Awardholders whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction (referred to as the “**Active Awardholders**”), the vesting of such Stock Awards (and, if applicable, the time at which such Stock Awards may be exercised) shall (contingent upon the effectiveness of the Corporate Transaction) be accelerated in full to a date prior to the effective time of such Corporate

Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective time of the Corporate Transaction), and the Stock Awards shall terminate if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and any reacquisition or repurchase rights held by the Company or any Affiliate with respect to such Stock Awards shall lapse (contingent upon the effectiveness of the Corporate Transaction).

(iii) Stock Awards Held by Former Awardholders. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Stock Awards or substitute similar stock awards for such outstanding Stock Awards, then with respect to any other Stock Awards that have not been assumed, continued or substituted and that are held by persons other than Active Awardholders, the vesting of such Stock Awards (and, if applicable, the time at which such Stock Awards may be exercised) shall not be accelerated unless otherwise provided in Section 9(d) or in a written agreement between the Company or any Affiliate and the holder of such Stock Awards, and such Stock Awards shall terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction; *provided, however*, that any reacquisition or repurchase rights held by the Company or any Affiliate with respect to such Stock Awards shall not terminate and may continue to be exercised notwithstanding the Corporate Transaction.

(iv) Payment for Stock Awards in Lieu of Exercise. Notwithstanding the foregoing, in the event a Stock Award will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the holder of such Stock Award may not exercise such Stock Award but will receive a payment, in such form as may be determined by the Board, equal in value to the excess, if any, of (i) the value of the property the holder of the Award would have received upon the exercise of the Stock Award, over (ii) the exercise price payable by the Awardholder in connection with such exercise.

(d) Change in Control. In the event that an Awardholder (i) is required to resign his or her position as a Non-Employee Director as a condition of a Change in Control, or (ii) is removed from his or her position as a Non-Employee Director in connection with a Change in Control, the outstanding Stock Awards held by such Awardholder 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).

(e) Parachute Payments.

(i) If the acceleration of the vesting and exercisability of Stock Awards provided for in Sections 9(c) and 9(d), together with payments and other benefits of an Awardholder, (collectively, the “**Payment**”) (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, or any comparable successor provisions, and (ii) but for this Section 9(e) would be subject to the excise tax imposed by Section 4999 of the Code, or any comparable successor provisions (the “**Excise Tax**”), then such Payment shall be either (1) provided to such Awardholder in full, or (2) provided to such Awardholder as to such lesser extent that would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, when taking into account applicable federal, state, local and

foreign income and employment taxes, the Excise Tax, and any other applicable taxes, results in the receipt by such Awardholder, on an after-tax basis, of the greatest amount of the Payment, notwithstanding that all or some portion of the Payment may be subject to the Excise Tax.

(ii) Unless the Company and such Awardholder otherwise agree in writing, any determination required under this Section 9(e) shall be made in writing in good faith by the Accountant. If a reduction in the Payment is to be made as provided above, reduction shall occur in the manner that results in the greatest economic benefit for Awardholder.

(iii) For purposes of making the calculations required by this Section 9(e), the Accountant may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Code and other applicable legal authority. The Company and the Awardholder shall furnish to the Accountant such information and documents as the Accountant may reasonably request in order to make such a determination. The Company shall bear all costs the Accountant may reasonably incur in connection with any calculations contemplated by this Section 9(e).

(iv) If, notwithstanding any reduction described above, the Internal Revenue Service (the “**IRS**”) determines that the Awardholder is liable for the Excise Tax as a result of the Payment, then the Awardholder shall be obligated to pay back to the Company, within thirty (30) days after a final IRS determination or, in the event that the Awardholder challenges the final IRS determination, a final judicial determination, a portion of the Payment (the “**Repayment Amount**”). The Repayment Amount with respect to the Payment shall be the smallest such amount, if any, as shall be required to be paid to the Company so that the Awardholder’s net after-tax proceeds with respect to the Payment (after taking into account the payment of the Excise Tax and all other applicable taxes imposed on the Payment) shall be maximized. The Repayment Amount with respect to the Payment shall be zero if a Repayment Amount of more than zero would not result in the Awardholder’s net after-tax proceeds with respect to the Payment being maximized. If the Excise Tax is not eliminated pursuant to this paragraph, the Awardholder shall pay the Excise Tax.

(v) Notwithstanding any other provision of this Section 9(e), if (i) there is a reduction in the Payment as described above, (ii) the IRS later determines that the Awardholder is liable for the Excise Tax, the payment of which would result in the maximization of the Awardholder’s net after-tax proceeds of the Payment (calculated as if the Payment had not previously been reduced), and (iii) the Awardholder pays the Excise Tax, then the Company shall pay or otherwise provide to the Awardholder that portion of the Payment that was reduced pursuant to this Section 9(e) contemporaneously or as soon as administratively possible after the Awardholder pays the Excise Tax so that the Awardholder’s net after-tax proceeds with respect to the Payment are maximized.

(vi) If the Awardholder either (i) brings any action to enforce rights pursuant to this Section 9(e), or (ii) defends any legal challenge to his or her rights under this Section 9(e), the Awardholder shall be entitled to recover attorneys’ fees and costs incurred in connection with such action, regardless of the outcome of such action; *provided, however*, that if such action is commenced by the Awardholder, the court finds that the action was brought in good faith.

10. AMENDMENT OF THE PLAN AND STOCK AWARDS.

(a) Amendment of Plan. Subject to the limitations, if any, of applicable law, the Board, at any time and from time to time, may amend the Plan. However, except as provided in Section 9(a) relating to Capitalization Adjustments, no amendment shall be effective unless approved by the shareholders of the Company to the extent shareholder approval is necessary to satisfy applicable law.

(b) Shareholder Approval. The Board, in its sole discretion, may submit any other amendment to the Plan for shareholder approval.

(c) No Impairment of Rights. Rights under any Stock Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (i) the Company requests the consent of the affected Awardholder, and (ii) such Awardholder consents in writing.

(d) Amendment of Stock Awards. The Board, at any time and from time to time, may amend the terms of any one or more Stock Awards; *provided, however*, that the rights under any Stock Award shall not be impaired by any such amendment unless (i) the Company requests the consent of the Awardholder, and (ii) the Awardholder consents in writing.

11. TERMINATION OR SUSPENSION OF THE PLAN.

(a) Plan Term. The Board may suspend or terminate the Plan at any time. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) No Impairment of Rights. Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the Awardholder.

12. EFFECTIVE DATE OF PLAN.

The Plan became effective on May 31, 2007.

13. CHOICE OF LAW.

The law of the state of Delaware shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

14. DEFINITIONS.

As used in the Plan, the following definitions shall apply to the capitalized terms indicated below:

(a) "Accountant" means the independent public accountants of the Company.

(b) “**Affiliate**” means, at the time of determination, any “parent” or “subsidiary” of the Company as such terms are defined in Rule 405 of the Securities Act and any “holding company” or “subsidiary” of the Company as such terms are defined in Section 8 and 7 respectively of the Companies Act. The Board shall have the authority to determine the time or times at which “parent” or “subsidiary” status is determined within the foregoing definition.

(c) “**Award Agreement**” means a written agreement between the Company and a Non-Employee Director evidencing the terms and conditions of a Stock Award grant. Each Award Agreement shall be subject to the terms and conditions of the Plan.

(d) “**Awardholder**” means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(e) “**Board**” means the Board of Directors of the Company.

(f) “**Capitalization Adjustment**” means any change that is made in, or other events that occur with respect to, the Ordinary Shares subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, share dividend, dividend in property other than cash, large nonrecurring cash dividend, share split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto), including, for the avoidance of doubt, capitalization of profits or reserves, capital distribution, rights issue, the conversion of one class of share to another or reduction of capital or otherwise. Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a Capitalization Adjustment.

(g) “**Change in Control**” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than thirty percent (30%) of the combined voting power of the Company’s then outstanding securities. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur on account of the acquisition of securities of the Company directly from the Company;

(ii) there is consummated a compromise or arrangement sanctioned by the Irish courts under the Companies Act, a scheme, contract or offer which has become binding on all shareholders of the Company pursuant to Section 457 of the Companies Act or a bid pursuant to Regulation 23 or 24 of the European Communities (Takeover Bids (Directive 2004/25/EC)) Regulations 2006 (as may be amended, updated or replaced from time to time), an offer or reverse takeover transaction which has been completed pursuant to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013, or a reorganization, merger, statutory share exchange, consolidation or similar transaction involving (directly or indirectly) the Company (each, a “**Business Combination**”) and (A) immediately after the consummation of such Business Combination, the

shareholders of the Company immediately prior thereto do not Own, directly or indirectly, either outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity or ultimate parent of the surviving Entity in such Business Combination in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such Business Combination, (B) an Exchange Act Person becomes the Owner, directly or indirectly, of securities representing more than thirty percent (30%) of the combined voting power of the surviving Entity or ultimate parent of the surviving Entity through the Business Combination, or (C) at least a majority of the members of the board of directors of the ultimate parent (or if there is no parent, the surviving Entity) immediately following such Business Combination were not Incumbent Board Members (as defined below) at the time the Board approved the execution of the definitive agreement providing for such Business Combination;

(iii) the shareholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by shareholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, exclusive license or other disposition; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the “**Incumbent Board Members**”) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the Incumbent Board Members then still in office, such new member shall, for purposes of the Plan, be considered as an Incumbent Board Member, but excluding for purposes of the Plan any such individual whose initial assumption of office occurs as a result of either an actual or threatened election contest or other actual or threatened solicitation of proxies or consents by or on behalf of any person or Entity other than the Board.

Notwithstanding the foregoing or any other provision of the Plan, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Awardholder shall supersede the foregoing definition with respect to Stock Awards subject to such agreement; *provided, however*, that (1) if no definition of Change in Control (or any analogous term) is set forth in such an individual written agreement, the foregoing definition shall apply, and (2) no Change in Control (or any analogous term) shall be deemed to occur with respect to Stock Awards subject to such an individual written agreement without a requirement that the Change in Control (or any analogous term) actually occur.

The Board may, in its sole discretion and without an Awardholder's consent, amend the definition of "Change in Control" to conform to the definition of "Change in Control" under Section 409A of the Code, and the regulations thereunder.

(h) "**Code**" means the Internal Revenue Code of 1986, as amended.

(i) "**Companies Act**" means the Companies Act 2014 of Ireland, together with all statutory modifications and re-enactments thereof and all statutes and statutory instruments which are to be read as one with, or construed or read together as one with, the aforementioned enactments and every statutory modification and re-enactment thereof for the time being in force.

(j) "**Company**" means:

(i) prior to a Change in Control, Jazz Pharmaceuticals plc; and

(ii) on or after a Change in Control, (A) Jazz Pharmaceuticals plc in the event that the surviving Entity resulting from a Change in Control is Jazz Pharmaceuticals plc, (B) the surviving Entity resulting from a Change in Control in the event that such surviving Entity is not Jazz Pharmaceuticals plc, (C) any Entity to which the assets of Jazz Pharmaceuticals plc and its Subsidiaries are sold, leased, exclusively licensed or otherwise disposed of in the event of a Change in Control under Section 14(g)(iv), or (D) any other successor to Jazz Pharmaceuticals plc in the event of a Change in Control, as applicable;

provided, however, that in the event Jazz Pharmaceuticals plc completes a reorganization that is not in connection with a Change in Control that results in Jazz Pharmaceuticals plc no longer being the ultimate parent company and reporting company under the Exchange Act, then "Company" means the ultimate parent that directly or indirectly holds Jazz Pharmaceuticals plc.

(k) "**Consultant**" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the Board of Directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, shall not cause a Director to be considered a "Consultant" for purposes of the Plan.

(l) "**Continuous Service**" means that the Awardholder's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Awardholder renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Awardholder renders such service, provided that there is no interruption or termination of the Awardholder's service with the Company or an Affiliate, shall not terminate an Awardholder's Continuous Service; *provided, however*, if the corporation for which an Awardholder is rendering service ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Awardholder's Continuous Service shall be considered to have terminated on the date such corporation ceases to qualify as an Affiliate. For example, a change in status from a Non-Employee Director of the Company to a Consultant of an Affiliate or an Employee of the Company will not constitute an interruption of Continuous Service. To the extent permitted by

law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal leave. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's leave of absence policy or in the written terms of the Awardholder's leave of absence.

(m) "**Corporate Transaction**" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

- (i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;
 - (ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;
 - (iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation;
- or
- (iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the Ordinary Shares outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

For the avoidance of doubt, any one or more of the above events may be effected pursuant to a compromise or arrangement sanctioned by the Irish courts under the Companies Act, a scheme, contract or offer which has become binding on all shareholders of the Company pursuant to Section 457 of the Companies Act or a bid pursuant to Regulation 23 or 24 of the European Communities (Takeover Bids (Directive 2004/25/EC)) Regulations 2006 (as may be amended, updated or replaced from time to time), or an offer or reverse takeover transaction which has been completed pursuant to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013.

(n) "**Director**" means a member of the Board.

(o) "**Disability**" means, with respect to an Awardholder, the inability of such Awardholder to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, as provided in Section 22(e)(3) and 409A(a)(2)(c)(i) of the Code.

(p) "**Effective Date**" means May 31, 2007.

(q) "**Employee**" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an "Employee" for purposes of the Plan.

(r) “**Entity**” means a corporation, partnership, limited liability company or other entity.

(s) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

(t) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” shall not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, or (iv) an Entity Owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their Ownership of shares of the Company.

(u) “**Fair Market Value**” means, as of any date, the value of the Ordinary Shares determined as follows:

(i) If the Ordinary Shares are listed on any established stock exchange or traded on the Nasdaq Global Select Market or the Nasdaq Global Market, the Fair Market Value of an Ordinary Share shall be the closing sales price for such Ordinary Share (or the closing bid, if no sales were reported) as quoted on such exchange (or the exchange or market with the greatest volume of trading in the Ordinary Shares) on the date of determination, as reported in *The Wall Street Journal* or such other source as the Board deems reliable.

(ii) If the Ordinary Shares are listed or traded on the Nasdaq Capital Market, the Fair Market Value of an Ordinary Share shall be the mean between the bid and asked prices for the Ordinary Shares on the date of determination, as reported in *The Wall Street Journal* or such other source as the Board deems reliable. Unless otherwise provided by the Board, if there is no closing sales price (or closing bid if no sales were reported) for the Ordinary Shares on the date of determination, then the Fair Market Value shall be the mean between the bid and asked prices for the Ordinary Shares on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Ordinary Shares, the Fair Market Value shall be determined by the Board in good faith and in a manner that complies with Section 409A of the Code.

(v) “**Non-Employee Director**” means a Director who is not an Employee.

(w) “**Nonstatutory Stock Option**” means an Option not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(x) “**Officer**” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(y) “**Option**” means a Nonstatutory Stock Option granted pursuant to the Plan.

(z) “**Optionholder**” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(aa) “**Ordinary Share**” or “**Ordinary Shares**” means the ordinary shares of the Company of nominal value US\$0.0001 per share.

(bb) “**Other Stock Award**” means an award based in whole or in part by reference to the Ordinary Shares which is granted pursuant to the terms and conditions of Section 6(c).

(cc) “**Own,**” “**Owned,**” “**Owner,**” “**Ownership**” A person or Entity shall be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(dd) “**Plan**” means this Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan.

(ee) “**Restricted Stock Award**” means an award of Ordinary Shares which is granted pursuant to the terms and conditions of Section 6(a).

(ff) “**Restricted Stock Unit Award**” means a right to receive Ordinary Shares which is granted pursuant to the terms and conditions of Section 6(b).

(gg) “**Rule 16b-3**” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(hh) “**Securities Act**” means the Securities Act of 1933, as amended.

(ii) “**Subsidiary**” means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other Entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

(jj) “**Stock Appreciation Right**” or “**SAR**” means a right to receive the appreciation on Ordinary Shares that is granted pursuant to the terms and conditions of Section 5.

(kk) “**Stock Award**” means any right to receive Ordinary Shares granted under the Plan, including a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right or any Other Stock Award.

Adopted by the Board of Directors of Jazz Pharmaceuticals, Inc. on May 1, 2007.

Approved by the stockholders of Jazz Pharmaceuticals, Inc. on May 9, 2007.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals, Inc. on August 11, 2010.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals, Inc. on October 24, 2011.

Adopted by the Board of Directors of Azur Pharma plc on December 21, 2011.

Approved by the shareholders of Azur Pharma plc on January 3, 2012.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on May 5, 2016.

Approved by the shareholders of Jazz Pharmaceuticals plc on August 4, 2016.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on November 3, 2016.

Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on April 30, 2020.

Approved by the shareholders of Jazz Pharmaceuticals plc on July 30, 2020.

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: August 4, 2020

By:

/s/ Renée Galá

Renée Galá
Executive Vice President and Chief Financial Officer

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 June 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: August 4, 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.