Jazz Pharmaceuticals plc
Form 10-Q
November 06, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
ý Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2018
or
¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to
Commission File Number: 001-33500
JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

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

Fifth Floor, Waterloo Exchange,
Waterloo Road, Dublin 4, Ireland
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý 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 ý 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	ý	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	¨
Emerging growth company	¨		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý

As of October 31, 2018, 60,321,590 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

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JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2018

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We own or have rights to various copyrights, trademarks and trade names used in our business in the U.S. and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase®, Defitelio® (defibrotide sodium), Defitelio® (defibrotide), CombiPlex®, Vyxeos® (daunorubicin and cytarabine) liposome for injection and Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion. This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 499,018	$ 386,035
Investments	565,000	215,000
Accounts receivable, net of allowances	279,437	224,129
Inventories	43,435	43,245
Prepaid expenses	23,189	23,182
Other current assets	54,310	76,686
Total current assets	1,464,389	968,277
Property, plant and equipment, net	198,053	170,080
Intangible assets, net	2,787,281	2,979,127
Goodwill	932,422	947,537
Deferred tax assets, net	37,582	34,559
Deferred financing costs	10,058	7,673
Other non-current assets	56,003	16,419
Total assets	$ 5,485,788	$ 5,123,672
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 37,373	$ 24,368
Accrued liabilities	257,453	198,779
Current portion of long-term debt	33,387	40,605
Income taxes payable	7,139	21,577
Deferred revenue	5,935	8,618
Total current liabilities	341,287	293,947
Deferred revenue, non-current	10,934	16,115
Long-term debt, less current portion	1,560,582	1,540,433
Deferred tax liabilities, net	337,021	383,472
Other non-current liabilities	208,647	176,608
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	472	472
Additional paid-in capital	2,078,032	1,935,486
Accumulated other comprehensive loss	(179,466)	(140,878)
Retained earnings	1,128,218	917,956
Total shareholders' equity	3,027,317	2,713,097
Total liabilities and shareholders' equity	$ 5,485,788	$ 5,123,672

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$465,197	$407,971	$1,402,139	$1,171,304
Royalties and contract revenues	4,176	3,884	12,326	10,990
Total revenues	469,373	411,855	1,414,465	1,182,294
Operating expenses:				
Cost of product sales (excluding amortization of intangible assets)	26,574	31,203	95,207	84,940
Selling, general and administrative	155,873	124,523	521,665	401,106
Research and development	51,160	47,362	169,959	132,447
Intangible asset amortization	46,989	47,313	154,955	99,164
Impairment charges	—	—	42,896	—
Acquired in-process research and development	—	75,000	—	77,000
Total operating expenses	280,596	325,401	984,682	794,657
Income from operations	188,777	86,454	429,783	387,637
Interest expense, net	(18,920)	(19,192)	(59,171)	(56,330)
Foreign exchange loss	(756)	(2,224)	(5,181)	(9,115)
Loss on extinguishment and modification of debt	—	—	(1,425)	—
Income before income tax provision and equity in loss of investees	169,101	65,038	364,006	322,192
Income tax provision	19,348	1,239	75,018	65,914
Equity in loss of investees	437	273	1,360	637
Net income	$149,316	$63,526	$287,628	$255,641
Net income per ordinary share:				
Basic	$2.47	$1.06	$4.78	$4.26
Diluted	$2.41	$1.03	$4.68	$4.17
Weighted-average ordinary shares used in per share calculations - basic	60,476	60,108	60,196	60,030
Weighted-average ordinary shares used in per share calculations - diluted	61,857	61,436	61,493	61,360

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income	$149,316	$63,526	$287,628	$255,641
Other comprehensive income (loss):				
Foreign currency translation adjustments	(11,984)	50,870	(43,945)	159,302
Unrealized gain (loss) on hedging activities, net of tax expense (benefit) of $107, $56, $758 and ($137), respectively	746	392	5,304	(956)
Other comprehensive income (loss)	(11,238)	51,262	(38,641)	158,346
Total comprehensive income	$138,078	$114,788	$248,987	$413,987

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

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

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net income	$287,628	$255,641
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	154,955	99,164
Share-based compensation	75,718	79,579
Impairment charges	42,896	—
Depreciation	11,363	9,288
Acquired in-process research and development	—	77,000
Loss on disposal of assets	652	360
Deferred income taxes	(44,658)	(53,359)
Provision for losses on accounts receivable and inventory	4,734	1,825
Loss on extinguishment and modification of debt	1,425	—
Amortization of debt discount and deferred financing costs	32,669	19,234
Other non-cash transactions	6,970	14,480
Changes in assets and liabilities:		
Accounts receivable	(55,518)	(22,273)
Inventories	(7,583)	(7,132)
Prepaid expenses and other current assets	6,989	(10,590)
Other long-term assets	(6,494)	(1,825)
Accounts payable	10,116	6,130
Accrued liabilities	65,074	(23,583)
Income taxes payable	(13,999)	8,495
Deferred revenue	(5,623)	23,163
Other non-current liabilities	7,244	12,931
Net cash provided by operating activities	574,558	488,528
Investing activities		
Proceeds from maturity of investments	565,000	150,000
Net proceeds from sale of assets	48,092	—
Acquired in-process research and development	—	(77,000)
Purchases of property, plant and equipment	(15,221)	(20,072)
Acquisition of intangible assets	(111,100)	—
Acquisition of investments	(915,000)	(290,000)
Net cash used in investing activities	(428,229)	(237,072)
Financing activities		
Proceeds from employee equity incentive and purchase plans	84,056	22,793
Proceeds from tenant improvement allowance on build-to-suit lease	1,253	—
Net proceeds from issuance of debt	—	559,484
Repayments under revolving credit facility	—	(850,000)
Payment of debt modification costs	(6,406)	—
Payment of employee withholding taxes related to share-based awards	(17,192)	(17,909)
Repayments of long-term debt	(17,370)	(27,070)

Share repurchases	(77,015)	(56,425)
Net cash used in financing activities	(32,674)	(369,127)
Effect of exchange rates on cash and cash equivalents	(672)	4,323
Net increase (decrease) in cash and cash equivalents	112,983	(113,348)
Cash and cash equivalents, at beginning of period	386,035	365,963
Cash and cash equivalents, at end of period	$499,018	$252,615

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

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

The Company and Summary of Significant Accounting Policies

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

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

- Xyrem® (sodium oxybate) oral solution, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy;
- Erwinaze® (asparaginase Erwinia chrysanthemi), a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia who have developed hypersensitivity to E. coli-derived asparaginase;
- Defitelio® (defibrotide sodium), a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy; and
- Vyxeos® (daunorubicin and cytarabine) liposome for injection, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications and new geographic markets;
- Acquiring or licensing rights to clinically meaningful and differentiated products on the market or product candidates at various stages of development; and
- Pursuing targeted development of post-discovery differentiated product candidates.

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

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

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared following the requirements of the U.S. Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or U.S. GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our annual consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2017.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, for any other interim period or for any future period.

Except for the revenue recognition accounting policy that was updated as a result of adopting Accounting Standards Update No. 2014-09, “Revenue from Contracts with Customers”, or ASU No. 2014-09, our significant accounting policies have

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not changed substantially from those previously described in our Annual Report on Form 10-K for the year ended December 31, 2017.

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 May 2014, the Financial Accounting Standards Board, or FASB, issued ASU No. 2014-09. The standard states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this, an entity will need to identify the contract with a customer; identify the separate performance obligations in the contract; determine the transaction price; allocate the transaction price to the separate performance obligations in the contract; and recognize revenue when (or as) the entity satisfies each performance obligation. We adopted ASU No. 2014-09 on January 1, 2018 on a modified retrospective basis. The adoption of ASU No. 2014-09 did not have a material impact on our results of operations and financial position as the timing of revenue recognition for product sales, net, which is our primary revenue stream, did not change. Refer to Note 13, Revenues, for revenue-related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments” which addresses how certain cash receipts and cash payments are presented and classified in the statement of cash flows. We adopted this standard on January 1, 2018 and adoption did not have a material impact on our consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, “Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory” which requires an entity to recognize the income tax consequences of an intra-entity asset transfer, other than an intra-entity asset transfer of inventory, when the transfer occurs. We adopted this standard on January 1, 2018 on a modified retrospective basis and adoption did not have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, “Business Combinations (Topic 805): Clarifying the Definition of a Business” which provides clarification on the definition of a business and adds guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. We adopted this standard on January 1, 2018. In the second quarter of 2018, we entered into an asset purchase agreement, or APA, with TerSera Therapeutics LLC, or TerSera, whereby TerSera agreed to purchase substantially all of our assets related to the manufacture, marketing and sale of Prialt® (ziconotide) intrathecal infusion. We entered into an amendment to the APA, and the transaction closed on September 27, 2018. We determined that the disposal group did not constitute a business under the new guidance. Refer to Note 2, Disposition, for further information on the sale of our rights to Prialt.

In August 2017, the FASB issued ASU No. 2017-12, “Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities”, or ASU No. 2017-12. ASU No. 2017-12 amends and simplifies existing guidance in order to allow companies to more accurately present the economic effects of risk management activities in their financial statements. ASU No. 2017-12 is effective for reporting periods beginning after December 15, 2018, with early adoption permitted. We elected to early adopt this standard on January 1, 2018 on a modified retrospective

basis. Adoption of this standard did not have a material impact on our consolidated financial statements.

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The cumulative effect of the changes made to our consolidated balance sheet as of January 1, 2018 for the adoption of the above accounting standards was as follows (in thousands):

	Balance at December 31, 2017	Transition Adjustments	Balance at January 1, 2018
Assets:			
Deferred tax assets, net	$ 34,559	$ 595	$35,154
Liabilities:			
Deferred revenue	8,618	(1,120)	7,498
Deferred revenue, non-current	16,115	(1,120)	14,995
Deferred tax liabilities, net	383,472	3,133	386,605
Shareholders' Equity:			
Accumulated other comprehensive loss	(140,878)	53	(140,825)
Retained earnings	917,956	(351)	917,605

Revenue Recognition

Our revenue comprises product sales, net and royalty and contract revenues. Revenues are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product Sales, Net

Product sales revenue is recognized when control has transferred to the customer, which occurs at a point in time, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

Reserves for Variable Consideration

Revenues from sales of products are recorded at the net sales price, which includes estimates of variable consideration for which reserves are established and which relate to returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans. Calculating certain of these reserves involves estimates and judgments and we determine their expected value based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and channel inventory data. These reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We reassess our reserves for variable consideration at each reporting date. Historically, adjustments to estimates for these reserves have not been material.

Reserves for returns, specialty distributor fees, wholesaler fees, government rebates, coupon programs and rebates under managed care plans are included within current liabilities in our condensed consolidated balance sheets. Reserves for government chargebacks and prompt payment discounts are shown as a reduction in accounts receivable.

Royalties and Contract Revenues

We enter into out-licensing agreements under which we license certain rights to our products or product candidates to third parties. If a licensing arrangement includes multiple goods or services, we consider whether the license is distinct. If the license to our intellectual property is determined to be distinct from the other performance obligations

identified in the arrangement, we recognize revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. If the license to our intellectual property is determined not to be distinct, it is combined with other goods or services into a combined performance obligation. We consider whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of

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measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting date and, if necessary, adjust the measure of performance and related revenue recognition. At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or that of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price.

For arrangements that include sales-based royalties and milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties and sales-based milestones relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty or sales-based milestone has been allocated has been satisfied (or partially satisfied).

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem. Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, including, without limitation, the potential U.S. introduction of a generic version of Xyrem before the entry dates specified in our settlements with the abbreviated new drug application, or ANDA, filers, or on terms that are different from those contemplated by the settlement agreements; the potential U.S. introduction of new products that compete with, or otherwise disrupt the market for, Xyrem in the treatment of cataplexy and/or excessive daytime sleepiness in narcolepsy; changes to or uncertainties around regulatory restrictions, including, among other things, changes to our Xyrem risk evaluation and mitigation strategy, or REMS; any increase in pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors; changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and REMS programs by government entities; operational disruptions at the Xyrem central pharmacy or any failure to comply with our REMS obligations to the satisfaction of the FDA; 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 specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including, without limitation, risks and uncertainties associated with: effectively commercializing our other products and product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; the regulatory approval process; the challenges of protecting and enhancing our intellectual property rights; our dependence on sole source suppliers for most of our products, including delays or problems in the supply or manufacture of our products and product candidates; competition; complying with applicable regulatory requirements; changes in healthcare laws and policy and related reforms; government investigations and other actions; obtaining and maintaining appropriate pricing and reimbursement for our products; business combination or product or product candidate acquisition transactions; and possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

Concentrations of Risk

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

holding our cash, cash equivalents and investments to the extent recorded on the balance sheet.

We manage our foreign currency transaction risk and interest rate risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of September 30, 2018, we had foreign exchange forward contracts with notional amounts totaling $210.1 million. As of September 30, 2018, the net liability fair value of outstanding foreign exchange forward contracts was $1.0 million. As of September 30, 2018, we had interest rate swap contracts with notional amounts totaling $300.0 million. These outstanding interest rate swap contracts had a fair value of $7.8 million as of September 30, 2018. The

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counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not significant.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the U.S., and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We monitor deteriorating economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and as of September 30, 2018 and December 31, 2017, allowances on receivables were not material. As of September 30, 2018, two customers accounted for 91% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliates, or Express Scripts, which accounted for 77% of gross accounts receivable, and McKesson Corporation and affiliates, or McKesson, which accounted for 14% of gross accounts receivable. As of December 31, 2017, two customers accounted for 86% of gross accounts receivable including Express Scripts, which accounted for 71% of gross accounts receivable, and McKesson, which accounted for 15% of gross accounts receivable.

We depend on single source suppliers for most of our products, product candidates and their 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 August 2018, the FASB issued ASU 2018-15, “Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract”, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The standard is effective for us beginning January 1, 2020 and early adoption is permitted. The new guidance is not expected to have a material impact on our results of operations and financial position.

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

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)”, or ASU No. 2016-02. Under the new guidance, lessees will be required to recognize a right-of-use asset, which represents the lessee’s right to use, or control the use of, a specified asset for the lease term, and a corresponding lease liability, which represents the lessee’s obligation to make lease payments under a lease, measured on a discounted basis. ASU No. 2016-02 is effective beginning January 1, 2019 and early adoption is permitted. ASU No. 2016-02 must be adopted on a modified retrospective transition basis at the beginning of the earliest comparative period presented in the consolidated financial statements or at the adoption date. The adoption of ASU No. 2016-02 will result in a significant increase in our consolidated balance sheet for right-of-use assets and lease liabilities. While we are continuing to assess all potential impacts of the standard, we currently believe the most significant impact relates to our accounting for the lease agreements we entered into in January 2015 and September 2017 to lease office space located in Palo Alto, California in buildings constructed or to be constructed by the landlord, which are accounted for as build-to-suit arrangements under existing accounting standards, and the lease agreement we entered into in August 2016 for office space in Dublin, Ireland. The future minimum lease payments under these leases at September 30, 2018 were $208.6 million. Based on our initial evaluation of the impact of ASU No. 2016-02 on our build-to-suit facility leases, we expect to de-recognize existing build-to-suit assets and liabilities upon the adoption of ASU No. 2016-02.

2. Disposition

On June 29, 2018, we entered into an APA with TerSera, pursuant to which TerSera agreed to purchase substantially all of our assets related to the manufacture, marketing and sale of Prialt, but excluding accounts receivable, and to assume certain related liabilities as set forth in the APA. We entered into an amendment to the APA, and the transaction closed, on September 27, 2018. The total sales price was $80.0 million, of which we received $50.0 million at closing, and, subject to certain conditions, we are entitled to receive $15.0 million payable on December 31, 2019 and $15.0 million payable on December 31, 2020, or earlier under certain circumstances.

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The related assets met the assets held for sale criteria and were reclassified to assets held for sale as of June 30, 2018. We adjusted the carrying value of the assets held for sale to fair value less costs to sell, which resulted in an impairment charge of $42.9 million in our condensed consolidated statements of income for the nine months ended September 30, 2018, primarily related to the carrying balances of intangible assets. Upon closing, we recognized a loss on disposal of $0.5 million within selling, general and administrative expenses in our consolidated statements of income for the three and nine months ended September 30, 2018.

We determined that the disposal of these assets does not qualify for reporting as a discontinued operation since it does not represent a strategic shift that has or will have a major effect on our operations and financial results.

3. Cash and Available-for-Sale Securities

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

	September 30, 2018					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$281,047	$ —	$ —	$281,047	$ 281,047	$ —
Time deposits	590,000	—	—	590,000	25,000	565,000
Money market funds	192,971	—	—	192,971	192,971	—
Totals	$1,064,018	$ —	$ —	$1,064,018	$ 499,018	$ 565,000

	December 31, 2017					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$225,235	$ —	$ —	$225,235	$ 225,235	$ —
Time deposits	235,000	—	—	235,000	20,000	215,000
Money market funds	140,800	—	—	140,800	140,800	—
Totals	$601,035	$ —	$ —	$601,035	$ 386,035	$ 215,000

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

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4. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of September 30, 2018 and December 31, 2017 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	September 30, 2018			December 31, 2017		
	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	$—	$ 590,000	$ 590,000	$—	$ 235,000	$ 235,000
Money market funds	192,971	—	192,971	140,800	—	140,800
Interest rate contracts	—	7,824	7,824	—	2,138	2,138
Foreign exchange forward contracts	—	261	261	—	15,495	15,495
Totals	$ 192,971	$ 598,085	$ 791,056	$ 140,800	$ 252,633	$ 393,433
Liabilities:						
Interest rate contracts	$—	$ —	$ —	$—	$ 392	$ 392
Foreign exchange forward contracts	—	1,258	1,258	—	5,017	5,017
Totals	$—	$ 1,258	$ 1,258	$—	$ 5,409	$ 5,409

As of September 30, 2018, 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 2018 or in 2017.

As of September 30, 2018, the estimated fair values of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, and our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, were approximately $619 million and $586 million, respectively. The fair values of the 2021 Notes and the 2024 Notes, which we refer to together as the Exchangeable Senior Notes, were estimated using quoted market prices obtained from brokers (Level 2). The estimated fair value of our borrowing under our term loan was approximately equal to its book value based on the borrowing rates currently available for variable rate loans (Level 2).

5. Derivative Instruments and Hedging Activities

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

To achieve a desired mix of floating and fixed interest rates on our variable rate debt, we entered into interest rate swap agreements in March 2017 which are effective from March 3, 2017 until July 12, 2021. These agreements hedge contractual term loan interest rates. As of September 30, 2018 and December 31, 2017, 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.

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The effective portion of changes in the fair value of derivatives designated as and that qualify as cash flow hedges is recorded in accumulated other comprehensive loss and is subsequently reclassified into earnings in the period that the hedged forecasted transaction affects earnings. The impact on accumulated other comprehensive loss and earnings from derivative instruments that qualified as cash flow hedges for the three and nine months ended September 30, 2018 and 2017 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Interest Rate Contracts:	2018	2017	2018	2017
Gain (loss) recognized in accumulated other comprehensive loss, net of tax	$876	$(59)	$5,285	$(2,234)
Loss (gain) reclassified from accumulated other comprehensive loss to interest expense, net of tax	(130)	451	19	1,278

Assuming no change in LIBOR-based interest rates from market rates as of September 30, 2018, $1.9 million of gains recognized in accumulated other comprehensive loss will be reclassified to earnings over the next 12 months.

We enter into foreign exchange forward contracts, with durations of up to 12 months, designed to limit the exposure to fluctuations in foreign exchange rates related to the translation of certain non-U.S. dollar denominated liabilities, including intercompany balances. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of September 30, 2018 and December 31, 2017, the notional amount of foreign exchange contracts where hedge accounting is not applied was $210.1 million and $98.7 million, respectively. The foreign exchange loss in our condensed consolidated statements of income included losses of $2.4 million and $10.9 million for the three and nine months ended September 30, 2018, respectively, and gains of $8.0 million and $19.6 million for the three and nine months ended September 30, 2017, respectively, associated with foreign exchange contracts not designated as hedging instruments.

The cash flow effects of our derivative contracts for the nine months ended September 30, 2018 and 2017 are included within net cash provided by operating activities in the condensed consolidated statements of cash flows.

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

	September 30, 2018			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets	$2,150	Accrued liabilities	$—
	Other non-current assets	5,674		
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	261	Accrued liabilities	1,258
Total fair value of derivative instruments		$8,085		$1,258

	December 31, 2017			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Interest rate contracts	Other non-current assets	$2,138	Accrued liabilities	$392
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	15,495	Accrued liabilities	5,017
Total fair value of derivative instruments		$17,633		$5,409

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

	September 30, 2018					
	Gross Amounts of Recognized	Gross Amounts Offset in the Consolidated	Net Amounts of Assets/ Liabilities Presented in the	Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Assets/ Liabilities	Balance Sheet	Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$1,957	$ —	$ 1,957	$(457)	$ —	$ 1,500
Derivative liabilities	(457)	—	(457)	457	—	—

	December 31, 2017					
	Gross Amounts of Recognized	Gross Amounts Offset in the Consolidated	Net Amounts of Assets/ Liabilities Presented in the	Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Assets/ Liabilities	Balance Sheet	Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$1,639	$ —	$ 1,639	$(875)	$ —	$ 764
Derivative liabilities	(875)	—	(875)	875	—	—

6. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 2,482	$ 3,542
Work in process	24,456	15,692
Finished goods	16,497	24,011
Total inventories	$ 43,435	$ 43,245

7. Goodwill and Intangible Assets

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

Balance at December 31, 2017	$947,537
Foreign exchange	(15,115)
Balance at September 30, 2018	$932,422

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

	September 30, 2018				December 31, 2017		
	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	14.6	$3,122,811	$ (590,198)	$2,532,613	$3,392,832	$ (562,473)	$2,830,359
Priority review voucher		111,100	—	111,100	—	—	—
Manufacturing contracts	—	12,391	(12,391)	—	12,824	(12,634)	190
Trademarks	—	2,899	(2,899)	—	2,910	(2,910)	—
Total finite-lived intangible assets		3,249,201	(605,488)	2,643,713	3,408,566	(578,017)	2,830,549
Acquired IPR&D assets		143,568	—	143,568	148,578	—	148,578
Total intangible assets		$3,392,769	$ (605,488)	$2,787,281	$3,557,144	$ (578,017)	$2,979,127

The decrease in the gross carrying amount of intangible assets as of September 30, 2018 compared to December 31, 2017 reflects the sale of the Prialt acquired developed technology asset to TerSera in September 2018 and the negative impact of foreign currency translation adjustments, which was due to the weakening of the euro against the U.S. dollar, partially offset by our purchase of a rare pediatric disease priority review voucher, or PRV, from Spark Therapeutics, Inc. As we may use the PRV to obtain priority review by the FDA for one of our future regulatory submissions or may sell or transfer the PRV to a third party, we capitalized the acquisition cost, including direct transaction costs, as a finite-lived intangible asset upon closing of the transaction in May 2018.

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 acquired developed technology intangible assets recorded as of September 30, 2018, and assuming the underlying assets will not be impaired and that we will not change the expected lives of the assets, future amortization expenses were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2018 (remainder)	$ 46,802
2019	187,208
2020	185,969
2021	184,955
2022	184,246
Thereafter	1,743,433
Total	$ 2,532,613

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8. Certain Balance Sheet Items

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

	September 30, 2018	December 31, 2017
Build-to-suit facility	$ 52,222	$ 51,721
Land and buildings	46,815	46,729
Construction-in-progress	46,058	21,738
Leasehold improvements	32,623	28,779
Manufacturing equipment and machinery	25,573	23,586
Computer software	19,135	19,969
Computer equipment	14,059	12,814
Furniture and fixtures	8,059	5,947
Subtotal	244,544	211,283
Less accumulated depreciation and amortization	(46,491)	(41,203)
Property, plant and equipment, net	$ 198,053	$ 170,080

Accrued liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Rebates and other sales deductions	$ 88,443	$ 81,368
Estimated loss contingency	57,753	—
Employee compensation and benefits	49,845	54,930
Clinical trial accruals	8,387	2,181
Selling and marketing accruals	5,837	3,189
Inventory-related accruals	3,290	3,002
Royalties	3,293	8,058
Accrued interest	2,678	7,297
Sales returns reserve	2,473	3,651
Professional fees	2,368	3,213
Derivative instrument liabilities	1,258	5,409
Other	31,828	26,481
Total accrued liabilities	$ 257,453	$ 198,779

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9. Debt

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

	September 30, 2018	December 31, 2017
2021 Notes	$ 575,000	$ 575,000
Unamortized discount and debt issuance costs on 2021 Notes	(66,269)	(81,627)
2021 Notes, net	508,731	493,373
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(144,018)	(158,680)
2024 Notes, net	430,982	416,320
Term loan	654,256	671,345
Total debt	1,593,969	1,581,038
Less current portion	33,387	40,605
Total long-term debt	$ 1,560,582	$ 1,540,433

Amendment of Credit Facility

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

On July 12, 2016, we amended the 2015 credit agreement to provide for a revolving credit facility of $1.25 billion and a $750.0 million term loan facility. We used the proceeds of $1.0 billion of loans under the revolving credit facility, together with cash on hand, to fund the acquisition of Celator Pharmaceuticals, Inc., or Celator.

On June 7, 2018, we entered into a second amendment to the 2015 credit agreement to provide for a revolving credit facility of $1.6 billion, which replaced the existing revolving credit facility of $1.25 billion, and a new $667.7 million term loan facility, which replaced the $750.0 million term loan facility, of which $659.4 million principal amount was outstanding as of September 30, 2018. We refer to the 2015 credit agreement as amended by the first and second amendments as the amended credit agreement. We expect to use the proceeds from future loans under the revolving credit facility, if any, for permitted capital expenditures, permitted acquisitions, to provide for ongoing working capital requirements and for other general corporate purposes.

Under the amended credit agreement, the term loan matures on June 7, 2023 and the revolving credit facility terminates, and any loans outstanding thereunder become due and payable, on June 7, 2023.

Borrowings under the amended credit agreement bear interest, at our option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 1.375% to 1.750% per annum, based upon our secured leverage ratio, or (b) the prime lending rate, plus an applicable margin ranging from 0.375% to 0.750% per annum, based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio.

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

We may make voluntary prepayments of principal at any time without payment of a premium. We are required to make mandatory prepayments of the term loan (without payment of a premium) with (1) net cash proceeds from certain non-ordinary

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course asset sales (subject to other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), and (3) casualty proceeds and condemnation awards (subject to other exceptions).

Principal repayments of the term loan, which are due quarterly, are equal to 5.0% per annum of the principal amount outstanding on June 7, 2018 of $667.7 million, with any remaining balance payable on the maturity date.

The amended credit agreement contains financial covenants that require Jazz Pharmaceuticals plc and our restricted subsidiaries to not (a) exceed a maximum secured net leverage ratio or (b) fall below a cash interest coverage ratio. As of September 30, 2018, we were in compliance with these financial covenants.

Exchangeable Senior Notes

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

As of September 30, 2018, the carrying values of the equity component of the 2021 Notes and the 2024 Notes, net of equity issuance costs, were $126.9 million and $149.8 million, respectively.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of September 30, 2018 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2018 (remainder)	$8,346
2019	33,387
2020	33,387
2021	608,387
2022	33,387
Thereafter	1,092,494
Total	$1,809,388

10. Commitments and Contingencies

Indemnification

In the normal course of business, we enter into agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. Our exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against us. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations.

We have agreed to indemnify our executive officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we did not recognize any

liabilities relating to these obligations as of September 30, 2018 and December 31, 2017. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability,

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or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

Facility Leases. In January 2015, we entered into an agreement to lease office space located in Palo Alto, California in a building subsequently constructed by the landlord. The term of this lease is 12 years from the commencement date as defined in the lease agreement and we have an option to extend the term twice for a period of five years each. We are the deemed owner of the building based on applicable accounting guidance for build-to-suit leases. Accordingly, the landlord's costs of constructing the building were capitalized on our condensed consolidated balance sheets offset by a corresponding financing obligation. We began to occupy this office space in October 2017. As of September 30, 2018, the total amount of the related financing obligation was $62.9 million, which is classified within current liabilities and non-current liabilities on our condensed consolidated balance sheets.

In September 2017, we entered into an agreement to lease office space located in Palo Alto, California in a second building to be constructed by the same landlord. We expect to occupy this office space by the end of 2019. This lease has a term of 12 years from the commencement date as defined in the lease agreement and we have an option to extend the term of the lease twice for a period of 5 years each. We are the deemed owner of the building during the construction period based on applicable accounting guidance for build-to-suit leases. As of September 30, 2018, we recorded project construction costs of $43.7 million incurred by the landlord as construction-in-progress in property, plant and equipment, net and a corresponding financing obligation in other non-current liabilities on our condensed consolidated balance sheets. We will increase the asset and financing obligation as additional building costs are incurred by the landlord during the construction period.

Operating Leases. We have noncancelable operating leases for our office buildings and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force.

Other Commitments. As of September 30, 2018, we had $54.7 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

Xyrem ANDA Litigation and Settlements. In December 2012, we received a notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Amneal Pharmaceuticals LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. In January 2013, we filed a lawsuit against Amneal in the federal district court of New Jersey, or District Court, alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. Additional patents covering Xyrem were issued after the date of the original lawsuit against Amneal, and lawsuits we brought against Amneal involving those patents were consolidated into a single case in the District Court.

In October 2018, we entered into a settlement agreement and related agreements resolving our patent infringement litigation against Amneal in the District Court, and the District Court subsequently approved an order dismissing the litigation. We previously settled lawsuits against the eight other companies that have sent us notices that they had filed ANDAs requesting approval to market a generic version of Xyrem. As a result, the settlement with Amneal represents settlement of all outstanding patent infringement litigation related to Xyrem. It is possible that additional companies may file ANDAs seeking to market a generic version of Xyrem or submit new drug applications referencing Xyrem, which could lead to additional patent litigation or challenges with respect to Xyrem.

The settlements with the nine ANDA filers are described below.

In our settlement with the first filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), or West-Ward, we granted West-Ward the right to sell an authorized generic version of Xyrem, or AG Product, in the U.S. beginning on January 1, 2023, or earlier under certain circumstances, including circumstances related to the licensing or market entry of another generic sodium oxybate product, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time. West-Ward has an option to continue to sell the West-Ward AG Product for up to five years, and we are entitled to receive a meaningful royalty on net sales of the West-Ward AG Product, as well as

payment for the supply of the West-Ward AG Product and reimbursement for a portion of the services costs associated with distribution of the West-Ward AG Product through the Xyrem REMS. We also granted West-Ward a license under the Xyrem patents to launch its own generic sodium oxybate product as early as six months after it has the right to sell the AG Product, but if it elects to sell its own generic sodium oxybate product, West-Ward will not be able to continue to sell the West-Ward AG Product.

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In our settlements with Amneal, Lupin Inc., or Lupin, and Par Pharmaceutical, Inc., or Par, we granted each of them 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. Such circumstances include events related to acceleration of West-Ward's AG Product launch date, the earlier launch of another party's AG Product, the launch of another generic sodium oxybate product, or a final decision that all unexpired claims of the Xyrem patents are not infringed, or are invalid and/or unenforceable. The volume of each of Amneal's, Lupin's and Par's AG Products is limited to an annual amount equal to a low single-digit percentage of Xyrem sales volume during the calendar year preceding the entry date of such party's AG Product, and each party's right to sell its AG Product ends on December 31, 2025. We also granted each of Amneal, Lupin and Par a license under the Xyrem patents to launch its own generic sodium oxybate product under its ANDA (assuming FDA approval of its ANDA is obtained or maintained) on or after December 31, 2025, or earlier under certain circumstances. Such circumstances include events related to launch of a generic sodium oxybate product by West-Ward or another company under its ANDA, or a final decision that all unexpired claims of the Xyrem patents are not infringed, or are invalid and/or unenforceable. If an acceleration event occurs, then each of Amneal, Par and Lupin will have the option to elect to market its AG Product until December 31, 2025, but such party will not be entitled to market its AG Product and its own generic sodium oxybate product simultaneously. We are entitled to receive a meaningful royalty on net sales of each of Amneal's, Lupin's and Par's AG Products, as well as payment for the supply of each party's AG Product and reimbursement for a portion of the services costs associated with distribution of each party's AG Product through the Xyrem REMS.

In our settlements with each of the other five ANDA filers, we granted each a license under the Xyrem patents to launch its own generic sodium oxybate product under its ANDA (assuming FDA approval of its ANDA is obtained or maintained) on or after December 31, 2025, or earlier under certain circumstances. Such circumstances include the launch by West-Ward or another company of a generic sodium oxybate product. The specific terms of all of the settlement agreements are confidential.

Xyrem Post-Grant Patent Review Matters. In January 2015, certain of the ANDA filers filed petitions for inter partes review, or IPR, with respect to the validity of six of our seven patents associated with the Xyrem REMS, or REMS patents. The Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office instituted IPR trials with respect to certain of these petitions. In July 2016, the PTAB issued final decisions that the claims of the six REMS patents are unpatentable. In March 2017, the PTAB issued a final decision that three claims of a seventh REMS patent are unpatentable. On July 13, 2018, the United States Court of Appeals for the Federal Circuit upheld the July 2016 and March 2017 PTAB decisions on appeal, and as a result, we will not be able to enforce claims the PTAB found unpatentable. We cannot predict whether new parties will petition for post-grant patent review in the future, the outcome of any future IPR or other proceeding or the impact any IPR or other proceeding might have on any future ANDA or other patent litigation proceedings or other aspects of our Xyrem business.

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

Other Contingencies

In May and October 2016 and in February 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients, and, for Xyrem, documents concerning the provision of financial assistance to Medicare patients. Other companies have disclosed similar subpoenas and continuing inquiries. We have a comprehensive program intended to ensure our compliance with applicable legal and regulatory requirements for pharmaceutical companies, including guidelines established by the Office of Inspector General of the U.S. Department of Health and Human Services regarding patient assistance programs, and we have been cooperating with the government's investigation. We have engaged in discussions with the U.S. Department of Justice, or DOJ, about a possible resolution, and in April 2018, we reached an agreement in principle with the DOJ on a proposal for a civil settlement of potential claims by the DOJ in the amount of $57.0 million, subject to accrual of interest on the settlement amount from the date of the agreement in principle, negotiation of a definitive settlement agreement and

other contingencies. During the nine months ended September 30, 2018, we recorded $57.8 million related to this matter, including related interest, within accrued liabilities on our condensed consolidated balance sheet with the related expense included in selling, general and administrative expenses on our condensed consolidated statement of income. Material issues remain subject to further negotiation and approval by us and the DOJ before the proposed settlement can be finalized. We cannot provide assurances that our efforts to reach a final settlement with the DOJ will be successful or, if they are, the timing or final terms of any such settlement. Any such settlement is also likely to involve entry into a corporate integrity agreement, which would impose costs and burdens on the operation of our business. If we do not reach a final settlement, the outcome of this investigation could include an enforcement action against us. If the federal government were to file an enforcement action against us as a result of the investigation and could establish the elements of a violation of relevant laws, we could be subject to damages, fines and penalties, which could be substantial, along with other criminal, civil or administrative

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sanctions, and we would expect to incur significant costs in connection with such enforcement action, regardless of the outcome.

11. Shareholders’ Equity

The following tables present a reconciliation of our beginning and ending balances in shareholders’ equity for the nine months ended September 30, 2018 and 2017 (in thousands):

	Total Shareholders' Equity
Shareholders' equity at January 1, 2018	$ 2,713,097
Effect of adoption of new accounting standards	(298)
Issuance of ordinary shares in conjunction with employee equity incentive and purchase plans	84,056
Employee withholding taxes related to share-based awards	(17,192)
Share-based compensation	75,682
Shares repurchased	(77,015)
Other comprehensive loss	(38,641)
Net income	287,628
Shareholders' equity at September 30, 2018	$ 3,027,317

	Total Shareholders' Equity
Shareholders' equity at January 1, 2017	$ 1,877,339
Issuance of 2024 Notes	149,767
Issuance of ordinary shares in conjunction with employee equity incentive and purchase plans	22,793
Employee withholding taxes related to share-based awards	(17,909)
Share-based compensation	79,745
Shares repurchased	(56,425)
Other comprehensive income	158,346
Net income	255,641
Shareholders' equity at September 30, 2017	$ 2,469,297

Share Repurchase Program

In November 2016, our board of directors authorized a share repurchase program pursuant to which we are authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300 million, exclusive of any brokerage commissions. In the nine months ended September 30, 2018, we spent a total of $77.0 million to purchase 0.5 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $154.03 per share. As of September 30, 2018, the remaining amount authorized under the share repurchase program was $105.7 million.

In November 2018, our board of directors increased the existing share repurchase program authorization by an aggregate purchase price of $320 million, exclusive of any brokerage commissions.

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Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of September 30, 2018 and December 31, 2017 were as follows (in thousands):

	Net Unrealized Gain From Hedging Activities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2017	$ 1,482	$ (142,360)	$ (140,878)
Effect of adoption of ASU No. 2017-12	53	—	53
Balance at January 1, 2018	1,535	(142,360)	(140,825)
Other comprehensive income (loss) before reclassifications	5,285	(43,945)	(38,660)
Amounts reclassified from accumulated other comprehensive loss	19	—	19
Other comprehensive income (loss), net	5,304	(43,945)	(38,641)
Balance at September 30, 2018	$ 6,839	$ (186,305)	$ (179,466)

During the nine months ended September 30, 2018, 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 gain on derivatives that qualify as cash flow hedges.

12. Net Income per Ordinary Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net income	$149,316	$63,526	$287,628	$255,641
Denominator:				
Weighted-average ordinary shares used in per share calculations - basic	60,476	60,108	60,196	60,030
Dilutive effect of employee equity incentive and purchase plans	1,381	1,328	1,297	1,330
Weighted-average ordinary shares used in per share calculations - diluted	61,857	61,436	61,493	61,360
Net income per ordinary share:				
Basic	$2.47	$1.06	$4.78	$4.26
Diluted	$2.41	$1.03	$4.68	$4.17

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans and the Exchangeable Senior Notes are determined by applying the treasury stock method to the assumed exercise of share options, the assumed vesting of outstanding restricted stock units, or RSUs, the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP, and the assumed issuance of ordinary shares upon exchange of the Exchangeable Senior Notes. The potential issue of ordinary shares issuable upon exchange of the Exchangeable Senior Notes had no effect on diluted net income per ordinary share because the average price of our ordinary shares for the three and nine months ended September 30, 2018 and 2017 did not exceed the effective exchange prices per ordinary share of the Exchangeable Senior Notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Exchangeable Senior Notes	5,504	3,958	5,504	3,238
Options to purchase ordinary shares and RSUs	2,230	2,998	2,959	3,175
Ordinary shares under ESPP	14	16	16	9

13. Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Xyrem	$357,251	$303,870	$1,030,036	$874,222
Erwinaze/Erwinase	41,134	49,173	150,474	149,585
Defitelio/defibrotide	36,177	31,213	111,736	97,351
Vyxeos	21,038	9,719	75,217	9,719
Prialt	5,792	7,930	20,839	21,303
Other	3,805	6,066	13,837	19,124
Product sales, net	465,197	407,971	1,402,139	1,171,304
Royalties and contract revenues	4,176	3,884	12,326	10,990
Total revenues	$469,373	$411,855	$1,414,465	$1,182,294

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
United States	$429,729	$372,846	$1,290,775	$1,068,716
Europe	30,816	30,297	94,165	89,027
All other	8,828	8,712	29,525	24,551
Total revenues	$469,373	$411,855	$1,414,465	$1,182,294

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Express Scripts	76%	74%	73%	74%
McKesson	15%	14%	18%	14%

Financing and payment

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

Contract Liabilities - Deferred Revenue

The deferred revenue balance as of September 30, 2018 primarily related to deferred upfront fees received from Nippon Shinyaku Co., Ltd., or Nippon Shinyaku, in connection with two license, development and commercialization agreements granting Nippon Shinyaku exclusive rights to develop and commercialize each of Defitelio and Vyxeos in Japan. We recognized contract revenues of $1.9 million and $5.6 million during the three and nine months ended September 30, 2018,

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respectively, relating to these upfront payments. The deferred revenue balances are being recognized over an average of four years representing the period we expect to perform our research and developments obligations under each agreement.

The following table presents a reconciliation of our beginning and ending balances in contract liabilities from contracts with customers for the nine months ended September 30, 2018 (in thousands):

	Contract Liabilities
Balance as of December 31, 2017	$ 24,733
Effect of adoption of ASU 2014-09	(2,240)
Amount recognized within royalties and contract revenues	(5,624)
Balance as of September 30, 2018	$ 16,869

14. Share-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Selling, general and administrative	$18,978	$20,903	$57,012	$61,582
Research and development	4,600	4,650	13,684	13,651
Cost of product sales	1,525	1,573	5,022	4,346
Total share-based compensation expense, pre-tax	25,103	27,126	75,718	79,579
Income tax benefit from share-based compensation expense	(3,552)	(6,354)	(12,066)	(23,816)
Total share-based compensation expense, net of tax	$21,551	$20,772	$63,652	$55,763

Share Options

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Shares underlying options granted (in thousands)	117	87	1,349	1,343
Grant date fair value	$53.93	$45.87	$46.95	$42.69
Black-Scholes option pricing model assumption information:				
Volatility	32%	35%	35%	35%
Expected term (years)	4.5	4.3	4.5	4.3
Range of risk-free rates	2.7-2.8%	1.6-1.8%	2.2-2.8%	1.6-1.8%
Expected dividend yield	—%	—%	—%	—%

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Restricted Stock Units

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
RSUs granted (in thousands)	71	35	564	537
Grant date fair value	$174.73	$148.60	$145.59	$137.23

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

As of September 30, 2018, compensation cost not yet recognized related to unvested share options and RSUs was $82.8 million and $102.7 million, respectively, which is expected to be recognized over a weighted-average period of 2.7 years and 2.6 years, respectively.

15. Income Taxes

Our income tax provision was $19.3 million and $75.0 million in the three and nine months ended September 30, 2018, respectively, compared to $1.2 million and $65.9 million for the same periods in 2017. The effective tax rates were 11.4% and 20.6% in the three and nine months ended September 30, 2018, respectively, compared to 1.9% and 20.5% for the same periods in 2017. The increase in the effective tax rate for the three months ended September 30, 2018 compared to the same period in 2017 was primarily due to the release of a valuation allowance held against certain foreign net operating losses in 2017 and the impacts of movements on unrecognized tax benefits, partially offset by a decrease in the U.S. corporate income tax rate. The effective tax rate for the nine months ended September 30, 2018 was in line with the same period in 2017. The effective tax rate for the three months ended September 30, 2018 was lower than the Irish statutory rate of 12.5% primarily due to the release of reserves related to unrecognized tax benefits upon the expiration of a statute of limitations. The effective tax rate for the nine months ended September 30, 2018 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, various expenses not deductible for income tax purposes and unrecognized tax benefits. We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

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

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have recorded an unrecognized tax benefit for certain tax benefits which we judge may not be sustained upon examination. Our most significant tax jurisdictions are Ireland, the U.S. (both at the federal level and in various state jurisdictions), Italy and France. These jurisdictions have statutes of limitations ranging from three to five years. However, in the U.S. (at the federal level and in most states), carryforward tax attributes that were generated in 2013 and earlier may still be adjusted upon examination by the tax authorities. Certain of our subsidiaries are currently under examination by the French tax authorities for the years ended December 31, 2012, 2013, 2015, 2016 and 2017. These examinations may lead to ordinary course adjustments or proposed adjustments to our taxes. In December 2015, we received proposed tax assessment notices, and, in October 2018, we received revised tax assessment notices from the French tax authorities for 2012 and 2013 relating to certain transfer pricing adjustments. The notices provide for additional French tax of approximately $43 million, including interest and penalties through the date of the proposed assessment, translated at the foreign exchange rate at September 30, 2018. We disagree with the assessments and are contesting

them vigorously.

During the three and nine months ended September 30, 2018, we recorded an income tax expense of $2.9 million as a provisional measurement period adjustment to the provisional estimates recorded as of December 31, 2017 in accordance with the SEC's Staff Accounting Bulletin No. 118, or SAB 118. The provisional measurement period adjustment was due to additional analysis on the one-time transition tax on deemed repatriated earnings of foreign subsidiaries. We will continue to analyze the impact of the U.S. Tax Cuts and Jobs Act of 2017 under SAB 118 and may record further adjustments to provisional amounts as our analyses are completed in the fourth quarter of 2018.

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

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

- Xyrem® (sodium oxybate) oral solution, the only product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in patients with narcolepsy;
- Erwinaze® (asparaginase Erwinia chrysanthemi), a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to E. coli-derived asparaginase;
- Defitelio® (defibrotide sodium), a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Europe (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children undergoing HSCT therapy; and
- Vyxeos® (daunorubicin and cytarabine) liposome for injection, a product approved in the U.S. and in Europe (where it is marketed as Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or t-AML, or acute myeloid leukemia, or AML, with myelodysplasia-related changes, or AML-MRC.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying and investing in growth opportunities such as new treatment indications and new geographic markets;
- Acquiring or licensing rights to clinically meaningful and differentiated products on the market or product candidates at various stages of development; and
- Pursuing targeted development of post-discovery differentiated product candidates.

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

In the three and nine months ended September 30, 2018, our total net product sales increased by 14% and 20%, respectively, compared to the same periods in 2017, primarily due to an increase in Xyrem net product sales and net product sales of Vyxeos, which launched in the U.S. in August 2017. We expect total net product sales to increase in 2018 over 2017, primarily due to expected growth in sales of Xyrem, Vyxeos and Defitelio. Our ability to increase net product sales is subject to a number of risks and uncertainties as set forth below and under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. For additional information regarding our net product sales, see "—Results of Operations."

Significant Developments Affecting Our Business

In August 2018, we announced that the U.S. Centers for Medicare and Medicaid Services granted approval for a New Technology Add-on Payment for Vyxeos for the treatment of adults with newly diagnosed t-AML or AML-MRC.

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In August 2018, we announced a five-year collaboration with The University of Texas MD Anderson Cancer Center to evaluate potential treatment options for hematologic malignancies, with a near-term focus on Vyxeos.

In August 2018, the European Commission, or EC, granted marketing authorization for Vyxeos for the treatment of adults with newly-diagnosed t-AML or AML-MRC, and shortly thereafter, we commenced a rolling launch of Vyxeos in the European Union, or EU.

In September 2018, Nippon Shinyaku Co., Ltd., or Nippon Shinyaku, announced that Japan's Ministry of Health, Labour and Welfare, or Ministry, granted orphan drug designation to NS-73 (defibrotide sodium) for the treatment of VOD following HSCT, and, in October 2018, Nippon Shinyaku announced that it had filed a new drug application, or NDA, for NS-73 to the Ministry.

In September 2018, we sold substantially all of the assets held by us related to Prialt® (ziconotide) intrathecal infusion to TerSera Therapeutics LLC, or TerSera. The total sales price was $80.0 million, of which we received $50.0 million at closing, and, subject to certain conditions, we are entitled to receive $15.0 million payable on December 31, 2019 and $15.0 million payable on December 31, 2020, or earlier under certain circumstances.

On October 11, 2018, we entered into a settlement agreement and related agreements resolving our patent infringement litigation against Amneal Pharmaceuticals LLC, or Amneal. We had filed patent lawsuits against Amneal after it sent us a notice that it had filed an abbreviated new drug application, or ANDA, requesting approval to market a generic version of Xyrem. We previously settled lawsuits against the eight other ANDA filers. As a result, the settlement with Amneal represents settlement of all outstanding patent infringement litigation related to Xyrem. Under the settlement agreements with the nine ANDA filers, (i) we granted the first ANDA filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), or West-Ward, the right to sell an authorized generic version of Xyrem, or AG Product, in the U.S. beginning on January 1, 2023, or earlier under certain circumstances and a license to launch its own generic sodium oxybate product as early as six months after it has the right to sell the AG Product, unless it elects to continue to sell the AG Product, which it may do for up to a total of five years; (ii) we granted each of three of the other ANDA filers (including Amneal) 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 a license to launch its own generic sodium oxybate product (assuming FDA approval of its ANDA is obtained or maintained) on or after December 31, 2025, or earlier under certain circumstances; and (iii) we granted each of the five other ANDA filers a license to launch its own generic sodium oxybate product (assuming FDA approval of its ANDA is obtained or maintained) on or after December 31, 2025, or earlier under certain circumstances. We are entitled to receive a meaningful royalty on net sales of each of the AG Products, as well as payment for the supply of each party's AG Product and reimbursement for a portion of the services costs associated with distribution of each party's AG Product through the Xyrem risk evaluation and mitigation strategy, or REMS. For a further description of these settlement agreements, see Note 10, 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.

On October 26, 2018, the FDA approved our supplemental NDA, or sNDA, to revise the labeling for Xyrem to include an indication to treat cataplexy or EDS in pediatric narcolepsy patients ages seven and older. On October 25, 2018, the FDA confirmed that pediatric exclusivity has also been granted. As a result, each of our patents covering Xyrem will have an additional six months added to its expiration date. This six-month addition will also apply to any existing patent that covers a future oxybate product. The patent term additions do not affect the entry dates specified in the settlement agreements we have entered into with the ANDA filers.

Continued Emphasis on Research and Development

During the nine months ended September 30, 2018, we continued our focus on research and development activities, which currently include clinical development of new product candidates, activities related to line extensions and new indications for existing products and the generation of additional clinical data for existing products, all in our sleep and hematology/oncology therapeutic areas.

A summary of our ongoing development activities is provided below:

Project	Disease Area	Status
Sleep		

Solriamfetol (JZP-110)	EDS in obstructive sleep apnea, or OSA, and EDS in narcolepsy	NDA accepted for filing by FDA in first quarter of 2018 with a target action date under the Prescription Drug User Fee Act, or PDUFA, of December 20, 2018; preparing to submit a marketing authorization application to the European Medicines Agency in late 2018

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Project	Disease Area	Status
Solriamfetol (JZP-110)	EDS in Parkinson's disease	Enrollment in Phase 2 trial completed in third quarter of 2018; top-line data expected early 2019
JZP-258 (oxybate; 90% sodium reduction)	EDS and cataplexy in narcolepsy	Expect top-line data in Phase 3 trial by second quarter of 2019
JZP-258	Idiopathic hypersomnia	Expect to commence patient enrollment in Phase 3 trial in fourth quarter of 2018
Oxybate once-nightly dosing	Narcolepsy	Program progressing; evaluation of several formulation options and technologies continues as part of once-nightly development process
Hematology/Oncology		
Vyxeos	Myelodysplastic syndrome	Preparing for Phase 2 trial with cooperative group with planned initiation in second quarter of 2019
Defibrotide	Prevention of VOD in high-risk patients following HSCT	First patient enrolled in Phase 3 trial in first quarter of 2017; interim analysis planned in 2019
Defibrotide	Prevention of acute Graft versus Host Disease following allogeneic HSCT	First patient enrolled in Phase 2 proof of concept trial in first quarter of 2018
Defibrotide	Transplant-associated thrombotic microangiopathy	Pivotal Phase 2 trial planned for 2019
Asparaginase	ALL and other hematological malignancies	Activities related to development of improved products, including a recombinant crisantaspase
CombiPlex combinations	Oncology/hematological disorders	Pre-clinical evaluation of oncology therapeutic combinations

In addition, we have entered into a number of licensing and collaboration agreements, including with:

- ImmunoGen, Inc., or ImmunoGen, for opt-in rights to license two early-stage, hematology-related antibody-drug conjugate, or ADC, product candidates, one of which has been granted orphan drug designation by the FDA, as well as an additional ADC product candidate;
- Pfenex, Inc., or Pfenex, for rights to multiple early-stage hematology product candidates and an option to negotiate a license for a recombinant pegaspargase product candidate; and
- XL-protein GmbH, or XLp, for rights to use XLp's PASylation® technology to extend the plasma half-life of selected asparaginase product candidates.

For 2018 and beyond, we expect that our research and development expenses will continue to increase from historical levels, particularly as we prepare for anticipated regulatory submissions, initiate and undertake additional clinical trials and related development work and potentially acquire rights to additional product candidates. Our ability to continue to undertake our planned development activities, as well as the success of these activities, are subject to a number of risks and uncertainties, including the risk factors under the headings "Risks Related to Our Business" and "Risks Related to Our Industry" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Challenges, Risks and Trends Related to Our Lead Marketed Products and Product Candidates Submitted for Regulatory Approval

Xyrem. Xyrem is our largest selling product, and our financial results are significantly influenced by sales of Xyrem, which accounted for 77% and 73% of our net product sales for the three and nine months ended September 30, 2018, respectively, and 74% of our net product sales for the year ended December 31, 2017. As a result, we continue to place a high priority on seeking to increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product. We also focus on enhancing and enforcing our intellectual property rights related to Xyrem, and on product development efforts to develop product, service and safety improvements for patients.

Our future plans assume that sales of Xyrem will increase, but we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in January 2018, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

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Our ability to maintain or increase Xyrem product sales is subject to risks and uncertainties, including those discussed in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, including those related to:

- the potential U.S. introduction of a generic version of Xyrem before the entry dates specified in our settlements with the ANDA filers, or on terms that are different from those contemplated by the settlement agreements, as further described below;
- the potential U.S. introduction of new products that compete with, or otherwise disrupt the market for, Xyrem in the treatment of cataplexy and/or EDS in narcolepsy;
- changes to or uncertainties around regulatory restrictions, including, among other things, changes to our Xyrem REMS, as further described below;
- potential challenges to our intellectual property around Xyrem, including the possibility of new ANDA or NDA filers or new post-grant patent review proceedings;
- any increase in pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors;
- changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and REMS programs by government entities;
- operational disruptions at the Xyrem central pharmacy or any failure to comply with our REMS obligations to the satisfaction of the FDA;
- any supply or manufacturing problems, including any problems with our sole source Xyrem active pharmaceutical ingredient, or API, provider;
- continued acceptance of Xyrem by physicians and patients, including as a result of negative publicity that surfaces from time to time;
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem; and
- our U.S.-based API and Xyrem suppliers' ability to obtain sufficient quotas from the U.S. Drug Enforcement Administration, or DEA, to satisfy our needs for Xyrem.

Although Xyrem is protected by patents covering its manufacture, formulation, distribution system and method of use, nine companies have sent us notices that they had filed ANDAs seeking approval to market a generic version of Xyrem, and we filed patent lawsuits against each of them, asserting that such generic products would violate our patents. As described above under the heading "—Significant Developments Affecting our Business," we have settled all patent litigation against those nine ANDA filers. It is possible that other companies may in the future file ANDAs seeking to market a generic version of Xyrem or NDAs referencing Xyrem, which could lead to additional patent litigation or challenges with respect to Xyrem.

In July 2016, the Patent Trial and Appeal Board, or PTAB, issued final decisions that the claims of six patents associated with the Xyrem REMS are unpatentable. In March 2017, the PTAB issued a final decision that three claims of a seventh Xyrem patent associated with the Xyrem REMS are unpatentable. In July 2018, the United States Court of Appeals for the Federal Circuit upheld the July 2016 and March 2017 PTAB decisions on appeal, and as a result, we will not be able to enforce claims the PTAB found unpatentable.

For a further description of the PTAB proceedings and the settlement agreements relating to Xyrem, see Note 10, 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.

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 ANDA litigation settlement agreements are subject to acceleration under certain circumstances, including as described above. For example, a company that has not settled ANDA litigation with us could obtain a final decision prior to January 1, 2023 that all unexpired claims of the Xyrem patents are invalid and/or unenforceable by prevailing against us in patent litigation or as a result of either an inter partes review, or IPR, challenge, which in turn could accelerate the launch dates for the AG Products and generic sodium oxybate products under our settlement agreements. Similarly, even in the absence of a final decision

that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, a company that has not settled ANDA litigation with us could obtain FDA approval for its generic sodium oxybate product and launch such product before the entry dates specified in our settlement agreements, if, for example, such company obtains a final determination that its product does not infringe our patents or if such company decides, before applicable patent litigation is concluded, to launch its product at risk of being held liable for damages for patent infringement.

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Such a launch could accelerate the launch dates for the AG Products and generic sodium oxybate products under our settlement agreements, depending on the circumstances. In addition, a substantial reduction in Xyrem net sales could lead to acceleration of the launch date for West-Ward's AG Product, which in turn would accelerate the launch dates for the other settling ANDA filers' AG Products and generic sodium oxybate products.

In addition, Xyrem could also be subject to potential future competition from other products. Companies could develop and launch sodium oxybate or other products that are similar, but not identical, to Xyrem, such as an alternative formulation or an alternative delivery technology. For example, Avadel Pharmaceuticals plc, or Avadel, is using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients. Avadel has stated that it is conducting a Phase 3 pivotal trial pursuant to an FDA-approved special protocol assessment, and has indicated that it intends to seek approval of its product candidate using a Section 505(b)(2) NDA approval pathway referencing Xyrem. We are also aware of products being developed by others for use as treatment options in cataplexy and/or EDS in patients with narcolepsy that have different safety profiles and mechanisms of action than Xyrem, including pitolisant, a product to treat adult patients with narcolepsy with or without cataplexy that received marketing approval in Europe in 2016. While pitolisant is currently not approved by the FDA for marketing in the U.S., the company that has exclusive U.S. commercialization rights to pitolisant established an expanded access program for the product and announced that the product has received Breakthrough Therapy and Fast Track designations from the FDA and that it is preparing an NDA submission for the product. If any company successfully develops, obtains FDA approval of and launches a product that is approved in the U.S. for the treatment of narcolepsy patients, it could result in a substantial reduction of Xyrem sales, which could have the additional impact of potentially triggering acceleration of market entry of AG Products or other generic sodium oxybate products under our ANDA litigation settlement agreements, as described elsewhere in this Quarterly Report on Form 10-Q. We expect that the launch of an AG Product or other generic version of Xyrem, or the approval and launch of other products that compete with Xyrem, could have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects.

In February 2015, the FDA approved the Xyrem REMS, which requires, among other things, that Xyrem be distributed through a single pharmacy. In the FDA's letter approving the February 2015 Xyrem REMS, the FDA stated that (i) the approval action should not be construed or understood as agreement with what the FDA stated was our position that dispensing through a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh its risks, and that the FDA has continuing concerns that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system, and (ii) as with all REMS, the FDA intends to evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. In October 2018, in connection with the FDA's approval of our sNDA to revise the labeling for Xyrem to include an indication to treat cataplexy or EDS in pediatric narcolepsy patients ages seven and older, the FDA modified the February 2015 Xyrem REMS to add provisions and material for pediatric patients and caregivers, but did not modify the current operation of the Xyrem REMS. We cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xyrem REMS, including in connection with the submission of applications for new oxybate indications or products, or whether FDA will approve modifications to the Xyrem REMS that we consider warranted in connection with the submission of applications for new oxybate indications or products. Any such modifications approved, required or rejected by the FDA could make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, impair the safety profile of Xyrem, disrupt continuity of care for Xyrem patients and/or negatively affect sales of Xyrem.

In January 2017, the FDA approved West-Ward's ANDA and waived the shared REMS requirement, permitting West-Ward to use a separate REMS program from the Xyrem REMS, or the generic sodium oxybate REMS, for the generic sodium oxybate product, on the condition that the generic sodium oxybate REMS be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. This could potentially include future sodium oxybate products approved under a Section 505(b)(2) approval pathway. We cannot predict whether a company marketing a sodium oxybate product approved under Section 505(b)(2) would be required or permitted to distribute its product through the generic sodium oxybate REMS or a separate REMS.

We were not involved in the development of the generic sodium oxybate REMS and were not consulted regarding any features of this REMS. A sodium oxybate distribution system that is less restrictive than the Xyrem REMS, such as the generic sodium oxybate REMS, which provides that generic sodium oxybate products could be distributed through multiple pharmacies, could increase the risks associated with sodium oxybate distribution. 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, public acceptance of Xyrem as a treatment for EDS and cataplexy in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, as patients, consumers and others may not differentiate generic sodium oxybate from Xyrem or differentiate between the different REMS programs, any of which could have a material adverse effect on our Xyrem business.

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We may face pressure to further modify the Xyrem REMS or to license or share intellectual property pertinent to the Xyrem REMS, including proprietary data required for the safe distribution of sodium oxybate, in connection with the FDA's approval of the generic sodium oxybate REMS or otherwise. We continue to evaluate potential challenges based on the FDA's waiver of the requirement for a single, shared system REMS in connection with the approvals of the ANDAs, including whether the FDA's waiver decision meets the conditions for such a waiver under applicable law. We cannot predict whether or when we may pursue any such challenges or whether any such challenges would be successful.

For further discussion regarding the risks associated with Xyrem, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales," "We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have" and "Risks Related to Our Intellectual Property" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Erwinaze/Erwinase. Sales of our second largest product, Erwinaze/Erwinase (which we refer to in this report as Erwinaze unless otherwise indicated or the context otherwise requires), accounted for 9% and 11% of our net product sales for the three and nine months ended September 30, 2018, respectively, and 12% for the year ended December 31, 2017. Erwinaze is licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL, a company that is wholly owned by the UK Department of Health and Social Care. A significant challenge to maintaining and potentially increasing sales is the limited supply of Erwinaze, which has resulted, and continues to result, in supply disruptions, and our need for PBL to minimize or avoid additional supply disruptions due to capacity constraints, production delays, quality or regulatory challenges and other manufacturing difficulties. We have been experiencing, and continue to experience, supply disruptions globally and expect further supply disruptions throughout the fourth quarter of 2018 and during 2019. These supply disruptions have adversely impacted our ability to generate our previously anticipated level of sales of and revenues from Erwinaze in 2018, and we expect that they will continue to adversely impact our ability to generate sales of and revenues from Erwinaze in 2019.

In January 2017, the FDA issued a warning letter to PBL indicating that it was not satisfied with PBL's responses to the FDA Form 483 issued to PBL in March 2016 and citing significant violations of the FDA's current Good Manufacturing Practices, or cGMP, for finished pharmaceuticals and significant deviations from cGMP for APIs. In March 2017, PBL filed a response to the warning letter with the FDA. In August 2018, the FDA conducted an inspection of the PBL manufacturing facility and issued an FDA Form 483 to PBL citing observations related to items referenced in the warning letter as well as other manufacturing practices, including data and records management. PBL continues to address the issues identified by the FDA in the warning letter and has submitted its response to the August 2018 Form 483. Following a site inspection of PBL by the UK Medicines and Healthcare Products Regulatory Agency, or MHRA, in December 2017, MHRA issued an inspection report listing several major findings, including major deficiencies and failures by PBL to comply with cGMP. In January 2018, PBL filed a response to the report with the MHRA. We cannot predict if or when PBL will correct the violations and deviations to the satisfaction of the FDA and MHRA or whether the FDA and MHRA will be satisfied with PBL's responses. Any failure by PBL to respond to the satisfaction of the FDA or MHRA could result in enforcement actions by the FDA or MHRA, including the FDA refusing admission of Erwinaze into the U.S. Any of these actions could have a material adverse effect on our sales of, and revenues from, Erwinaze and further limit our future maintenance and potential growth of the market for this product.

The current manufacturing capacity for Erwinaze is completely absorbed by demand for the product. As a consequence, there is no product inventory that can be used to absorb supply disruptions resulting from quality, manufacturing, regulatory or other issues. PBL has experienced and continues to experience product quality and manufacturing issues that have resulted, and continue to result, in disruptions in our ability to supply certain markets from time to time and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. We cannot predict whether the required remediation activities by PBL in connection with its January 2017 FDA warning letter, the December 2017 MHRA report or the August 2018 FDA Form 483 will further strain manufacturing capacity or otherwise adversely affect Erwinaze supply. As capacity constraints and supply disruptions

continue, whether as a result of continued quality or manufacturing challenges at PBL, regulatory issues or otherwise, we will be unable to build product inventory, our ability to supply the market will continue to be compromised and physicians' decisions to use Erwinaze will continue to be negatively impacted. If we continue to fail to obtain a sufficient supply of Erwinaze from PBL, our sales of and revenues from Erwinaze, our future maintenance and potential growth of the market for this product, our reputation and our business, financial condition, results of operations and growth prospects would be further materially adversely affected.

In addition, our agreement with PBL, including our license, expires in December 2020, subject to five-year extensions unless terminated by either party in writing by December 31, 2018. The parties are in discussions regarding the agreement, but we cannot predict whether the term of the agreement will be extended or, if extended, the terms of any such extension. If the agreement is terminated and we do not enter into a new agreement with PBL, we will lose our license to sell Erwinaze in any market after December 2020, except under specified terms for a post-termination transition period. We cannot predict the

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extent to which potential uncertainty related to our ongoing rights to Erwinaze will impact our sales of and revenues from Erwinaze.

Our ability to successfully maintain sales of Erwinaze is subject to a number of other challenges, including the development of new asparaginase treatments or treatment protocols and potential competition from future biosimilar products. For further discussion of these and other risks and uncertainties associated with Erwinaze, see the risk factors set forth in "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Defitelio/defibrotide. Sales of Defitelio/defibrotide were 8% of our net product sales for the three and nine months ended September 30, 2018 and for the year ended December 31, 2017. We seek to increase sales of Defitelio through selling and marketing activities. However, our ability to maintain and grow sales and to realize the anticipated benefits from our investment in Defitelio is subject to a number of risks and uncertainties, including continued acceptance by hospital pharmacy and therapeutics committees in the U.S., the continued availability of favorable pricing and adequate coverage and reimbursement, the limited experience of, and need to educate, physicians in recognizing, diagnosing and treating VOD, and the limited size of the population of VOD patients who are indicated for treatment with Defitelio. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product will be negatively affected and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

For further discussion of these and other risks and uncertainties associated with Defitelio, see the risk factors set forth in "Risks Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Vyxeos. In August 2017, the FDA approved our NDA for Vyxeos for the treatment of adults with newly-diagnosed t AML or AML-MRC. We launched and began selling Vyxeos in the U.S. in August 2017, and our commercial launch in the U.S. is still at an early stage. Sales of Vyxeos were 5% of our net product sales for the three and nine months ended September 30, 2018 and 2% of our net product sales for the year ended December 31, 2017. In August 2018, the EC granted marketing authorization for Vyxeos, and as part of our rolling launch of Vyxeos in the EU, we are in the process of making pricing and reimbursement submissions in EU member states.

Our ability to realize the anticipated benefits from our investment in Vyxeos is subject to a number of additional risks and uncertainties, including potential delays or problems in the supply or manufacture of Vyxeos, acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries, the availability of adequate coverage, pricing and reimbursement approvals and potential competition from existing products and products in development. Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location. There have been batch failures due to mechanical, component and other issues, and batches have been produced that have otherwise not been in compliance with applicable specifications. We are continuing to work with Baxter to address manufacturing complexities. If we fail to obtain a sufficient supply of Vyxeos due to manufacturing or regulatory challenges, our sales of and revenues from Vyxeos, our future maintenance and potential growth of the market for this product, and our business, financial condition, results of operations and growth prospects could be materially adversely affected. In any event, if sales of Vyxeos do not reach the levels we expect, our anticipated revenue from the product will be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. For further discussion of these and other risks and uncertainties associated with Vyxeos, see the risk factors set forth in "Risks Factors" in Part II, Item 1A of this Quarterly Report on Form 10 Q.

Solriamfetol. In the fourth quarter of 2017, we submitted an NDA to the FDA to seek approval for solriamfetol in the treatment of EDS associated with OSA and EDS associated with narcolepsy. In the first quarter of 2018, the FDA accepted the NDA for filing with a standard review and set a target action date under PDUFA of December 20, 2018. We cannot predict whether our NDA will be approved by the FDA in a timely manner, or at all. Our ability to realize the anticipated benefits from an approved solriamfetol product and our investment in solriamfetol is subject to a number of risks and uncertainties, including, among other things, the outcome of DEA scheduling review, which will need to be completed after NDA approval, if any, but before commercial launch, market acceptance for an approved solriamfetol product, potential competition from other products in development and the availability of adequate pricing, coverage and reimbursement by government programs and third party payors. For further discussion of these

and other risks and uncertainties associated with solriamfetol, see the risk factors set forth in “Risks Factors” Part II, Item 1A of this Annual Report on Form 10-Q.

Other Challenges and Risks

We anticipate that we will continue to face a number of other challenges and risks to our business and our ability to execute our strategy in 2018 and beyond. Some of these challenges and risks are specific to our business, and others are common to companies in the pharmaceutical industry with development and commercial operations.

Drug pricing by pharmaceutical companies is currently, and is expected to continue to be, under close scrutiny, including with respect to companies that have increased the price of products after acquiring those products from other companies.

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Several states have recently passed laws aimed at increasing transparency relating to drug pricing, and other states may do so in the future. Both the U.S. House of Representatives and the U.S. Senate have conducted several hearings with respect to pharmaceutical drug pricing practices, including in connection with the investigation of specific price increases by several pharmaceutical companies. Moreover, REMS and the improper use of REMS as a means of improperly blocking or delaying competition for branded pharmaceutical products have increasingly drawn public scrutiny from Congress, the Federal Trade Commission, or FTC, and the FDA. Congress, for example, has introduced proposed legislation aimed at preventing companies from using REMS and other restricted distribution programs as a means to deny potential competitors access to product samples needed for bioequivalence testing. The FDA has stated that it will seek to coordinate with the FTC in identifying and publicizing practices the FTC finds to be anticompetitive and has further stated that the FDA has concerns related to the role of REMS programs in delaying approval of generic products. For example, in May 2018, FDA published a list of companies that it said had potentially been blocking access to the samples of their branded products, including one of our subsidiaries that sells FazaClo through a REMS program. If we become the subject of any government investigation with respect to our drug pricing or other business practices, including as they relate to the Xyrem REMS, we could incur significant expense and could be distracted from operation of our business and execution of our strategy.

In May and October 2016 and in February 2017, we received subpoenas from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to Medicare patients and, for Xyrem, documents concerning the provision of financial assistance to Medicare patients. Other companies have disclosed similar subpoenas and continuing inquiries. We have a comprehensive program intended to ensure our compliance with applicable legal and regulatory requirements for pharmaceutical companies, including guidelines established by the Office of Inspector General of the U.S. Department of Health and Human Services regarding patient assistance programs, and we have been cooperating with the government's investigation. We have engaged in discussions with the U.S. Department of Justice, or DOJ, about a possible resolution, and in April 2018, we reached an agreement in principle with the DOJ on a proposal for a civil settlement of potential claims by the DOJ in the amount of $57.0 million, subject to accrual of interest on the settlement amount from the date of the agreement in principle, negotiation of a definitive settlement agreement and other contingencies. We cannot provide assurances that our efforts to reach a final settlement with the DOJ will be successful or, if they are, the timing or final terms of any such settlement. Any such settlement is also likely to involve entry into a corporate integrity agreement, which would impose costs and burdens on the operation of our business. If we do not reach a final settlement, the outcome of this investigation could include an enforcement action against us. If the federal government were to file an enforcement action against us as a result of the investigation and could establish the elements of a violation of relevant laws, we could be subject to damages, fines and penalties, which could be substantial, along with other criminal, civil or administrative sanctions, and we would expect to incur significant costs in connection with such enforcement action, regardless of the outcome. For more information, see Note 10, 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 and the risk factors under the headings "Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and these changes could have a material adverse effect on our business and financial condition" and "We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Other key challenges and risks that we face include risks and uncertainties related to:

- the challenges of protecting and enhancing our intellectual property rights;
- the challenges of achieving and maintaining commercial success of our products;
- delays or problems in the supply or manufacture of our products and product candidates, particularly with respect to certain products as to which we maintain limited inventories, our dependence on single source suppliers for most of our products, product candidates and APIs, and the requirement that we and our product suppliers be qualified by the FDA to manufacture product and comply with applicable manufacturing regulations;

- the need to obtain and maintain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and pharmaceutical pricing in the U.S. and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the U.S. in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by government programs and third party payors;
- our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business;
- the challenges of compliance with the requirements of the FDA, the DEA and comparable non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas

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where needed, marketing and promotional activities, patient assistance programs, adverse event reporting and product recalls or withdrawals;

- the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, and the uncertainty of clinical success, such as the risk that results from preclinical studies and/or early clinical trials may not be predictive of results obtained in later and larger clinical trials planned or anticipated to be conducted for our product candidates;
- the inherent uncertainty associated with the regulatory approval process, especially as we continue to increase investment in our product pipeline development projects and undertake multiple planned regulatory submissions for our product candidates;
- the risks associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historical business, the increase in geographic dispersion among our centers of operation and the risks that we may acquire unanticipated liabilities along with acquired businesses or otherwise fail to realize the anticipated benefits (commercial or otherwise) from such transactions; and
- possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

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

Results of Operations

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

	Three Months Ended September 30,		Increase/		Nine Months Ended September 30,		Increase/	
	2018	2017	(Decrease)		2018	2017	(Decrease)	
Product sales, net	$465,197	$407,971	14	%	$1,402,139	$1,171,304	20	%
Royalties and contract revenues	4,176	3,884	8	%	12,326	10,990	12	%
Cost of product sales (excluding amortization of intangible assets)	26,574	31,203	(15	)%	95,207	84,940	12	%
Selling, general and administrative	155,873	124,523	25	%	521,665	401,106	30	%
Research and development	51,160	47,362	8	%	169,959	132,447	28	%
Intangible asset amortization	46,989	47,313	(1	)%	154,955	99,164	56	%
Impairment charges	—	—	N/A(1)		42,896	—	N/A(1)	
Acquired in-process research and development	—	75,000	N/A(1)		—	77,000	N/A(1)	
Interest expense, net	18,920	19,192	(1	)%	59,171	56,330	5	%
Foreign exchange loss	756	2,224	(66	)%	5,181	9,115	(43	)%
Loss on extinguishment and modification of debt	—	—	N/A(1)		1,425	—	N/A(1)	
Income tax provision	19,348	1,239	1,462	%	75,018	65,914	14	%
Equity in loss of investees	437	273	60	%	1,360	637	114	%

(1) Comparison to prior period not meaningful.

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Revenues

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

	Three Months Ended September 30,		Increase/ (Decrease)		Nine Months Ended September 30,		Increase/ (Decrease)	
	2018	2017			2018	2017		
Xyrem	$357,251	$303,870	18	%	$1,030,036	$874,222	18	%
Erwinaze/Erwinase	41,134	49,173	(16	)%	150,474	149,585	1	%
Defitelio/defibrotide	36,177	31,213	16	%	111,736	97,351	15	%
Vyxeos	21,038	9,719	116	%	75,217	9,719	674	%
Prialt	5,792	7,930	(27	)%	20,839	21,303	(2	)%
Other	3,805	6,066	(37	)%	13,837	19,124	(28	)%
Product sales, net	465,197	407,971	14	%	1,402,139	1,171,304	20	%
Royalties and contract revenues	4,176	3,884	8	%	12,326	10,990	12	%
Total revenues	$469,373	$411,855	14	%	$1,414,465	$1,182,294	20	%

Product Sales, Net

Xyrem product sales increased in the three and nine months ended September 30, 2018 compared to the same periods in 2017 due to an increase in sales volume and a higher average net selling price. Xyrem product sales volume increased by 9% in both the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily driven by an increase in the average number of patients on Xyrem. Price increases were instituted in January 2018 and July 2017. Erwinaze/Erwinase product sales decreased in the three months ended September 30, 2018 compared to the same period in 2017 primarily due to restricted supply. Erwinaze/Erwinase net product sales for the nine months ended September 30, 2018 were consistent with the same period in 2017. Ongoing supply challenges at the manufacturer have resulted in fluctuations in inventory and continue to negatively impact our ability to supply the market. We are experiencing supply disruptions globally and expect further supply disruptions throughout the fourth quarter of 2018 and during 2019. Defitelio/defibrotide product sales increased in the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily due to higher volumes and, to a lesser extent, the positive impact of foreign exchange rates. Vyxeos product sales increased in the three and nine months ended September 30, 2018 compared to the same periods in 2017 following the launch in the U.S. in August 2017. Prialt product sales decreased in the three and nine months ended September 30, 2018 compared to the same periods in 2017. We completed the sale of our rights to Prialt to TerSera in September 2018. Other product sales decreased in the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily due to a decrease in sales of our psychiatry products due to generic competition. We expect total product sales will increase in 2018 over 2017, primarily due to anticipated growth in sales of Xyrem, Vyxeos and Defitelio.

Royalties and Contract Revenues

Royalties and contract revenues increased in the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily due to higher contract revenues from out-licensing agreements. We expect royalties and contract revenues to increase in 2018 compared to 2017 due to higher contract revenue from out-licensing agreements.

Cost of Product Sales

Cost of product sales decreased in the three months ended September 30, 2018 compared to the same period in 2017 primarily due to lower royalty expenses. Cost of product sales increased in the nine months ended September 30, 2018 compared to the same period in 2017 primarily due to an increase in net product sales. Gross margin as a percentage of net product sales was 94.3% and 93.2% in the three and nine months ended September 30, 2018, respectively, compared to 92.4% and 92.7% for the same periods in 2017. The increase in the gross margin percentage in the three and nine months ended September 30, 2018 was primarily due to change in product mix. We do not expect our gross margin as a percentage of net product sales to change materially in 2018 compared to 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in the three months ended September 30, 2018 compared to the same period in 2017 primarily due to higher marketing and promotional expenses primarily driven by promotional costs for the

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potential U.S. commercial launch of solriamfetol and for the rolling launch of Vyxeos in the EU, as well as an increase in compensation-related expenses driven by higher headcount. Selling, general and administrative expenses increased in the nine months ended September 30, 2018 compared to the same period in 2017 primarily due to an accrued estimated loss contingency, including related interest, of $57.8 million. In April 2018, we reached an agreement in principle with the DOJ on a proposal for a civil settlement of potential claims by the DOJ in the amount of $57.0 million, subject to accrual of interest on the settlement amount from the date of the agreement in principle, negotiation of a definitive settlement agreement and other contingencies. For a further description of this matter, see Note 10, 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. Selling, general and administrative expenses for the nine months ended September 30, 2018 also included higher marketing and promotional expenses primarily due to marketing and promotional costs for the potential U.S. commercial launch of solriamfetol and for the rolling launch of Vyxeos in the EU, and an increase in compensation-related expenses driven by higher headcount, compared to the same period in 2017. We expect selling, general and administrative expenses in 2018 to increase compared to 2017, primarily due to an estimated loss contingency, an increase in compensation-related expenses and other expenses resulting from the expansion and support of our business and an increase in expenses related to the preparation for the potential U.S. commercial launch of solriamfetol and the continuation of the commercial launch of Vyxeos in the U.S. and the EU.

Research and Development Expenses

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Clinical studies and outside services	$26,501	$26,197	$86,889	$67,885
Personnel expenses	17,340	15,777	52,588	48,331
Milestone expense	—	—	11,000	—
Other	7,319	5,388	19,482	16,231
Total	$51,160	$47,362	$169,959	$132,447

Research and development expenses increased by $3.8 million and $37.5 million in the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. Clinical studies and outside services costs for the three months ended September 30, 2018 were consistent with the same period in 2017. Clinical studies and outside services costs increased by $19.0 million in the nine months ended September 30, 2018 compared to the same period in 2017 primarily due to an increase in expenses related to our ongoing pre-clinical and clinical development programs, regulatory activities and support of partner programs, partially offset by lower clinical trial costs following the completion of three Phase 3 clinical trials for solriamfetol. Personnel expenses increased by $1.6 million and $4.3

million in the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017, primarily due to increased headcount in support of our development programs. Milestone expense of $11.0 million in the nine months ended September 30, 2018 related to milestone payments following FDA acceptance of our NDA for solriamfetol in March 2018.

For 2018 and beyond, we expect that our research and development expenses will continue to increase from historical levels, particularly as we prepare for anticipated regulatory submissions, 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

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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 for the three months ended September 30, 2018 was consistent with the same period in 2017. Intangible asset amortization for the nine months ended September 30, 2018 increased by $55.8 million compared to the same period in 2017, primarily due to the commencement of amortization of the Vyxeos intangible asset upon FDA approval in August 2017. We expect intangible asset amortization to increase in 2018 compared to 2017 primarily due to the full year of amortization of the Vyxeos intangible asset.

Impairment Charges

In June 2018, we entered into an asset purchase agreement, or APA, with TerSera, pursuant to which TerSera agreed to purchase substantially all of the assets held by us related to Prialt. In connection with the entry into the APA, which was subsequently amended, we reclassified the Prialt assets to be transferred to TerSera as assets held for sale and recorded these assets at fair value, less estimated sales costs, resulting in the recognition of an impairment charge of $42.9 million in the nine months ended September 30, 2018. The transaction closed on September 27, 2018.

Acquired In-Process Research and Development

Acquired in-process research and development, or IPR&D, expense in the three and nine months ended September 30, 2017 primarily related to an upfront payment of $75.0 million in connection with a collaboration and option agreement with ImmunoGen to acquire rights to opt into exclusive, worldwide licenses to develop and commercialize two early-stage, hematology-related ADC programs, as well as an additional program to be designated during the term of the agreement.

Interest Expense, Net

Interest expense, net for the three months ended September 30, 2018 was consistent with the same period in 2017. Interest expense, net increased by $2.8 million in the nine months ended September 30, 2018 compared to the same period in 2017, primarily due to interest expense on our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, which were issued in August 2017, partially offset by higher interest income and a reduction in interest expense following repayment of our revolving credit facility in full in the third quarter of 2017. We expect interest expense, net will be higher in 2018 compared to 2017 primarily due to the amortization of the debt discount on the 2024 Notes, partially offset by higher interest income.

Foreign Exchange Loss

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

Loss on Extinguishment and Modification of Debt

In the nine months ended September 30, 2018, we recorded a loss of $1.4 million in connection with the amendment of our 2015 credit agreement in June 2018, related to unamortized debt issuance costs and original issue discount associated with extinguished debt and new third party fees associated with modified debt.

Income Tax Provision

Our income tax provision was $19.3 million and $75.0 million in the three and nine months ended September 30, 2018, respectively, compared to $1.2 million and $65.9 million for the same periods in 2017. The effective tax rates were 11.4% and 20.6% in the three and nine months ended September 30, 2018, respectively, compared to 1.9% and 20.5% for the same periods in 2017. The increase in the effective tax rate for the three months ended September 30, 2018 compared to the same period in 2017 was primarily due to the release of a valuation allowance held against certain foreign net operating losses in 2017 and the impacts of movements on unrecognized tax benefits, partially offset by a decrease in the U.S. corporate income tax rate. The effective tax rate for the nine months ended September 30, 2018 was in line with the same period in 2017. The effective tax rate for the three months ended September 30, 2018 was lower than the Irish statutory rate of 12.5% primarily due to the release of reserves related to unrecognized tax benefits upon the expiration of a statute of limitations. The effective tax rate for the nine months ended September 30, 2018 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the

Irish statutory rate, various expenses not deductible for income tax purposes and unrecognized tax benefits.

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Equity in Loss of Investees

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

Liquidity and Capital Resources

As of September 30, 2018, we had cash, cash equivalents and investments of $1.1 billion, borrowing availability under our revolving credit facility of $1.6 billion and long-term debt principal balance of $1.8 billion. Our long-term debt included $659.4 million aggregate principal amount term loan, $575.0 million principal amount of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, and $575.0 million principal amount of the 2024 Notes. We generated cash flows from operations of $574.6 million during the nine months ended September 30, 2018, and we expect to continue to generate positive cash flows from operations during 2018.

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

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

In November 2016, our board of directors authorized a share repurchase program pursuant to which we are authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300 million, 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. In the nine months ended September 30, 2018, we spent a total of $77.0 million to purchase 0.5 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $154.03 per share. As of September 30, 2018, the remaining amount authorized under the share repurchase program was $105.7 million.

In November 2018, our board of directors increased the existing share repurchase program authorization by an aggregate purchase price of $320 million, exclusive of any brokerage commissions.

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

	Nine Months Ended September 30,

	2018	2017
Net cash provided by operating activities	$574,558	$488,528
Net cash used in investing activities	(428,229)	(237,072)
Net cash used in financing activities	(32,674)	(369,127)
Effect of exchange rates on cash and cash equivalents	(672)	4,323
Net increase (decrease) in cash and cash equivalents	$112,983	$(113,348)

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Net cash provided by operating activities of $574.6 million for the nine months ended September 30, 2018 related to net income of $287.6 million, adjusted for non-cash items of $286.7 million primarily related to intangible asset amortization, share-based compensation expense and impairment charges and a net cash inflow of $0.2 million related to changes in operating assets and liabilities. Net cash provided by operating activities of $488.5 million for the nine months ended September 30, 2017 related to net income of $255.6 million, adjusted for acquired IPR&D expense of $77.0 million and non-cash items of $170.6 million primarily related to intangible asset amortization and share-based compensation expense. This was partially offset by a net cash outflow of $14.7 million related to changes in operating assets and liabilities.

Net cash used in investing activities for the nine months ended September 30, 2018 primarily related to the net acquisition of investments of $350.0 million, acquisition of intangible assets of $111.1 million related to the purchase of a priority review voucher and purchases of property and equipment of $15.2 million, partially offset by net proceeds of $48.1 million from the sale of our rights to Prialt to TerSera. Net cash used in investing activities for the nine months ended September 30, 2017 primarily related to the net acquisition of investments of $140.0 million, upfront payments for acquired IPR&D of $77.0 million primarily related to a collaboration and option agreement with ImmunoGen and purchases of property and equipment of $20.1 million.

Net cash used in financing activities for the nine months ended September 30, 2018 primarily related to repurchase of ordinary shares under our share repurchase program of $77.0 million, repayment of our term loan principal of $17.4 million, payment of employee withholding taxes of $17.2 million related to share-based awards and payment of debt modification costs of $6.4 million, partially offset by proceeds from employee equity incentive and purchase plans of $84.1 million and proceeds from tenant improvement allowance on a build-to-suit lease of $1.3 million. Net cash used in financing activities for the nine months ended September 30, 2017 primarily related to repayment of borrowings under our prior revolving credit facility of $850.0 million, repurchase of ordinary shares under our share repurchase program of $56.4 million, repayment of our term loan principal of $27.1 million and payment of employee withholding taxes of $17.9 million related to share-based awards, partially offset by net proceeds from issuance of debt of $559.5 million and proceeds from employee equity incentive and purchase plans of $22.8 million.

Debt

The summary of our outstanding indebtedness under our financing arrangements is included in Note 9, Debt, of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. As of September 30, 2018, no amounts were outstanding under our revolving credit facility. During the nine months ended September 30, 2018, there were no material changes to our Exchangeable Senior Notes as set forth in Note 11, Debt, of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2017. In June 2018, we entered into a second amendment of our 2015 credit agreement, which increased our revolving credit facility from $1.25 billion to $1.6 billion, extended the maturity dates of our term loan facility and revolving credit facility from July 12, 2021 to June 7, 2023 and reduced the applicable margin for determining the interest rates on outstanding borrowings under the facilities. For more information, see 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.

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Contractual Obligations

The table below presents a summary of our contractual obligations as of September 30, 2018 (in thousands):

	Payments Due by Period				
Contractual Obligations (1)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Term loan - principal	$659,388	$33,387	$66,773	$559,228	$—
Term loan - interest (2)	93,293	22,005	40,661	30,627	—
Exchangeable Senior Notes - principal	1,150,000	—	575,000	—	575,000
Exchangeable Senior Notes - interest (3)	84,094	19,406	38,813	17,250	8,625
Revolving credit facility - commitment fee (4)	19,000	4,056	8,122	6,822	—
Commitment to equity method investees	22,300	7,000	14,000	1,300	—
Purchase and other obligations (5)	152,366	54,746	39,782	41,168	16,670
Operating lease obligations (6)	41,410	8,508	12,097	10,652	10,153
Facility lease obligations (7)	191,518	9,215	29,239	31,020	122,044
Total	$2,413,369	$158,323	$824,487	$698,067	$732,492

(1) This table does not include potential future milestone payment or royalty obligations to third parties under asset purchase, product development, license and other agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable. In 2014, we signed a definitive agreement with Aerial BioPharma LLC, or Aerial, under which we acquired worldwide development, manufacturing and commercial rights to solriamfetol (other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights). Aerial and SK are currently eligible to receive milestone payments up to an aggregate of $259 million based on development, regulatory and sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales of solriamfetol. In July 2016, we entered into an agreement with Pfenex 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. This agreement was amended in December 2017. Under the amended agreement, Pfenex received upfront, option and development milestone payments totaling $35.3 million and may be eligible to receive additional payments of up to $189 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 $87 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 September 30, 2018. The interest rate for our term loan borrowing was 3.62% as of September 30, 2018. Interest that is fixed, associated with our interest rate swaps, is calculated based on the fixed interest swap rate as of September 30, 2018.

(3) We used the fixed interest rates of 1.875% on the 2021 Notes and 1.50% on the 2024 Notes to estimate interest owed as of September 30, 2018 until the respective final maturity dates of these notes.

(4) Our revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.25% and assumed undrawn amounts of $1.6 billion as of September 30, 2018 to estimate commitment fees owed.

(5) Consists primarily of non-cancelable commitments to our third party manufacturers and to ImmunoGen under our 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.

(7) This includes a lease agreement we entered into in January 2015 to lease office space located in Palo Alto, California in a building subsequently constructed by the landlord, which we occupied beginning in October 2017, and a lease agreement we entered into in September 2017 to lease additional office space located in Palo Alto, California in a second building to be constructed by the same landlord, which we expect to occupy by the end of 2019. Not included in the table above are our estimated costs of approximately $20 million associated with the design, development and construction of tenant improvements under the lease agreement entered into in September 2017, which estimate does not include a tenant improvement allowance to be provided by the landlord.

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

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

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2017. Except for the revenue recognition policy that was updated as a result of adopting ASU No. 2014-09, “Revenue from Contracts with Customers”, 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, 2017.

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” “foreseeable,” “likely,” “unforeseen” and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other risk factors in greater detail under Part II, Item 1A of this Quarterly Report on Form 10-Q. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our plans, objectives, estimates, expectations and intentions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results and the timing of events may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we undertake no obligation to update or supplement any forward-looking statements publicly, or to update or supplement the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three and nine months ended September 30, 2018, 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, 2017.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2018.

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

Changes in Internal Control over Financial Reporting. During the quarter ended September 30, 2018, 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.

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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 10, 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 Xyrem and the Significant Impact of Xyrem Sales

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

Xyrem is our largest selling product, and our financial results are significantly influenced by sales of Xyrem, which accounted for 77% and 73% of our net product sales for the three and nine months ended September 30, 2018 and 74% of our net product sales for the year ended December 31, 2017. Our future plans assume that sales of Xyrem will increase, but we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in January 2018, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

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

- the potential U.S. introduction of a generic version of Xyrem before the entry dates specified in our settlements with the abbreviated new drug application, or ANDA, filers, or on terms that are different from those contemplated by the settlement agreements, as further described below;
- the potential U.S. introduction of new products that compete with, or otherwise disrupt the market for, Xyrem in the treatment of cataplexy and/or excessive daytime sleepiness, or EDS, in narcolepsy;
- changes to or uncertainties around regulatory restrictions, including, among other things, changes to our Xyrem risk evaluation and mitigation strategy, or REMS, as further described below;
- potential challenges to our intellectual property around Xyrem, including the possibility of new ANDA or new drug application, or NDA, filers or new post-grant patent review proceedings;
- any increase in pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors;
- changes in healthcare laws and policy, including changes in requirements for patient assistance programs, rebates, reimbursement and coverage by federal healthcare programs, and changes resulting from increased scrutiny on pharmaceutical pricing and REMS programs by government entities;
- operational disruptions at the Xyrem central pharmacy or any failure to comply with our REMS obligations to the satisfaction of the U.S. Food and Drug Administration, or FDA;
- any supply or manufacturing problems, including any problems with our sole source Xyrem active pharmaceutical ingredient, or API, provider;
- continued acceptance of Xyrem by physicians and patients, including as a result of negative publicity that surfaces from time to time;

- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem; and
- our U.S.-based API and Xyrem suppliers' ability to obtain sufficient quotas from the U.S. Drug Enforcement Administration, or DEA, to satisfy our needs for Xyrem.

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

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

The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem.

Although Xyrem is protected by patents covering its manufacture, formulation, distribution system and method of use, nine companies have sent us notices that they had filed ANDAs with the FDA seeking approval to market a generic version of Xyrem, and we filed patent lawsuits against each of them, asserting that such generic products would violate our patents covering Xyrem. We settled lawsuits against all nine ANDA filers, and the settlements are described below.

In our settlement with the first filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), or West-Ward, we granted West-Ward the right to sell an authorized generic version of Xyrem, or AG Product, in the U.S. beginning on January 1, 2023, or earlier under certain circumstances, including circumstances related to the licensing or market entry of another generic sodium oxybate product, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time. We also granted West-Ward a license to launch its own generic sodium oxybate product as early as six months after it has the right to sell the AG Product, but if it elects to continue to sell the AG Product, which it may do for up to a total of five years, West-Ward will not be able to continue to sell the West-Ward AG Product. In our settlements with Amneal Pharmaceuticals LLC, or Amneal, Lupin Inc., or Lupin, and Par Pharmaceutical, Inc., or Par, we granted each of them 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. Such circumstances include events related to acceleration of West-Ward's AG Product launch date, the earlier launch of another party's AG Product, the launch of another generic sodium oxybate product, or a final decision that all unexpired claims of the Xyrem patents are not infringed, or are invalid and/or unenforceable. We also granted each of Amneal, Lupin and Par a license to launch its own generic sodium oxybate product under its ANDA(assuming FDA approval of its ANDA is obtained or maintained) on or after December 31, 2025, or earlier under certain circumstances. Such circumstances include events related to launch of a generic sodium oxybate product by West-Ward or another company under its ANDA, or a final decision that all unexpired claims of the Xyrem patents are not infringed, or are invalid and/or unenforceable. If an acceleration event occurs, then Amneal, Par and Lupin will have the option to elect to market its AG Product until December 31, 2025, but such party will not be entitled to market its AG Product and its own generic sodium oxybate product simultaneously. In our settlements with each of the other ANDA filers, we granted each a license to launch its own generic sodium oxybate product under its ANDA (assuming FDA approval of its ANDA is obtained or maintained) on or after December 31, 2025, or earlier under certain circumstances, including the launch by West-Ward or another company of a generic sodium oxybate product. In accordance with legal requirements, we have submitted our Xyrem settlement agreements to the U.S. Federal Trade Commission, or FTC, and the U.S. Department of Justice, or DOJ, for review.

For further description of these settlements and legal proceedings, see Note 10, 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 and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Challenges, Risks and Trends Related to Our Lead Marketed Products and Product Candidates Submitted for Regulatory Approval" included in Part I, Item 2 of this Quarterly Report on Form 10-Q. It is possible that additional companies may file ANDAs seeking to market a generic version of Xyrem or NDAs referencing Xyrem, which could lead to additional patent litigation or challenges with respect to Xyrem.

Certain ANDA filers filed petitions for inter partes review, or IPR, by the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO, with respect to the validity of certain distribution, method of use and formulation patents covering Xyrem. After reviewing these patents through the IPR proceedings, the PTAB determined that all of the claims of six patents associated with the Xyrem REMS, or REMS patents and three claims

of a seventh REMS patent, are unpatentable. In July 2018, the United States Court of Appeals for the Federal Circuit, or the Federal Circuit, upheld these PTAB decisions on appeal, and as a result, we will not be able to enforce claims the PTAB found unpatentable. For further description of these legal proceedings, see Note 10, 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. We cannot predict whether new parties will petition for post-grant patent review in the future, the outcome of any future IPR or other proceeding or the impact any IPR or other proceeding might have on any future ANDA or other patent litigation proceedings or other aspects of our Xyrem business.

In January 2017, the FDA approved West-Ward's ANDA for a generic sodium oxybate product. The FDA's letter approving West-Ward's ANDA notes that, as the first ANDA applicant, West-Ward is eligible for 180 days of generic drug exclusivity. West-Ward's ANDA approval also includes a waiver that permits West-Ward to use a separate REMS program from the Xyrem REMS on the condition that the REMS approved with West-Ward's ANDA, or the generic sodium oxybate REMS, be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. In January 2017, the FDA tentatively

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approved two additional ANDAs for generic sodium oxybate products, and we believe that it is likely that the FDA will approve or tentatively approve additional ANDAs that have been filed.

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 ANDA litigation settlement agreements are subject to acceleration under certain circumstances, including as described above.

For example, a company that has not settled ANDA litigation with us could obtain a final decision prior to January 1, 2023 that all unexpired claims of the Xyrem patents are invalid and/or unenforceable by prevailing against us in patent litigation or as a result of an IPR challenge. In such event, West-Ward's AG Product launch date would be accelerated to approximately the date of that final decision, which would also accelerate the permitted launch of Par, Lupin and Amneal's AG Products and could accelerate the launch of other generic sodium oxybate products

Another circumstance that could accelerate the launch of an AG Product or a generic sodium oxybate product is market entry of another generic sodium oxybate product. For example, if a company that has not settled ANDA litigation with us obtains FDA approval for its generic sodium oxybate product and is able to distribute its product through an approved generic sodium oxybate REMS, such company could launch its generic product before the entry dates specified in our settlement agreements even in the absence of a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, subject in some cases to West-Ward's 180-day exclusivity. Circumstances that could result in such a launch include, for example, a judicial determination that such company's product does not infringe our patents; a judicial determination that our Xyrem patents are valid and infringed but that an injunction against such company launching its product is not warranted; or a decision by such company, before applicable patent litigation is concluded, to launch its product at risk of being held liable for damages for patent infringement. It is also possible that we could enter into a settlement agreement with a future ANDA filer that would permit such filer to enter the market on or prior to the launch date(s) agreed with West-Ward. If a company launches a generic sodium oxybate product in any of these scenarios, except in limited circumstances related to an "at risk" launch, the launch date for West-Ward's AG Product would be accelerated to a date on or prior to the date of such entry, which could lead to acceleration of the other settling ANDA filers' AG Product and generic sodium oxybate product launch dates as described above.

Another circumstance that could trigger acceleration of West-Ward's launch date for an AG Product, which would also lead to acceleration of Par, Lupin and Amneal's launch date 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 substantially erodes Xyrem net sales prior to January 1, 2023.

Other companies could also develop and launch sodium oxybate or other products that are similar, but not identical, to Xyrem, such as an alternative formulation or a different delivery technology, and seek approval in the U.S. through an NDA approval pathway under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, by referencing Xyrem and relying, to some degree, on the FDA's approval of Xyrem and related determinations of safety and efficacy. Avadel Pharmaceuticals plc, or Avadel, a company that is using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients, has stated that it is conducting a Phase 3 pivotal trial pursuant to an FDA-approved special protocol assessment, and has indicated that it intends to seek approval of its product candidate using a Section 505(b)(2) NDA approval pathway referencing Xyrem.

We are also aware of products being developed by others for use as treatment options in cataplexy and/or EDS in patients with narcolepsy that have different safety profiles and mechanisms of action than Xyrem, including pitolisant, a product to treat adult patients with narcolepsy with or without cataplexy that received marketing approval in Europe in 2016. While pitolisant is currently not approved by the FDA for marketing in the U.S., the company that has exclusive U.S. commercialization rights to pitolisant established an expanded access program for the product and announced that it has received Breakthrough Therapy and Fast Track designations from the FDA for its investigational product and that it is preparing an NDA submission for the product. The receipt of marketing approval

and commercialization of products that may be approved in the U.S. for the treatment of narcolepsy patients could, depending on the targeted patient population, reduce Xyrem sales, which could have the additional effect of potentially triggering acceleration of market entry of AG Products or other generic sodium oxybate products under our ANDA litigation settlement agreements, as described above and elsewhere in this Quarterly Report on Form 10-Q. After any introduction of a generic product, whether or not it is an AG Product, a significant percentage of the prescriptions written for Xyrem may be filled with the generic product. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products where a generic version is available. This would result in reduction in sales of, and revenue from, Xyrem, although we would continue to receive royalty and other revenue based on sales of an AG Product in accordance with the terms of our settlement agreements. Any ANDA holder launching any AG Product or another generic sodium oxybate product will establish the price of the AG Product and/or its own generic sodium oxybate product. However, generic competition often

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results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic product available.

We expect that the launch of any generic sodium oxybate product, including any AG Product, or the approval and launch of other products that compete with Xyrem, would be likely to have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects.

For further discussion regarding legal proceedings and settlement agreements related to Xyrem, the risks associated with our ANDA settlement agreements, the approval and tentative approval of ANDAs, the potential launch of AG Products or other generic versions of Xyrem, or the approval and launch of other sodium oxybate or other products that compete with Xyrem, as well as other risks and challenges we face with respect to Xyrem, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Challenges, Risks and Trends Related to Our Lead Marketed Products and Product Candidates Submitted for Regulatory Approval" included in Part I, Item 2 of this Quarterly Report on Form 10-Q, the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales," "Risks Related to Our Intellectual Property," and "We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have" in this Part II, Item 1A, and Note 10, 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.

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

The FDA requires that we maintain a REMS for Xyrem to help ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. In February 2015, the FDA approved the current Xyrem REMS, which requires, among other things, that Xyrem be distributed through a single pharmacy. In the FDA's February 2015 letter approving the Xyrem REMS, the FDA stated that (i) the approval action should not be construed or understood as agreement with what the FDA stated was our position that dispensing through a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh its risks, and that the FDA has continuing concerns that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system, and (ii) as with all REMS, the FDA intends to evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. In October 2018, in connection with the FDA's approval of our supplemental NDA, or sNDA, to revise the labeling for Xyrem to include an indication to treat cataplexy or EDS in pediatric narcolepsy patients ages seven and older, the FDA modified the February 2015 Xyrem REMS to add provisions and material for pediatric patients and caregivers, but did not modify the current operation of the Xyrem REMS. We cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xyrem REMS, including in connection with the submission of applications for new oxybate indications or products, or whether FDA will approve modifications to the Xyrem REMS that we consider warranted in connection with the submission of applications for new oxybate indications or products. Any modifications approved, required or rejected by the FDA could make it more difficult or expensive for us to distribute Xyrem, make distribution easier for sodium oxybate competitors, impair the safety profile of Xyrem, disrupt continuity of care for Xyrem patients and/or negatively affect sales of Xyrem.

In August 2015, we implemented the Xyrem REMS, as approved by the FDA in February 2015, and we plan to implement the October 2018 modifications to the Xyrem REMS within 120 days of that approval. We have submitted and expect to continue to submit ongoing assessments as set forth in the FDA's Xyrem REMS approval letters. However, we cannot guarantee that our implementation and ongoing assessments will be satisfactory to the FDA or that the Xyrem REMS will satisfy the FDA's expectations in its evaluation of the Xyrem REMS on an ongoing basis. Any failure to comply with the REMS obligations, or determination by the FDA that the Xyrem REMS is not meeting its goals, could result in enforcement action by the FDA; lead to changes in our Xyrem REMS obligations; negatively affect sales of Xyrem; result in additional costs and expenses for us; and/or take a significant amount of time, any of

which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

While we have an exclusive agreement with Express Scripts Specialty Distribution Services, Inc., the central pharmacy for Xyrem, through June 2019 (subject to a one-year extension at our discretion unless either party provides 180 days' notice to the other of its intent to terminate the agreement), if the central pharmacy does not fulfill its contractual obligations to us, fails to meet the requirements of the Xyrem REMS applicable to the central pharmacy, provides timely notice that it wants to terminate our agreement, refuses or fails to adequately serve patients, or fails to promptly and adequately address operational challenges or challenges in implementing REMS modifications, whether expected or unexpected, the fulfillment of Xyrem prescriptions and our sales would be adversely affected. If we change to a new central pharmacy, new contracts might be required with government and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and certified and

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would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under the Xyrem REMS. Transitioning to a new pharmacy could result in product shortages, which would negatively affect sales of Xyrem, result in additional costs and expenses for us and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Section 505-1(i)(1) of the FDCA generally provides that (i) an ANDA that references a drug subject to a REMS with elements to assure safe use, or ETASU, is required to have a REMS with the same elements as the reference listed drug, or RLD, and (ii) the ANDA drug and the RLD shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and approve an ANDA with a separate REMS with differing but comparable aspects of ETASU under certain circumstances. These requirements do not apply to an application submitted under Section 505(b)(2) of the FDCA, even if that application references a drug subject to a REMS with ETASU.

In January 2017, the FDA approved West-Ward's ANDA and waived the shared REMS requirement. The FDA's waiver of the shared REMS requirement permits West-Ward to use a separate REMS program from the Xyrem REMS, or the generic sodium oxybate REMS, for the generic sodium oxybate product, on the condition that the generic sodium oxybate REMS be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. This could potentially include future sodium oxybate products approved under a Section 505(b)(2) approval pathway. We cannot predict whether a company marketing a sodium oxybate product approved under Section 505(b)(2) would be required or permitted to distribute its product through the generic sodium oxybate REMS or a separate REMS. In connection with the waiver, FDA issued a statement that it considers the generic sodium oxybate REMS to have the same ETASU as the Xyrem REMS and operationalizes those elements in a comparable manner to achieve the same level of safety as the Xyrem REMS. We were not involved in development of the generic sodium oxybate REMS and were not consulted regarding any features of this REMS. A sodium oxybate distribution system that is less restrictive than the Xyrem REMS, such as the generic sodium oxybate REMS, which provides that generic sodium oxybate products could be distributed through multiple pharmacies, could increase the risks associated with sodium oxybate distribution. 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, public acceptance of Xyrem as a treatment for EDS and cataplexy in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, as patients, consumers and others may not differentiate generic sodium oxybate from Xyrem or differentiate between the different REMS programs, any of which could have a material adverse effect on our Xyrem business.

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

In September 2016, Jazz Pharmaceuticals, Inc., our wholly owned subsidiary, submitted a Citizen Petition to the FDA requesting that, for safety reasons, the FDA refuse to approve any sodium oxybate ANDA with a proposed package insert or REMS that omits the portions of the Xyrem package insert and the Xyrem REMS that instruct prescribers on adjusting the dose of the product when it is co-administered with divalproex sodium (also known as valproate or valproic acid). In January 2017, the FDA granted the Citizen Petition with respect to the Xyrem package insert. The FDA concluded that it will not approve any sodium oxybate ANDA referencing Xyrem that does not include in its package insert the portions of the currently approved Xyrem package insert related to the drug-drug interaction, or DDI, with divalproex sodium. Our Xyrem DDI patents cover these instructions on the Xyrem package insert and Xyrem REMS. 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 method of administration patents notwithstanding the FDA's response to the Citizen Petition, or whether any such strategy would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of any of our 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.

For further discussion regarding these matters, see the risk factors under the headings "The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem" and "Risks Related to Our Intellectual Property" in this Part II, Item 1A.

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REMS and the improper use of REMS as a means of improperly blocking or delaying competition for branded pharmaceutical products have increasingly drawn public scrutiny from Congress, the FTC and the FDA. Congress, for example, has introduced proposed legislation aimed at preventing companies from using REMS and other restricted distribution programs as a means to deny potential competitors access to product samples needed for bioequivalence testing. The FDA has stated that it will seek to coordinate with the FTC in identifying and publicizing practices the FTC finds to be anticompetitive and has further stated that the FDA has concerns related to the role of REMS programs in delaying approval of generic products. For example, in May 2018, FDA published a list of companies that it said had potentially been blocking access to the samples of their branded products, including one of our subsidiaries that sells FazaClo through a REMS program. It is possible that the FTC, the FDA, other governmental authorities or other third parties could claim that, or launch an investigation into whether, we are using our REMS programs in an anticompetitive manner (including in light of the FDA's statement in the February 2015 Xyrem REMS approval letter that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the FDCA) or have engaged in other anticompetitive practices. The FDCA further states that a REMS ETASU shall not be used by an NDA holder to block or delay generic drugs or drugs covered by an application under Section 505(b)(2) from entering the market. Several of the ANDA applicants asserted that our REMS patents should not have been listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book, and that the Xyrem REMS is blocking competition. We cannot predict the outcome of any potential government investigation of these claims or the impact of any similar claims that may be made in the future.

The FDA has required that Xyrem's labeling include a boxed warning regarding the risk of central nervous system depression and misuse and abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. Our Xyrem REMS includes unique features that provide more extensive information about adverse events, including deaths, than is generally available for other products that are not subject to similar REMS requirements. As required by the FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to the FDA and could result in the FDA requiring changes to Xyrem labeling, including additional warnings or boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of Xyrem.

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

Risks Related to Our Business

While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products and, in the case of our product candidates, our ability to obtain regulatory approval in the U.S. and Europe and, if approved, to successfully launch and commercialize those product candidates. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to Xyrem, we are commercializing a portfolio of products, including our other lead marketed products, Erwinaze, Defitelio and Vyxeos, and we are making significant investments in solriamfetol and other product candidates that are currently not approved as marketed products in any jurisdiction.

Erwinaze

Erwinaze (called Erwinase in markets outside the U.S.), a biologic product, is used in conjunction with chemotherapy to treat patients with acute lymphoblastic leukemia, or ALL, with hypersensitivity to E. coli-derived asparaginase. Erwinaze was approved by the FDA under a biologics license application, or BLA, and was launched in the U.S. in

November 2011. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere. Erwinaze 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 agreement with PBL, including our license, expires in December 2020, subject to five-year extensions unless terminated by either party in writing by December 31, 2018. The parties are in discussions regarding the agreement, but we cannot predict whether the term of the agreement will be extended or, if extended, the terms of any such extension. If the agreement is terminated and we do not enter into a new agreement with PBL, we will lose our license to sell Erwinaze in any market after December 2020, except under specified terms for a post-termination transition period. We cannot predict the extent to which potential uncertainty related to our ongoing rights to Erwinaze will impact our sales of and revenues from Erwinaze.

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A significant challenge to our ability to maintain and potentially increase sales is the limited supply of Erwinaze, which has resulted, and continues to result, in supply disruptions, and our need for PBL to minimize or avoid additional supply disruptions due to capacity constraints, production delays, quality or regulatory challenges and other manufacturing difficulties. We have been experiencing, and continue to experience, supply disruptions globally and expect further supply disruptions throughout the fourth quarter of 2018 and during 2019. These supply disruptions have adversely impacted our ability to generate our previously anticipated level of sales of and revenues from Erwinaze in 2018, and we expect that they will continue to adversely impact our ability to generate sales of and revenues from Erwinaze in 2019. See the discussion regarding Erwinaze supply issues in the risk factor under the heading "The loss of our single source suppliers, delays or problems in the supply of our products for commercial sale or our product candidates for use in our clinical trials, or our or our suppliers' failure to comply with manufacturing regulations, could materially and adversely affect our business, financial condition, results of operations and growth prospects" in this Part II, Item 1A. Our ability to maintain and successfully and sustainably grow sales of Erwinaze is also subject to a number of additional challenges, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to E. coli-derived asparaginase within that population and our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise in certain additional countries if we decide to launch promotional efforts in those countries.

We also face numerous other risks that may impact Erwinaze sales, including regulatory risks, the development of new asparaginase treatments or treatment protocols that could reduce the rate of hypersensitivity in patients with ALL, the development of new treatment protocols for ALL that may not include asparaginase-containing regimens, difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements, and potential competition from future biosimilar products. In addition, if we fail to comply with our obligations under our agreement with the licensor and supplier of Erwinaze or lose rights to Erwinaze, including if our agreement terminates at the end of its current term in December 2020, or if we otherwise fail to maintain or grow sales of Erwinaze, our growth prospects could be negatively affected.

Defitelio

We made a significant investment in Defitelio in 2014, adding the product to our portfolio as a result of our acquisition of Gentium S.r.l, which we refer to as the Gentium Acquisition, and then securing worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. We began to commercialize Defitelio in certain European countries in 2014. In March 2016, the FDA approved our NDA for Defitelio for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT. We launched Defitelio in the U.S. shortly after FDA approval.

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

- the continued acceptance of Defitelio in the U.S. by hospital pharmacy and therapeutics committees and the continued availability of favorable pricing and adequate coverage and reimbursement by government programs and third party payors;
- the limited experience of, and need to educate, physicians in recognizing, diagnosing and treating VOD, particularly in adults;
- the possibility that physicians recognizing VOD symptoms may not initiate or may delay initiation of treatment while waiting for those symptoms to improve, or may terminate treatment before the end of the recommended dosing schedule;
- our ability to successfully maintain or grow sales of Defitelio in Europe and other non-U.S. countries;
- delays or problems in the supply or manufacture of the product;
- the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in HSCT treatment protocols reduce the incidence of VOD diagnosis);
- our ability to meet the post-marketing commitments and requirements imposed by the FDA in connection with its approval of our NDA for Defitelio; and
- our ability to obtain marketing approval in other countries and to develop the product for additional indications.

The process of maintaining pricing and reimbursement approvals is complex and varies from country to country. Many European countries periodically review their reimbursement classes, which could have an adverse impact on the reimbursement status of Defitelio. We cannot predict the outcome of any periodic reviews required to maintain pricing and reimbursement approvals across Europe. In addition, orphan products that have a significant impact on patient survival, such as Defitelio, may be budgeted on a local rather than national level. The balance of all of these factors will determine our ability to maintain favorable pricing and reimbursement approvals across Europe. Furthermore, after initial pricing and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced countries. If any of these events occurs, our anticipated revenue from Defitelio and our other products in the EU would be negatively affected. If we are unable to maintain favorable pricing and reimbursement approvals in countries that represent significant markets, especially

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where a country's reimbursed price influences other countries, our anticipated revenue from and growth prospects for Defitelio in the EU could be negatively affected. In addition, our ability to commercialize Defitelio successfully in the U.S. will depend on, among other things, the continued availability of adequate coverage or reimbursement by U.S. government programs and third party payors.

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

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

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

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

Vyxeos

We made a significant investment in Vyxeos through the acquisition of Celator Pharmaceuticals, Inc., which we refer to as the Celator Acquisition. Vyxeos is the first injectable fixed ratio, drug delivery combination oncology product based on our CombiPlex technology platform approved by the FDA and the EC. In August 2017, the FDA approved our NDA for Vyxeos for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or t-AML, or acute myeloid leukemia, or AML, with myelodysplasia-related changes, or AML-MRC. We launched and began shipping Vyxeos in the U.S. in August 2017, and our U.S. commercial launch is still at an early stage. In August 2018, the EC granted marketing authorization for Vyxeos, and as part of our rolling launch of Vyxeos in the EU, we are in the process of making pricing and reimbursement submissions in EU member states. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected EU member states would be delayed, which could negatively impact anticipated revenue from Vyxeos. In addition, we are seeking or plan to seek approval to market Vyxeos in additional countries.

Our ability to realize the anticipated benefits from our investment in Vyxeos is subject to a number of additional 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;
- delays or problems in the supply or manufacture of the product, including the ability of the third parties upon which we rely to manufacture Vyxeos and its APIs to manufacture sufficient quantities in accordance with applicable specifications;
- the need to establish pricing and reimbursement support for Vyxeos in the U.S., the EU and in other countries;
- the acceptance of Vyxeos in the U.S., the EU and other countries by hospital pharmacy and therapeutics committees and the availability of adequate coverage and reimbursement by government programs and third party payors;

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- the increasing complexity of the AML landscape requiring changes in patient identification and treatment selection, including diagnostic tests and monitoring that clinicians may find challenging to incorporate;
- the use of new and novel compounds in AML that are either used off-label or are only approved for use in combination with other agents and that have not been tested in combination with Vyxeos; and
- the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos, particularly given the ongoing clinical trials by other companies with the same patient population.

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

In addition, the FDA imposed two post-marketing requirements in connection with its approval of our NDA for Vyxeos, including the requirement that we conduct a safety study to characterize infusion-related reactions in patients treated with Vyxeos and a clinical trial to determine dosing to minimize toxicity in patients with moderate and severe renal impairment. The marketing authorization in the EU for Vyxeos also requires us to comply with certain manufacturing-related post-approval commitments. In the event that we are unable to comply with these or other post-marketing obligations imposed as part of the marketing approval for Vyxeos in the U.S. or EU, our sales of and revenues from Vyxeos could be materially adversely affected, and our future maintenance and potential growth of the market for this product may be limited.

If we fail to maintain or increase revenue from sales of Erwinaze, Defitelio and Vyxeos, our business, financial condition, results of operations and growth prospects could be materially adversely affected. In addition to the specific risks described above, sales volumes and revenues from each of these products could be negatively affected by other risks and uncertainties described elsewhere in this Part II, Item 1A.

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

Solriamfetol

In 2017, we announced positive efficacy results from our two Phase 3 clinical trials of solriamfetol, a late-stage investigational compound being developed for potential treatment of EDS in patients with obstructive sleep apnea, or OSA, and from our Phase 3 clinical trial of solriamfetol in patients with narcolepsy. We submitted an NDA to the FDA in the fourth quarter of 2017 to seek approval for solriamfetol in the treatment of EDS associated with OSA and EDS associated with narcolepsy. In the first quarter of 2018, the FDA accepted the NDA for filing with a standard review and set a target action date under the Prescription Drug User Fee Act, or PDUFA, of December 20, 2018. We cannot predict whether our NDA will be approved by the FDA in a timely manner, or at all. Our ability to realize the anticipated benefits from an approved solriamfetol product is subject to a number of risks and uncertainties, including, among other things, the outcome of DEA scheduling review, which will need to be completed after NDA approval, if any, but before commercial launch, market acceptance for an approved solriamfetol product, potential competition from other products in development and the availability of adequate pricing, coverage and reimbursement by government programs and third party payors, as well as other risks and uncertainties described elsewhere in this Part II, Item 1A.

Other Product Candidates

In furtherance of our growth strategy, we have made significant investments in a number of other product candidates, including ongoing development activities for two other product candidates in our sleep therapeutic area.

Any failure or delay in completing necessary clinical trials and conducting other activities, including chemistry, manufacturing and controls, or CMC, activities, that are required to complete our planned regulatory submissions and obtain regulatory approvals could materially and adversely affect our business, financial condition, results of operations and growth prospects. See the discussion under the heading “Conducting clinical trials is costly and time-consuming, and the outcomes are uncertain. A failure to prove that our product candidates are safe and effective

in clinical trials, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects" in this Part II, Item 1A for a discussion of risks related to our clinical trials of solriamfetol and other product candidates. See also the discussions under the headings "The loss of our single source suppliers, delays or problems in the supply of our products for commercial sale or our product candidates for use in our clinical trials, or our or our suppliers' failure to comply with manufacturing regulations, could materially and adversely affect our business, financial condition, results of operations and growth prospects" and "The regulatory approval process is expensive, time-consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates" in this Part II, Item 1A.

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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.

The loss of our single source suppliers, delays or problems in the supply of our products for commercial sale or our product candidates for use in our clinical trials, or our or our suppliers' failure to comply with manufacturing regulations, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the API and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. We and our suppliers may encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. These difficulties can be heightened when we or our suppliers are required to produce finished product at commercial scale or to produce increased quantities to meet growing demand. In addition, we and our suppliers are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and other equivalent rules and regulations prescribed by non-U.S. regulatory authorities. We have cGMP responsibilities for the products we manufacture in our own facilities and also have oversight responsibilities for the manufacturing conducted by third party suppliers operating under contract with us. If we or any of our suppliers encounter manufacturing, quality or compliance difficulties with respect to any of our products, we may be unable to obtain or maintain regulatory approval, or meet commercial demand, for such products, which could adversely affect our business, financial condition, results of operations and growth prospects. In addition, the failure of any of our suppliers to comply with cGMP or other rules and regulations while manufacturing products on our behalf could result in regulatory action directed at the adequacy of our oversight of our contract suppliers, which could result in enforcement actions against us by the FDA and other regulatory entities.

We have a manufacturing and development facility in Athlone, Ireland. We are using this facility for the manufacture of Xyrem and development-stage products, including JZP-507 and JZP-258, and we expect to manufacture these products commercially at our Athlone facility should these candidates receive regulatory approval. However, other than our Athlone facility and our 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 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. 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. These single source arrangements put us at risk of interruption in supply in the event of manufacturing, quality or compliance difficulties at our suppliers.

Siegfried USA, LLC and its affiliates, or Siegfried, have been our sole supplier of sodium oxybate, the API for Xyrem, since 2012. Siegfried supplies sodium oxybate to our U.S.-based manufacturer of Xyrem and, through a Siegfried affiliate in Europe, to our Athlone facility. We expect that Siegfried will continue to be our sole supplier of sodium oxybate for the foreseeable future, and we cannot assure you that Siegfried can or will continue to supply on a timely basis, or at all, sufficient quantities of API to enable the manufacture of the quantities of Xyrem that we need.

Patheon Pharmaceuticals Inc., which we refer to together with its affiliates as Patheon, is our sole U.S.-based manufacturer and supplier of Xyrem. Although we manufacture Xyrem in our Athlone facility, we expect to rely on Patheon as our U.S.-based supplier of Xyrem for the foreseeable future, and we cannot assure you that Patheon can or will continue to supply on a timely basis, or at all, the quantities of Xyrem that we need from Patheon.

Sodium oxybate is a Schedule I controlled substance in the U.S. The DEA limits the quantity of Schedule I controlled substances that may be manufactured and procured in the U.S. in any given calendar year through a quota system and,

as a result, quotas from the DEA are required to manufacture and procure sodium oxybate in the U.S. Accordingly, we require DEA quotas for Siegfried in the U.S. to manufacture sodium oxybate and for Patheon, our U.S.-based Xyrem supplier, to procure the sodium oxybate from Siegfried to manufacture and supply us with Xyrem. Because the DEA typically grants quotas on an annual basis, Siegfried and Patheon are required to request and justify allocation of sufficient annual DEA quotas, as well as any additional DEA quotas necessary if our commercial or clinical requirements exceed the allocated quotas throughout the year. For the last few years, our suppliers were allocated only a portion of the published annual aggregate quota for the API. If one or more ANDA filers were to begin manufacturing a generic sodium oxybate product, generic manufacturers would need to obtain a portion of the annual aggregate API quota, which could decrease the DEA quota allocation obtained on our behalf by Siegfried and Patheon. In the past, we have had to engage in lengthy efforts to obtain the needed quotas after the original annual quotas had first been allocated. If, in the future, we and our third party suppliers cannot obtain the quotas that are

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needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

Erwinaze is licensed from, and manufactured for us by, a single source, PBL, a company that is wholly owned by the UK Department of Health and Social Care. The FDA's approval of the BLA for Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze by PBL. We cannot predict if or when PBL will comply with its manufacturing-related post-marketing commitments that are part of the BLA approval. In January 2017, the FDA issued a warning letter to PBL indicating that it was not satisfied with PBL's response to the FDA Form 483 issued to PBL in March 2016 and citing significant violations of cGMP for finished pharmaceuticals and significant deviations from cGMP for APIs. In March 2017, PBL filed a response to the warning letter with the FDA. In August 2018, the FDA conducted an inspection of the PBL manufacturing facility and issued an FDA Form 483 to PBL citing observations related to items referenced in the warning letter as well as other manufacturing practices, including data and records management. PBL continues to address the issues identified by the FDA in the warning letter and has submitted its response to the August 2018 Form 483. We cannot predict if or when PBL will correct the violations and deviations to the satisfaction of the FDA or whether the FDA will be satisfied with PBL's response. Any failure to do so to the satisfaction of the FDA could result in the FDA refusing admission of Erwinaze into the U.S., as well as additional enforcement actions by the FDA and other regulatory entities.

In the United Kingdom, or UK, where PBL's manufacturing facilities are located, PBL is subject to similar inspections conducted by the UK Medicines and Healthcare Products Regulatory Agency, or MHRA. Following a site inspection of PBL by MHRA in December 2017, MHRA issued an inspection report listing several major findings, including major deficiencies and failures by PBL to comply with cGMP. In January 2018, PBL filed a response to the report with the MHRA. We cannot predict if or when PBL will correct the violations and deviations to the satisfaction of MHRA or whether the MHRA will be satisfied with PBL's responses. Any failure by PBL to do so to the satisfaction of the MHRA could result in an enforcement action by the MHRA.

Inability to comply with regulatory requirements of the FDA, the MHRA or other competent authorities in the EU member states in which Erwinaze is subject to marketing authorization could adversely affect Erwinaze supply, particularly in light of the ongoing limited supply of Erwinaze, and could result in: enforcement actions by the FDA, MHRA or other EU member states' competent authorities (including the issuance of the local equivalents of FDA Form 483s or warning letters); the approval of the FDA or other competent authorities being suspended, varied, or revoked; product release being delayed or suspended; or product being seized or recalled. Any of these actions could have a material adverse effect on our sales of, and revenues from, Erwinaze and further limit our future maintenance and potential growth of the market for this product. In addition, if the FDA or any non-U.S. regulatory authority mandates any changes to the specifications for Erwinaze, we may face challenges having product produced to meet such specifications, and our supplier may increase its price to supply Erwinaze meeting such specifications, which may result in additional costs to us or a delay in supply and may decrease any profit we would otherwise achieve with Erwinaze.

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

If quality, manufacturing or regulatory issues persist, under our agreement with PBL, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the

agreement by us due to the uncured material breach or the cessation of manufacturing by our supplier. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming, might not be successful and would increase the likelihood of a delay or disruption in manufacturing or exacerbate the supply shortage. If we continue to fail to obtain a sufficient supply of Erwinaze from PBL, our sales of and revenues from Erwinaze, our future maintenance and potential growth of the market for this product, our reputation and our business, financial condition, results of operations and growth prospects would continue to be materially adversely affected.

We are our sole supplier of, and we believe that we are currently the sole worldwide producer of, the defibrotide drug compound. We manufacture the defibrotide compound in a single facility located in Villa Guardia, near Como, Italy. Patheon currently processes the defibrotide compound into its finished vial form, and Patheon is the sole provider of our commercial and clinical supply of Defitelio. If Patheon does not or is not able to supply us with Defitelio for any reason, it may take time

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and resources to implement and execute the necessary technology transfer to another processor, and such delay could negatively impact our anticipated revenues from Defitelio and could potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need.

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

Vyxeos is manufactured using our CombiPlex technology platform. CombiPlex products represent formulations with increased manufacturing complexities associated with producing drug delivery vehicles encapsulating two or more drugs that are maintained at a fixed ratio and, in the case of Vyxeos, two drugs that are co-encapsulated in a freeze-dried format. Given that our Vyxeos launch is at an early stage, there is limited experience with this complex manufacturing process. Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location. Baxter manufactured batches that were used in the Phase 3 clinical trial for Vyxeos; there have since been batch failures due to mechanical, component and other issues, and batches have been produced that have otherwise not been in compliance with applicable specifications. We are continuing to work with Baxter to address manufacturing complexities. If we fail to obtain a sufficient supply of Vyxeos due to manufacturing or regulatory challenges, our sales of and revenues from Vyxeos, our future maintenance and potential growth of the market for this product, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

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 are unable to obtain a sufficient supply of Vyxeos in accordance with applicable specifications on a timely basis for any reason, we may not have sufficient product for our planned commercial and clinical uses and 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, which could limit our future maintenance and potential growth of the market for this product. See also the discussion under the heading “While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other products and, in the case of our product candidates, our ability to obtain regulatory approval in the U.S. and Europe and, if approved, to successfully launch and commercialize those product candidates. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects” in this Part II, Item 1A.

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

To conduct our ongoing and any future clinical trials of, complete marketing authorization submissions for, and potentially launch our other product candidates, we need to have sufficient quantities of product manufactured. For example, Siegfried has supplied us with both the API and finished product for our development activities involving solriamfetol, including our ongoing Phase 2 clinical trial. We expect that Siegfried will manufacture and supply solriamfetol drug product for commercial sale if solriamfetol receives regulatory approval and that, in the short term, Siegfried will be the sole provider of our commercial supply of solriamfetol. If Siegfried does not or is not able to supply us with solriamfetol for any reason, it may take time and resources to implement and execute the necessary technology transfer to another provider, and such delay could negatively impact our anticipated revenues from solriamfetol.

JZP-258 and JZP-507 are currently manufactured at our Athlone facility, and we expect to manufacture these products commercially at our Athlone facility should we seek and receive regulatory approval. However, there can be no assurance that we or our suppliers will be able to produce sufficient supplies of our product candidates in a timely manner or in accordance with applicable specifications. In addition, to obtain FDA approval of any product candidate,

we or our supplier or suppliers for that product must obtain approval by the FDA to manufacture and supply product, in some cases based on qualification data provided to the FDA as part of our NDA submission. Any delay in generating, or failure to generate, data required in connection with submission of the CMC portions of any NDA could negatively impact our ability to meet our anticipated submission dates, and therefore our anticipated timing for obtaining FDA approval, or our ability to obtain FDA approval at all. In addition, any failure of us or a supplier to obtain approval by the FDA to manufacture and supply product or any delay in receiving, or failure to receive, adequate supplies of a product on a timely basis or in accordance with applicable specifications could negatively impact our ability to successfully launch and commercialize products and generate sales of products at the levels we expect.

Failure by us or our third party suppliers to comply with regulatory requirements could adversely affect our or their ability to supply products or ingredients. All facilities and manufacturing techniques used for the manufacture of

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pharmaceutical products must be operated in conformity with applicable cGMP requirements. DEA regulations also govern U.S. facilities where controlled substances such as sodium oxybate are manufactured. Our manufacturing facilities and manufacturing facilities of our suppliers have been and are subject to periodic unannounced inspection by the FDA, the EMA, the DEA, the Italian Health Authority and other regulatory authorities, including state authorities and similar authorities in other jurisdictions, to confirm compliance with cGMP and other requirements. We and our third party suppliers must continually expend time, money and effort in production, record keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal and regulatory requirements subjects us and our suppliers to possible legal or regulatory action, including restrictions on supply or shutdown, which may adversely affect our or a supplier's ability to supply the ingredients or finished products we need. Moreover, our or our third party suppliers' facilities could be damaged by fire, flood, earthquake, power loss, telecommunication and information system failure, terrorism or similar events. Any of these events could cause a delay or interruption in manufacturing and potentially a supply shortage of our products, which could negatively impact our anticipated revenues.

If, for any reason, our suppliers, including any new suppliers, do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

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

Our ability to develop and deliver products in a timely and competitive manner depends on our third party suppliers being able to continue to meet our ongoing commercial and development needs. Any delay in supplying, or failure to supply, products or product candidates by any of our suppliers could result in our inability to meet the commercial demand for our products, or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

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 any of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved and any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and its diagnosis;
- the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;

- the conditions for reimbursement required by, and appropriate pricing and availability of reimbursement from, third party payors;
- availability of sufficient product inventory to meet demand, particularly with respect to Erwinaze;
- physicians' decisions relating to treatment practices based on availability of product inventory, particularly with respect to Erwinaze;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- with respect to Xyrem, physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the Xyrem REMS;
- the cost of treatment in relation to alternative treatments, including generic products; and
- the availability of financial or other assistance for patients who are uninsured or underinsured.

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Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse events resulting from the use or misuse of our products or any similar products distributed by other companies, including generic versions of our products, could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, from time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the API in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Patients, physicians and regulators may therefore view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of its connection to GHB. Xyrem's label includes information about adverse events from GHB. Moreover, a sodium oxybate distribution system that is less restrictive than the Xyrem REMS, such as the generic sodium oxybate REMS approved by the FDA in January 2017, may increase the risks associated with sodium oxybate distribution, as patients, consumers and others may not differentiate generic sodium oxybate from Xyrem or differentiate between the different REMS programs. Any negative outcomes, including but not limited to risks to the public, caused by or otherwise related to the separate generic sodium oxybate REMS could have a significant negative impact in terms of product liability, goodwill, and prescribers' willingness to prescribe, and patients' willingness to take, Xyrem, any of which could have a material adverse effect on our Xyrem revenues.

In addition, we have periodically increased the price of Xyrem, most recently in January 2018, and may do so again in the future. We also have made and may in the future make similar price increases on our other products. Price increases on our products and negative publicity regarding pricing and price increases generally, whether on our products or products distributed by other pharmaceutical companies, could negatively affect market acceptance of our products. For additional discussion about payor acceptance, see the risk factor under the heading "Access and adequate reimbursement coverage may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably" in this Part II, Item 1A.

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

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

While Xyrem is the only product approved by the FDA and currently marketed in the U.S. for the treatment of both cataplexy and EDS in patients with narcolepsy, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors or selective norepinephrine reuptake inhibitors, even though these products are not approved by the FDA for the treatment of cataplexy. Other treatments for EDS in patients with narcolepsy include stimulants and wakefulness promoting agents, such as Provigil® (modafinil) and Nuvigil® (armodafinil), as well as generic versions of Provigil, the only other products both approved by the FDA and currently marketed for the treatment of EDS in patients with narcolepsy. Provigil, its generic equivalents and Nuvigil are also approved for improving wakefulness in patients with EDS associated with treated OSA or shift work disorder.

We are also aware of products being developed by others for use as treatment options in cataplexy and/or EDS in patients with narcolepsy, including pitolisant, a product to treat adult patients with narcolepsy with or without

cataplexy that received marketing approval in Europe in 2016. While pitolisant is currently not approved by the FDA for marketing in the U.S., the company that has exclusive U.S. commercialization rights to pitolisant established an expanded access program for the product and announced that the product has received Breakthrough Therapy and Fast Track designations from the FDA and that it is preparing an NDA submission for the product. The receipt of marketing approval and commercialization of pitolisant in the U.S. for the treatment of narcolepsy patients could, depending on the targeted patient population, negatively impact our ability to maintain and grow sales of Xyrem. Nine companies filed ANDAs with the FDA seeking to market generic versions of Xyrem, and we have settled patent litigation against all nine companies. The FDA has approved or tentatively approved some of these ANDAs, and we believe that it is likely that the FDA will approve or tentatively approve additional ANDAs that have been filed. For a description of the settlement agreements and the risks related to the launch of a generic sodium oxybate product, see Note 10, Commitments and Contingencies—Legal Proceedings of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1

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of this Quarterly Report on Form 10-Q, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Challenges, Risks and Trends Related to Our Lead Marketed Products and Product Candidates Submitted for Regulatory Approval" included in Part I, Item 2 of this Quarterly Report on Form 10-Q, and the risk factor under the heading "The launch of a generic version of Xyrem or other sodium oxybate products that compete with Xyrem would adversely affect sales of Xyrem."

Other companies could also develop products that are similar, but not identical, to Xyrem, such as an alternative formulation or an alternative delivery technology, and seek approval in the U.S. through a Section 505(b)(2) NDA approval pathway, which allows companies to seek approval of a product that is similar, but not identical, to a previously-approved brand-name product, and to rely to some degree on the previously-approved product's safety and efficacy data. For example, Avadel has stated that it is conducting a Phase 3 pivotal trial pursuant to an FDA-approved special protocol assessment, and has indicated that it intends to seek approval of its product candidate using a Section 505(b)(2) NDA approval pathway referencing Xyrem. If Avadel successfully develops, obtains FDA approval of and is able to launch this product candidate, Avadel's product may compete with Xyrem and could result in a substantial reduction of Xyrem sales, which could have the additional impact of potentially triggering acceleration of market entry of AG Products or other generic sodium oxybate products under our ANDA litigation settlement agreements. We expect that the launch of an AG Product or other generic version of Xyrem, or the approval and launch of other products that compete with Xyrem, could have a material adverse effect on our sales of Xyrem and on our business, financial condition, results of operations and growth prospects. For further discussion regarding these and other risks and challenges we face with respect to Xyrem, see the risk factors under the headings "Risks Related to Xyrem and the Significant Impact of Xyrem Sales" and "Risks Related to Our Intellectual Property" in this Part II, Item 1A.

While there is currently no direct competition to Erwinaze to treat ALL patients with hypersensitivity to E. coli-derived asparaginase, other companies have developed or are developing new treatments for ALL, including new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL, and new treatment protocols are being developed for ALL that may not include asparaginase-containing regimens. For example, a number of companies are developing new immunotherapy treatments for relapsed or refractory ALL patients, including one treatment that was recently approved. The development of these new treatments could negatively impact our ability to grow sales of Erwinaze in patient populations where the benefit of an asparaginase-containing regimen is not well established. As a biologic product, Erwinaze also faces potential competition from biosimilar products.

AML, the cancer indication for which we commercialize Vyxeos, has alternative established therapies. A key consideration in the treatment of AML patients is the patient's suitability for chemotherapy. The patient population studied in the Vyxeos Phase 3 clinical trial included AML patients deemed able to tolerate chemotherapy. The existing options for the treatment of newly-diagnosed t-AML patients who can tolerate chemotherapy include cytarabine in combination with an anthracycline (i.e., daunorubicin), known as 7+3. In addition, we are aware of several other products that have been recently approved by the FDA or are in development for use as treatment options for AML patients, such as targeted agents (e.g., FLT-3, IDH-1, IDH-2, CD-33 and CAR T cell), immunotherapies and agents disrupting leukemia cell survival. Some of the patient populations being studied for, or treated by, these products overlap with the patient population studied in the Vyxeos Phase 3 clinical trial. The existence of established treatment options and the development of competing products for the treatment of newly-diagnosed t-AML or AML-MRC could negatively impact our ability to successfully commercialize Vyxeos and achieve the level of sales we expect, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In the fourth quarter of 2017, we submitted an NDA for solriamfetol to the FDA for the treatment of patients with EDS in narcolepsy and EDS in OSA. In the first quarter of 2018, the FDA accepted the NDA for filing with a standard review and set a target action date under PDUFA of December 20, 2018. If solriamfetol is approved, we expect that the product will be subject to scheduling review under the U.S. Controlled Substances Act, or CSA, before it can be commercially launched. Other treatments for excessive sleepiness in patients with narcolepsy include stimulants, wake-promoting agents, such as Provigil and Nuvigil, and generic versions of stimulants and wake-promoting agents.

We are also aware that stimulants are prescribed for patients who have OSA. Solriamfetol, if approved by the FDA, will likely face competition from this genericized market. In addition, we are aware of several other products in development to treat excessive sleepiness in patients with narcolepsy or OSA, including, for example, pitolisant, mazindol, modafinil combinations and Avadel's once-nightly sodium oxybate formulation.

Many of our competitors are able to deploy more personnel to market and sell their products than we do. We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any necessary growth in a timely or cost-effective

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manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner, or at all. In particular, we compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in hematology/oncology markets, and our failure to compete effectively in this area could negatively affect our sales of Erwinaze, Defitelio, Vyxeos and other products. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of our products. If our specialty sales force and sales organization are not appropriately sized to adequately promote any current or potential future products, the commercial potential of our current products and any future products may be diminished.

Our products and product candidates may also compete in the future with new products currently under development by others. Any products that we develop are likely to be in a highly competitive market, and many of our competitors may succeed in developing products that may render our products obsolete or noncompetitive.

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

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

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

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

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

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

Any failure to identify and manage these risks and uncertainties effectively could have a material adverse effect on our business.

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

- high acquisition costs;
- the need to incur substantial debt or engage in dilutive issuances of equity securities to pay for acquisitions;
- the potential disruption of our historical core business;
- the strain on, and need to continue to expand, our existing operational, technical, financial and administrative infrastructure;
- the difficulties in assimilating employees and corporate cultures;
- the failure to retain key managers and other personnel;
- the challenges in controlling additional costs and expenses in connection with and as a result of any acquisition;
- the need to write down assets or recognize impairment charges;

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- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures; and
- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

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

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

Since 2014, we have made significant investments into expanding our product development pipeline and expect to continue to increase our research and development activities. Significant clinical, development and financial resources are required to progress product candidates through clinical trials and the regulatory approval process to develop them into commercially viable products. We have a number of product candidates under development. We also intend to pursue clinical development of other product candidates that we may acquire or in-license in the future. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

As a condition to regulatory approval, each product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. Results of limited preclinical studies, including studies of our product candidates in animal models, may not predict the results of human clinical trials of those product candidates. Similarly, results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. In that case, the FDA or any equivalent non-U.S. regulatory agency may determine our data is not sufficiently compelling to warrant marketing approval and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in preclinical studies or earlier clinical trials. If a product candidate fails at any stage of development and does not receive regulatory approval, we will not be able to commercialize it and receive any return on our investment in that product candidate.

The FDA accepted for filing with standard review our NDA for solriamfetol to the FDA in the first quarter of 2018. The NDA was submitted to the FDA based on positive results from two Phase 3 clinical trials, but if the FDA determines that our safety or efficacy data do not warrant marketing approval, we may be required to conduct additional clinical trials, which could be costly and time-consuming, or we may not be able to commercialize solriamfetol, in which event we would not receive any return on our investment.

Our development pipeline projects may not be successful, and any adverse events or other data generated during the course of studies related to our product candidates and/or studies related to additional indications for our commercialized products could result in action by the FDA or a non-U.S. regulatory agency, which may restrict our ability to sell, or adversely affect sales of, currently marketed products, or such events or other data could otherwise have a material adverse effect on a related commercial product, including with respect to its safety profile. Any failure or delay in completing clinical trials for line extensions or the generation of additional clinical data could materially

and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

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

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;

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- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, known as an ethics committee in Europe, to conduct a clinical trial at a prospective study site;
- delays or failures in recruiting patients to participate in a clinical trial;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA and other regulatory agencies' requirements, commonly referred to as good clinical practices;
- unforeseen safety issues, including negative results from ongoing preclinical studies and clinical trials and adverse events associated with product candidates;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- difficulty identifying or enrolling eligible patients, in some cases based on the number of clinical trials with enrollment criteria targeting the same patient population;
- failure of our third party clinical trial managers to satisfactorily perform their contractual duties, comply with regulations or meet expected deadlines; or
- insufficient funds to complete the trials.

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

We are headquartered in Dublin, Ireland and have multiple offices in the U.S., Canada, the UK, Italy and other countries in Europe. Our headcount has grown to approximately 1,290 as of November 2018. This includes employees in 14 countries in North America and Europe, a European commercial presence, a complex distribution network for products in Europe and additional territories, and manufacturing facilities in Italy and Ireland. In addition, we may expand our international operations into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations, financial condition and growth prospects, including, among other things:

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

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

In addition, in June 2016, eligible members of the electorate in the UK decided by referendum to leave the EU. On March 29, 2017, the government of the UK initiated the formal procedure for withdrawal from the EU. We have a significant office in Oxford, England, which focuses on commercialization of our products outside of the U.S., among other activities. We do not know to what extent, or when, the UK's withdrawal from the EU or any other future changes to membership in the EU will impact our business, if at all. In particular, our ability to conduct international business out of the UK may be adversely affected. For a further discussion, see the risks under the heading "The results

of the UK's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business" in this Part II, Item 1A. 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 trade tensions. However, these tariffs and other trade restrictions could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our financial results.

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We rely on third parties to conduct clinical trials with our product candidates, and if they do not properly and successfully perform their legal and regulatory obligations, as well as their contractual obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We rely on contract research organizations and other third parties, such as cooperative groups, to assist us in designing, coordinating, managing, monitoring and otherwise conducting clinical trials with our product candidates. We do not control these third parties, and, as a result, they may not treat our clinical studies as a high priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of these clinical trials is conducted in accordance with its general investigational plan and protocol, as well as good clinical practices, and for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations assisting us with clinical trials, other third parties conducting clinical trials with our product candidates, or our trial sites fail to comply with applicable good clinical practices, the clinical data generated in these clinical trials may be deemed unreliable, and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of these clinical trials comply with good clinical practices. In addition, these clinical trials must be conducted with product candidates produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our failure, or the failure of our product suppliers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their contractual duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

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

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

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

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

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such confidential information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result we manage a number of third party vendors who may or could have access to our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties. As a result, our information technology systems, including the functions of third parties that are involved or have access to those systems, are large and complex. The size and complexity of our information technology systems, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable

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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 their frequency, levels of 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 information. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue.

Significant disruptions of our, our third party vendors’ and/or business partners’ information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our b