Jazz Pharmaceuticals plc
Form 10-Q
May 08, 2018
Table of Contents

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 March 31, 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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	¨ (Do not check if a smaller reporting company)	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 April 30, 2018, 59,996,224 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

Table of Contents

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2018

INDEX

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), Prialt® (ziconotide) intrathecal infusion, CombiPlex® and Vyxeos® (daunorubicin and cytarabine) liposome for injection. 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.

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$453,169	$386,035
Investments	255,000	215,000
Accounts receivable, net of allowances	281,424	224,129
Inventories	46,384	43,245
Prepaid expenses	27,476	23,182
Other current assets	62,868	76,686
Total current assets	1,126,321	968,277
Property, plant and equipment, net	178,920	170,080
Intangible assets, net	2,953,146	2,979,127
Goodwill	960,509	947,537
Deferred tax assets, net	38,103	34,559
Deferred financing costs	7,144	7,673
Other non-current assets	22,985	16,419
Total assets	$5,287,128	$5,123,672
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$46,933	$24,368
Accrued liabilities	240,544	198,779
Current portion of long-term debt	45,117	40,605
Income taxes payable	36,048	21,577
Deferred revenue	6,977	8,618
Total current liabilities	375,619	293,947
Deferred revenue, non-current	13,641	16,115
Long-term debt, less current portion	1,537,044	1,540,433
Deferred tax liabilities, net	382,072	383,472
Other non-current liabilities	192,181	176,608
Commitments and contingencies (Note 9)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	472	472
Additional paid-in capital	1,955,756	1,935,486
Accumulated other comprehensive loss	(98,768)	(140,878)
Retained earnings	929,050	917,956
Total shareholders' equity	2,786,571	2,713,097
Total liabilities and shareholders' equity	$5,287,128	$5,123,672

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

Table of Contents

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

	Three Months Ended March 31,	
	2018	2017
Revenues:		
Product sales, net	$440,847	$373,678
Royalties and contract revenues	3,766	2,375
Total revenues	444,613	376,053
Operating expenses:		
Cost of product sales (excluding amortization of intangible assets)	33,919	25,065
Selling, general and administrative	207,213	144,255
Research and development	62,667	44,928
Intangible asset amortization	53,007	25,665
Total operating expenses	356,806	239,913
Income from operations	87,807	136,140
Interest expense, net	(20,605)	(18,844)
Foreign exchange loss	(1,728)	(1,464)
Income before income tax provision and equity in loss of investees	65,474	115,832
Income tax provision	19,146	29,160
Equity in loss of investees	337	161
Net income	$45,991	$86,511
Net income per ordinary share:		
Basic	$0.77	$1.44
Diluted	$0.75	$1.41
Weighted-average ordinary shares used in per share calculations - basic	59,928	59,880
Weighted-average ordinary shares used in per share calculations - diluted	61,178	61,178

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

Table of Contents

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

	Three Months Ended March 31,	
	2018	2017
Net income	$45,991	$86,511
Other comprehensive income (loss):		
Foreign currency translation adjustments	38,853	18,112
Unrealized gain (loss) on hedging activities, net of tax expense (benefit) of $458 and $(89), respectively	3,204	(622)
Other comprehensive income	42,057	17,490
Total comprehensive income	$88,048	$104,001

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

Table of Contents

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

	Three Months Ended March 31,	
	2018	2017
Operating activities		
Net income	$ 45,991	$ 86,511
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	53,007	25,665
Share-based compensation	24,303	25,193
Depreciation	3,722	3,130
Loss on disposal of property, plant and equipment	256	82
Deferred income taxes	(15,307)	(15,000)
Provision for losses on accounts receivable and inventory	590	948
Amortization of debt discount and deferred financing costs	10,617	5,615
Other non-cash transactions	16,026	1,405
Changes in assets and liabilities:		
Accounts receivable	(56,591)	(8,483)
Inventories	(3,312)	(4,258)
Prepaid expenses and other current assets	(3,534)	(10,637)
Other long-term assets	(3,988)	(2,170)
Accounts payable	23,136	5,865
Accrued liabilities	47,484	(15,743)
Income taxes payable	14,183	30,753
Deferred revenue	(1,875)	27,490
Other non-current liabilities	7,651	8,174
Net cash provided by operating activities	162,359	164,540
Investing activities		
Purchases of property, plant and equipment	(7,149)	(3,574)

Acquisition of investments	(235,000)	(60,000)
Proceeds from maturity of investments	195,000	60,000
Net cash used in investing activities	(47,149)	(3,574)
Financing activities		
Proceeds from employee equity incentive and purchase plans	10,588	5,676
Repayments of long-term debt	(9,023)	(9,023)
Payment of employee withholding taxes related to share-based awards	(14,594)	(14,431)
Share repurchases	(34,546)	(13,896)
Repayments under revolving credit facility	—	(150,000)
Net cash used in financing activities	(47,575)	(181,674)
Effect of exchange rates on cash and cash equivalents	(501)	1,740
Net increase (decrease) in cash and cash equivalents	67,134	(18,968)
Cash and cash equivalents, at beginning of period	386,035	365,963
Cash and cash equivalents, at end of period	$ 453,169	$ 346,995

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

Table of Contents

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. 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 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 months ended March 31, 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 ASU No. 2014-09, "Revenue from Contracts with Customers", or ASU No. 2014-09, our significant accounting policies have not changed

substantially from those previously described in our Annual Report on Form 10-K for the year ended December 31, 2017.

Table of Contents

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. Please see Note 12 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”. ASU No. 2016-15 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. The impact of ASU No. 2017-01 will be dependent upon the nature of our future acquisition or disposition transactions, if any.

In August 2017, the FASB issued ASU No. 2017-12, “Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities”. 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.

Table of Contents

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

Table of Contents

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 certain 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; ongoing patent litigation and related proceedings or the possibility of new ANDA filers and challenges; changes to or uncertainties around regulatory restrictions, including, among other things, changes to our Xyrem risk evaluation and mitigation strategy, or REMS; 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 the risk of 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 March 31, 2018, we had foreign exchange forward contracts with notional amounts totaling $186.5 million. As of March 31, 2018, the net liability fair value of outstanding foreign exchange forward contracts was $0.2 million. As of March 31, 2018, we had interest rate swap contracts with notional amounts totaling $300.0 million. These

Table of Contents

outstanding interest rate swap contracts had a net asset fair value of $5.4 million as of March 31, 2018. The counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not material.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the U.S., and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We monitor deteriorating economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and as of March 31, 2018 and December 31, 2017, allowances on receivables were not material. As of March 31, 2018, five customers accounted for 93% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliates, or Express Scripts, which accounted for 72% of gross accounts receivable, and McKesson Corporation and affiliates, or McKesson, which accounted for 19% 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 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)”. 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 for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the consolidated financial statements. 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 March 31, 2018 were $213.9 million.

2. Cash and Available-for-Sale Securities

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

	March 31, 2018					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$136,883	$ —	$ —	$136,883	$ 136,883	$ —
Time deposits	390,000	—	—	390,000	135,000	255,000
Money market funds	181,286	—	—	181,286	181,286	—
Totals	$708,169	$ —	$ —	$708,169	$ 453,169	$ 255,000

11

Table of Contents

	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.

3. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of March 31, 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):

	March 31, 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	$—	$ 390,000	$ 390,000	$—	$ 235,000	$ 235,000
Money market funds	181,286	—	181,286	140,800	—	140,800
Interest rate contracts	—	5,416	5,416	—	2,138	2,138
Foreign exchange forward contracts	—	907	907	—	15,495	15,495
Totals	$181,286	$ 396,323	$ 577,609	$140,800	$ 252,633	$ 393,433
Liabilities:						
Interest rate contracts	$—	$ —	$ —	$—	$ 392	$ 392
Foreign exchange forward contracts	—	1,120	1,120	—	5,017	5,017
Totals	$—	$ 1,120	$ 1,120	$—	$ 5,409	$ 5,409

As of March 31, 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 March 31, 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 $602 million and $561 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

Table of Contents

under our term loan was approximately equal to its book value based on the borrowing rates currently available for variable rate loans (Level 2).

4. 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 March 31, 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.

The effective portion of changes in the fair value of derivatives designated as and that qualify as cash flow hedges is recorded in accumulated other comprehensive loss and is subsequently reclassified into earnings in the period that the hedged forecasted transaction affects earnings. The impact on accumulated other comprehensive loss and earnings from derivative instruments that qualified as cash flow hedges for the three months ended March 31, 2018 and 2017 was as follows (in thousands):

	Three Months Ended March 31,	
Interest Rate Contracts:	2018	2017
Gain (loss) recognized in accumulated other comprehensive loss, net of tax	$3,037	$(855)
Loss reclassified from accumulated other comprehensive loss to interest expense, net of tax	167	233

Assuming no change in LIBOR-based interest rates from market rates as of March 31, 2018, $0.6 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 March 31, 2018 and December 31, 2017, the notional amount of foreign exchange contracts where hedge accounting is not applied was $186.5 million and $98.7 million, respectively. The foreign exchange loss in our condensed consolidated statements of income included gains of $3.8 million associated with foreign exchange contracts not designated as hedging instruments for the three months ended March 31, 2018.

The cash flow effects of our derivative contracts for the three months ended March 31, 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):

	March 31, 2018			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets	$706	Accrued liabilities	$—
	Other non-current assets	4,710		
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	907	Accrued liabilities	1,120

Total fair value of derivative instruments	$6,323	$1,120

Table of Contents

	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

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

	March 31, 2018					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$2,711	$ —	$ 2,711	$(71)	$ —	$ 2,640
Derivative liabilities	(71)	—	(71)	71	—	—

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

5. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2018	December 31, 2017
Raw materials	$ 5,083	$ 3,542
Work in process	21,238	15,692
Finished goods	20,063	24,011
Total inventories	$ 46,384	$ 43,245

6. Goodwill and Intangible Assets

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

Balance at December 31, 2017	$947,537
Foreign exchange	12,972
Balance at March 31, 2018	$960,509

Table of Contents

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

	March 31, 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	$3,426,056	$ (625,755)	$2,800,301	$3,392,832	$ (562,473)	$2,830,359
Manufacturing contracts	—	13,192	(13,192)	—	12,824	(12,634)	190
Trademarks	—	2,918	(2,918)	—	2,910	(2,910)	—
Total finite-lived intangible assets		3,442,166	(641,865)	2,800,301	3,408,566	(578,017)	2,830,549
Acquired IPR&D assets		152,845	—	152,845	148,578	—	148,578
Total intangible assets		$3,595,011	$ (641,865)	$2,953,146	$3,557,144	$ (578,017)	$2,979,127

The increase in the gross carrying amount of intangible assets as of March 31, 2018 compared to December 31, 2017 reflected the positive impact of foreign currency translation adjustments, which was due to the strengthening of the euro against the U.S. dollar.

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

Based on finite-lived intangible assets recorded as of March 31, 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)	$ 158,964
2019	211,923
2020	208,917
2021	207,837
2022	207,083
Thereafter	1,805,577
Total	$ 2,800,301

7. Certain Balance Sheet Items

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

	March 31, 2018	December 31, 2017
Build-to-suit facility	$52,222	$ 51,721
Land and buildings	46,857	46,729
Leasehold improvements	29,491	28,779
Construction-in-progress	27,820	21,738
Manufacturing equipment and machinery	24,794	23,586
Computer software	19,391	19,969
Computer equipment	12,481	12,814
Furniture and fixtures	6,739	5,947
Subtotal	219,795	211,283

Less accumulated depreciation and amortization	(40,875)	(41,203)
Property, plant and equipment, net	$178,920	$ 170,080

Table of Contents

Accrued liabilities consisted of the following (in thousands):

	March 31, 2018	December 31, 2017
Rebates and other sales deductions	$88,878	$ 81,368
Estimated loss contingency	57,000	—
Employee compensation and benefits	40,966	54,930
Royalties	7,050	8,058
Selling and marketing accruals	4,546	3,189
Clinical trial accruals	4,053	2,181
Professional fees	3,597	3,213
Inventory-related accruals	3,223	3,002
Sales returns reserve	3,107	3,651
Accrued interest	2,638	7,297
Derivative instrument liabilities	1,120	5,409
Accrued construction-in-progress	838	2,827
Other	23,528	23,654
Total accrued liabilities	$240,544	$ 198,779

8. Debt

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

	March 31, 2018	December 31, 2017
2021 Notes	$575,000	$575,000
Unamortized discount and debt issuance costs on 2021 Notes	(76,668)	(81,627)
2021 Notes, net	498,332	493,373
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(153,908)	(158,680)
2024 Notes, net	421,092	416,320
Term loan	662,737	671,345
Total debt	1,582,161	1,581,038
Less current portion	45,117	40,605
Total long-term debt	$1,537,044	$1,540,433

Exchangeable Senior Notes

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

As of March 31, 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.

16

Table of Contents

9. Commitments and Contingencies

Indemnification

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

We have agreed to indemnify our executive officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we did not recognize any liabilities relating to these obligations as of March 31, 2018 and December 31, 2017. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

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 consolidated balance sheets offset a corresponding financing obligation. We began to occupy this office space in October 2017. As of March 31, 2018, the total amount of the related financing obligation was $64.4 million, which is classified within current liabilities and non-current liabilities in 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 March 31, 2018, we recorded project construction costs of $24.8 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 in our 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 March 31, 2018, we had $74.4 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

We are involved in legal proceedings, including the following matters:

Xyrem ANDA Litigation. On December 10, 2012, we received a notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Amneal Pharmaceuticals, Inc., formerly known as Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On January 18, 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. On November 21, 2013, we received a notice of Paragraph IV Certification from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 27, 2013, we filed a lawsuit against Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents.

Table of Contents

In May 2014, the District Court granted a request by Amneal to consolidate its case with the Par case. Additional patents covering Xyrem have been issued since May 2014 and have been listed in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book, for Xyrem. Amneal and Par gave us additional notices of Paragraph IV Certifications regarding such patents, and we filed additional lawsuits against Amneal and Par in the District Court alleging that our patents covering Xyrem are infringed or will be infringed by Amneal's and Par's ANDAs and seeking a permanent injunction to prevent Amneal and Par from introducing a generic version of Xyrem that would infringe our patents. In August 2016, we and Par stipulated to dismiss claims relating to our patents covering the formulation of Xyrem on the grounds that Par had notified the FDA that it had converted its Paragraph IV Certifications to Paragraph III Patent Certifications, or Paragraph III Certifications. In September 2017, we and Amneal stipulated to dismiss claims relating to certain of our patents covering the formulation of Xyrem on the grounds that Amneal had notified the FDA that it had converted its Paragraph IV Certifications as to these patents to Paragraph III Certifications.

On October 30, 2014, we received a notice of Paragraph IV Certification from Teva Pharmaceutical Industries Ltd., formerly known as Watson Laboratories, Inc., or Teva, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Teva in the District Court alleging that our patents covering Xyrem are or will be infringed by Teva's ANDA and seeking a permanent injunction to prevent Teva from introducing a generic version of Xyrem that would infringe these patents. In March 2015, Teva moved to dismiss the portion of the case based on our Orange Book-listed REMS patents on the grounds that these patents do not cover patentable subject matter. In November 2015, the District Court administratively terminated this motion to dismiss (without prejudice) pending the outcome of inter partes review, or IPR, proceedings before the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office relating to the patents that were the subject of Teva's motion. Since March 2015, we received an additional notice of Paragraph IV Certification from Teva regarding newly issued patents for Xyrem listed in the Orange Book, and we filed an additional lawsuit against Teva in the District Court alleging that our patents covering Xyrem are or will be infringed by Teva's ANDA and seeking a permanent injunction to prevent Teva from introducing a generic version of Xyrem that would infringe these patents.

In April 2015, the District Court issued an order consolidating all then-pending lawsuits against Amneal, Par and Teva into one case.

On July 23, 2015, we received a notice of Paragraph IV Certification from Lupin Inc., or Lupin, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On September 2, 2015, we filed a lawsuit in the District Court alleging that our patents covering Xyrem are or will be infringed by Lupin's ANDA and seeking a permanent injunction to prevent Lupin from introducing a generic version of Xyrem that would infringe our patents.

In January, April and June 2016, the District Court issued orders consolidating all of the cases then pending against Amneal, Par, Teva and Lupin into a single case for all purposes. Although no trial date has been set for the consolidated case, discovery is scheduled to conclude in the fourth quarter of 2018, and the trial in this consolidated case could occur as early as later that quarter. As discussed in more detail below, we entered into settlement agreements and related agreements in January 2018 and March 2018 with Par and Teva, respectively; as a result, the remaining parties in the consolidated case are Amneal and Lupin.

On November 21, 2017, we received a notice of Paragraph IV Certification from Mallinckrodt Inc., or Mallinckrodt, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On January 2, 2018, we filed a lawsuit in the District Court alleging that our patents covering Xyrem are or will be infringed by Mallinckrodt's ANDA and seeking a permanent injunction to prevent Mallinckrodt from introducing a generic version of Xyrem that would infringe our patents.

We cannot predict whether additional generic manufacturers will file ANDAs and require new patent litigation, the specific timing or outcome of events with respect to the remaining defendants or the impact of developments involving any specific parties or patents on other ongoing proceedings with any ANDA filer.

Xyrem ANDA Litigation Settlements. On January 9, 2018, we entered into a settlement agreement and related agreements resolving our patent infringement litigation against Par in the District Court, as well as related discovery proceedings and certain IPR proceedings currently on appeal to the United States Court of Appeals for the Federal Circuit, or Federal Circuit. On January 19, 2018, the District Court approved an order dismissing the litigation. In connection with the settlement, we granted Par the right to sell a limited volume of an authorized generic version of Xyrem, or the Par AG Product, in the U.S. for a term beginning on July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025, or the Par AG Sales Period. Such circumstances include events related to acceleration of the launch date of the authorized generic version of Xyrem by the first ANDA filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC), or West-Ward, under the terms of our settlement with West-Ward, the earlier launch of another party's authorized generic or generic sodium oxybate product, or a final decision that all unexpired claims of the Xyrem patents are not infringed, invalid and/or unenforceable. The volume of the Par AG Product is limited to an annual amount equal to a low single-digit percentage

Table of Contents

of Xyrem sales volume during the calendar year preceding the entry date of the Par AG Product. We also granted Par a non-exclusive license under the Xyrem patents to make, have made and market its own generic sodium oxybate product under Par's ANDA (assuming FDA approval is obtained) effective 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 party under its ANDA, or a final decision that all unexpired claims of the Xyrem patents are not infringed, invalid and/or unenforceable. If the Par license to market its own generic sodium oxybate product accelerates, then Par will have the option to elect to market the Par AG Product until December 31, 2025, but Par will not be entitled to market the Par AG Product and its own generic sodium oxybate product simultaneously. We are entitled to receive a meaningful royalty on net sales of the Par AG Product over the Par AG Sales Period, as well as payment for the supply of the Par AG Product and reimbursement for a portion of the services costs associated with the operation of the Xyrem REMS and distribution of the Par AG Product.

On March 30, 2018, we entered into a settlement agreement resolving our patent infringement litigation against Teva in the District Court. On April 5, 2018, the District Court approved an order dismissing the litigation. In connection with the settlement, we granted Teva a license to manufacture, market and sell its own generic sodium oxybate product on or after December 31, 2025, or earlier depending on the occurrence of certain events.

We had previously entered into settlement agreements with four other ANDA filers, including the first filer, West-Ward. The specific terms of all of the settlement agreements are confidential. The settlements do not resolve the consolidated case against Amneal and Lupin, or the case against the most recent ANDA filer, Mallinckrodt, which remain pending.

Xyrem Post-Grant Patent Review Matters. In January 2015, certain of the ANDA filers filed petitions for IPR with respect to the validity of six of our seven patents associated with the Xyrem REMS, or REMS patents. The PTAB 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 2016, the PTAB partially instituted an IPR on three claims of a seventh REMS patent, declining to review 25 of 28 claims, and in March 2017, the PTAB issued a final decision that the three claims they reviewed are unpatentable. The July 2016 and March 2017 PTAB decisions are part of a consolidated appeal currently pending before the Federal Circuit. If the Federal Circuit upholds the PTAB decisions on appeal, we will not be able to enforce claims the PTAB found unpatentable. On April 24, 2018, the Supreme Court of the United States issued an opinion holding that the PTAB does not have authority to partially review a patent where an IPR petitioner has asked for review of all of the claims. As a result of that ruling, the Federal Circuit is considering how to adjudicate the appeal of the PTAB's March 2017 decision. We cannot predict whether additional post-grant patent review challenges will be filed by any of the ANDA filers or any other entity, the outcome of any future IPR or other proceeding, the outcome of the appeal of the July 2016 and March 2017 PTAB decisions with respect to the REMS patents or the impact any IPR or other proceeding might have on ongoing ANDA 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 other 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 three months ended March 31, 2018, we recorded $57.0 million related to this matter 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 could also 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

Table of Contents

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.

10. Shareholders' Equity

The following tables present a reconciliation of our beginning and ending balances in shareholders' equity for the three months ended March 31, 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	10,588
Employee withholding taxes related to share-based awards	(14,594)
Share-based compensation	24,276
Shares repurchased	(34,546)
Other comprehensive income	42,057
Net income	45,991
Shareholders' equity at March 31, 2018	$ 2,786,571

	Total Shareholders' Equity
Shareholders' equity at January 1, 2017	$ 1,877,339
Issuance of ordinary shares in conjunction with employee equity incentive and purchase plans	5,676
Employee withholding taxes related to share-based awards	(14,431)
Share-based compensation	25,297
Shares repurchased	(13,896)
Other comprehensive income	17,490
Net income	86,511
Shareholders' equity at March 31, 2017	$ 1,983,986

Share Repurchase Program

In November 2016, our board of directors authorized a share repurchase program pursuant to which we are authorized to repurchase a number of ordinary shares having an aggregate purchase price of up to $300.0 million, exclusive of any brokerage commissions. In the three months ended March 31, 2018, we spent a total of $34.5 million to purchase 0.2 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $145.34 per share. As of March 31, 2018, the remaining amount authorized under the share repurchase program was $148.2 million.

Table of Contents

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of March 31, 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 before reclassifications	3,037	38,853	41,890
Amounts reclassified from accumulated other comprehensive loss	167	—	167
Other comprehensive income, net	3,204	38,853	42,057
Balance at March 31, 2018	$ 4,739	$ (103,507)	$ (98,768)

During the three months ended March 31, 2018, other comprehensive income reflects foreign currency translation adjustments, primarily due to the strengthening of the euro against the U.S. dollar, and the net unrealized gain on derivatives that qualify as cash flow hedges.

11. Net Income per Ordinary Share

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

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

	Three Months Ended March 31,	
	2018	2017
Numerator:		
Net income	$45,991	$86,511
Denominator:		
Weighted-average ordinary shares used in per share calculations - basic	59,928	59,880
Dilutive effect of employee equity incentive and purchase plans	1,250	1,298
Weighted-average ordinary shares used in per share calculations - diluted	61,178	61,178
Net income per ordinary share:		
Basic	$0.77	$1.44
Diluted	$0.75	$1.41

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans and the Exchangeable Senior Notes are determined by applying the treasury stock method to the assumed exercise of share options, the assumed vesting of outstanding restricted stock units, or RSUs, the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP, and the assumed issuance of ordinary shares upon exchange of the Exchangeable Senior Notes. The potential issue of ordinary shares issuable upon exchange of the Exchangeable Senior Notes had no effect on diluted net income per ordinary share because the average price of our ordinary shares for the three months ended March 31, 2018 and 2017 did not exceed the effective exchange prices per ordinary share of the Exchangeable Senior Notes.

Table of Contents

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

	Three Months Ended March 31,	
	2018	2017
Exchangeable Senior Notes	5,504	2,878
Options to purchase ordinary shares and RSUs	3,279	3,406
Ordinary shares under ESPP	26	—

12. Revenues

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

	Three Months Ended March 31,	
	2018	2017
Xyrem	$316,777	$272,326
Erwinaze/Erwinase	50,627	51,388
Defitelio/defibrotide	35,061	35,900
Vyxeos	26,228	—
Prialt® (ziconotide) intrathecal infusion	6,126	7,717
Other	6,028	6,347
Product sales, net	440,847	373,678
Royalties and contract revenues	3,766	2,375
Total revenues	$444,613	$376,053

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

	Three Months Ended March 31,	
	2018	2017
United States	$405,687	$339,183
Europe	28,331	31,352
All other	10,595	5,518
Total revenues	$444,613	$376,053

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

	Three Months Ended March 31,	
	2018	2017
Express Scripts	71%	72%
McKesson	20%	17%

Contract Liabilities - Deferred Revenue

The deferred revenue balance as of March 31, 2018 primarily related to deferred upfront fees received from Nippon Shinyaku Co., Ltd., or Nippon, in connection with two license, development and commercialization agreements

granting Nippon exclusive rights to develop and commercialize each of Defitelio and Vyxeos in Japan. We recognized contract revenues of $1.9 million during the three months ended March 31, 2018 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.

Table of Contents

The following table presents a reconciliation of our beginning and ending balances in contract liabilities from contracts with customers for the three months ended March 31, 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	(1,875)
Balance as of March 31, 2018	$ 20,618

13. Share-Based Compensation

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

	Three Months Ended March 31,	
	2018	2017
Selling, general and administrative	$18,234	$19,805
Research and development	4,375	4,142
Cost of product sales	1,694	1,246
Total share-based compensation expense, pre-tax	24,303	25,193
Income tax benefit from share-based compensation expense	(3,668)	(7,624)
Total share-based compensation expense, net of tax	$20,635	$17,569

Share Options

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

	Three Months Ended March 31,	
	2018	2017
Shares underlying options granted (in thousands)	1,152	1,171
Grant date fair value	$46.08	$42.19
Black-Scholes option pricing model assumption information:		
Volatility	35 %	35 %
Expected term (years)	4.5	4.3
Range of risk-free rates	2.2-2.5%	1.7-1.8%
Expected dividend yield	— %	— %

Restricted Stock Units

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

	Three Months Ended March 31,	
	2018	2017
RSUs granted (in thousands)	461	468
Grant date fair value	$140.60	$135.46

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.

Table of Contents

As of March 31, 2018, compensation cost not yet recognized related to unvested share options and RSUs was $101.6 million and $121.5 million, respectively, which is expected to be recognized over a weighted-average period of 2.9 years and 3.0 years, respectively.

14. Income Taxes

Our income tax provision was $19.1 million in the three months ended March 31, 2018 compared to $29.2 million for the same period in 2017. The effective tax rate was 29.2% in the three months ended March 31, 2018 compared to 25.2% for the same period in 2017. The increase in the effective tax rate for the three months ended March 31, 2018 compared to the same period in 2017 was primarily due to the impact of the accrued estimated loss contingency and a decrease in originating tax credits, partially offset by a decrease in the U.S. corporate income tax. The effective tax rate for the three months ended March 31, 2018 was higher than the Irish statutory rate of 12.5% primarily due to various expenses not deductible for income tax purposes, income taxable at a rate higher than the Irish statutory rate 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 Pharmaceuticals, Inc. The balance is net of deferred tax assets which are comprised primarily of U.S. federal and state tax credits, U.S. federal and state and foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain foreign and U.S. federal and state deferred tax assets. Each reporting period, we evaluate the need for a valuation allowance on our deferred tax assets by jurisdiction and adjust our estimates as more information becomes available.

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have recorded an unrecognized tax benefit for certain tax benefits which we judge may not be sustained upon examination. Our most significant tax jurisdictions are Ireland, the U.S. (both at the federal level and in various state jurisdictions), Italy and France. These jurisdictions have statute 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 and 2013. These examinations may lead to ordinary course adjustments or proposed adjustments to our taxes. In December 2015, we received proposed tax assessment notices from the French tax authorities for 2012 and 2013 relating to certain transfer pricing adjustments. The notices propose additional French tax of approximately $47 million, including interest and penalties through the date of the assessment, translated at the foreign exchange rate at March 31, 2018. We disagree with the proposed assessment and intend to contest it vigorously.

For the three months ended March 31, 2018, we have not recorded any measurement period adjustments to the provisional estimates recorded as of December 31, 2017 in accordance with the SEC’s Staff Accounting Bulletin No. 118, or SAB 118. We will continue to analyze the impact of the U.S. Tax Cuts and Jobs Act under SAB 118 and will record adjustments to provisional amounts as our analyses are refined.

15. Subsequent Event

On April 30, 2018, we entered into an agreement with Spark Therapeutics, Inc., or Spark, to purchase a rare pediatric disease priority review voucher, or PRV, from Spark. In consideration for the PRV, we will pay Spark $110.0 million upon closing of the transaction, which is subject to customary closing conditions, including expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. 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 will capitalize the acquisition cost within intangible assets on our condensed consolidated balance sheet upon closing of the transaction.

24

Table of Contents

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, or SOS, 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. 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 months ended March 31, 2018, our total net product sales increased by 18% compared to the same period 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 February 2018, we announced that the National Comprehensive Cancer Network added Vyxeos to the Clinical Practice Guidelines in Oncology for AML.

Table of Contents

In February 2018, we enrolled the first patient in a Phase 2 proof of concept trial to evaluate the safety and efficacy of defibrotide for the prevention of acute Graft versus Host Disease, or aGvHD, in patients following allogeneic HSCT.
In March 2018, the FDA accepted for filing with a standard review our new drug application, or NDA, seeking marketing approval for solriamfetol, an investigational medicine for the treatment of excessive sleepiness, or ES, in adult patients with obstructive sleep apnea, or OSA, or narcolepsy. The FDA has set a target action date under the Prescription Drug User Fee Act, or PDUFA, of December 20, 2018.
In April 2018, we reached an agreement in principle with the U.S. Department of Justice, or 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 more information, see Note 9, 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 "— Other Challenges and Risks."
In April 2018, we entered into an agreement with Spark Therapeutics, Inc., or Spark, to purchase a rare pediatric disease priority review voucher, or PRV, which we may use to obtain priority review by the FDA for one of our future regulatory submissions. In consideration for the PRV, we will pay Spark $110.0 million upon closing of the transaction, which is subject to customary closing conditions, including expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, or HSR Act.
In April 2018, we submitted a supplemental new drug application, or sNDA, to the FDA seeking revised labeling for Xyrem to include an indication to treat cataplexy and EDS in pediatric narcolepsy patients, along with a pediatric written request report.
Continued Emphasis on Research and Development
During the three months ended March 31, 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)	ES in OSA	NDA accepted for filing in first quarter of 2018 with a target action date under PDUFA of December 20, 2018; preparing to submit a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, in late 2018
Solriamfetol (JZP-110)	ES in narcolepsy	NDA accepted for filing in first quarter of 2018 with a target action date under PDUFA of December 20, 2018; preparing to submit an MAA to the EMA in late 2018
Solriamfetol (JZP-110)	ES in Parkinson's disease	First patient enrolled in Phase 2 trial in first quarter of 2017; targeting completion of enrollment by late 2018
Xyrem (sodium oxybate)	EDS and cataplexy in pediatric narcolepsy patients with cataplexy	sNDA and pediatric written request report submitted to the FDA in the second quarter of 2018
JZP-507 (oxybate; 50% sodium reduction)	EDS and cataplexy in narcolepsy	NDA submission under evaluation
JZP-258 (oxybate; 90% sodium reduction)	EDS and cataplexy in narcolepsy	First patient enrolled in Phase 3 trial in first quarter of 2017; expect to complete enrollment in fourth quarter of 2018; subject to results of trial, expect to submit an NDA to the FDA in 2019
JZP-258	Idiopathic hypersomnia, or IH	Expect to initiate Phase 3 trial in second half of 2018

Oxybate once-nightly dosing	Narcolepsy	Program progressing; evaluation of deuterated oxybate and other formulation options continues as part of once-nightly development process

Table of Contents

Project	Disease Area	Status
Hematology/Oncology		
Vyxeos	High-risk AML	Submitted an MAA to the EMA in fourth quarter of 2017; request for accelerated assessment accepted
Vyxeos	Myelodysplastic syndrome, or MDS	Preparing for Phase 2 trial with cooperative group with planned initiation in second half of 2018
Defibrotide	Prevention of VOD in high-risk patients following HSCT	First patient enrolled in Phase 3 trial in first quarter of 2017
Defibrotide	Prevention of aGvHD following allogeneic HSCT	First patient enrolled in Phase 2 proof of concept trial in first quarter of 2018
Defibrotide	Transplant-associated thrombotic microangiopathy, or TA-TMA	Expect to activate sites in pivotal Phase 2 trial in fourth quarter of 2018
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 are engaged in a number of licensing and collaboration agreements, including with:

- ImmunoGen, Inc. 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. 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 a number of 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 72% of our net product sales for the three months ended March 31, 2018 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.

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 certain 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 EDS in narcolepsy;

Table of Contents

- 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;
- challenges and potential challenges to our intellectual property around Xyrem, including uncertainty in ongoing ANDA litigation or the possibility of new ANDA filers and challenges;
- 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 filed ANDAs with the FDA seeking approval to market a generic version of Xyrem. We filed patent lawsuits against each of the ANDA filers in the federal district court of New Jersey, or District Court, asserting that such generic products would violate our patents covering Xyrem. We have settled lawsuits against six of the ANDA filers. 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, 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, unless it elects to continue to sell the AG Product, which it may do for up to a total of five years. In our settlement with Par Pharmaceutical, Inc., or Par, we granted Par the right to sell a limited volume of an AG Product beginning on July 1, 2023, or earlier under certain circumstances, including acceleration of West-Ward's AG Product launch date. We also granted Par a license to launch its own generic sodium oxybate product on or after December 31, 2025, or earlier under certain circumstances, including circumstances related to the launch of a generic sodium oxybate product by West-Ward or another company under its ANDA. We have also settled all lawsuits with four of the other ANDA filers, granting each of them a license to launch its own generic sodium oxybate product 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 under its ANDA.

Patent lawsuits against two of the remaining non-settling ANDA filers have been consolidated as one case and remain pending. Although no trial date has been set, discovery is scheduled to conclude in the fourth quarter of 2018, and the trial in this consolidated case could occur as early as later that quarter. The most recent ANDA was filed in November 2017, and we filed a patent lawsuit against that filer in the District Court in January 2018. We cannot predict the timing or outcome of the ANDA litigation proceedings against the remaining non-settling ANDA filers. We do not know whether additional ANDAs have been or will be filed.

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. Those PTAB decisions are currently on appeal to the United States Court of Appeals for the Federal Circuit, or Federal Circuit. If the Federal Circuit

upholds the PTAB decisions on appeal, we will not be able to enforce claims the PTAB found unpatentable. On April 24, 2018, the Supreme Court of the United States issued an opinion holding that the PTAB does not have authority to partially review a patent where an inter partes review petitioner has asked for review of all of the claims. As a result of that ruling, the Federal Circuit is considering how to adjudicate the appeal of the PTAB's March 2017 decision.

Table of Contents

For a further description of these legal proceedings and certain of the settlement agreements relating to Xyrem, see Note 9, 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 any commercial launch of an AG Product or a generic sodium oxybate product is uncertain. We do not believe a launch by an ANDA filer is likely to occur prior to either a date agreed in a settlement agreement between us and such ANDA filer or a final decision in patent litigation. However, notwithstanding our patents and the terms of settlement agreements licensing those patents as of future dates, it is possible that any non-settling company that obtains and maintains FDA approval of an ANDA for a generic version of Xyrem or an NDA for another sodium oxybate product could introduce such product before our patents expire or before the entry dates specified in our settlement agreements, including if it is determined that our patents are invalid or unenforceable, if such company obtains a final judicial determination that its products do not infringe our patents, or if such company decides, before applicable patent litigation is concluded, to launch a sodium oxybate product at risk of being held liable for damages for patent infringement. In addition, even if we prevail in litigation at trial or on appeal, we cannot guarantee that a court will grant an injunction that prevents a defendant from marketing a product that infringes our patents. Instead the court may order a party that is found to infringe to pay damages, which could be significant. If a non-settling company launches a product in any of these scenarios, it could accelerate the launch dates for the AG Products and generic sodium oxybate products under our settlements agreements, depending on the circumstances.

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 a product to treat adult patients with narcolepsy with or without cataplexy that received marketing approval in Europe in 2016. While this product is currently not approved by the FDA for marketing in the U.S., the company that has exclusive U.S. commercialization rights to this product recently established an expanded access program for the product and has stated that it expects to submit an NDA to the FDA for the treatment of narcolepsy in adult patients during the first half of 2018. 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 a 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 current Xyrem REMS, which requires, among other things, that Xyrem be distributed through a single pharmacy. In the FDA's 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. 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 permit 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 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 announced approval of 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, 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

Table of Contents

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 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 11% of our net product sales for the three months ended March 31, 2018 and 12% for the year ended December 31, 2017. A significant challenge to our ability to maintain current sales levels and to increase sales is our extremely limited inventory of Erwinaze, past and continuing supply disruptions and our need to minimize or avoid additional supply disruptions due to capacity constraints, production delays, quality or regulatory challenges and other manufacturing difficulties. Erwinaze is licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL.

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. PBL continues to address the issues identified by the FDA in the warning letter. 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 limit our future maintenance and potential growth of the market for this product.

Moreover, the current manufacturing capacity for Erwinaze is completely absorbed by demand for the product. As a consequence of constrained manufacturing capacity, we have had an extremely limited or no ability to build product inventory levels that can be used to absorb supply disruptions resulting from quality, regulatory or other issues. We have experienced product quality, manufacturing and inventory challenges that have resulted, and may continue to result from time to time, in disruptions in our ability to supply certain markets and have caused, and may in the future cause, us to implement batch-specific, modified product use instructions. Most recently, we have been experiencing temporary supply disruptions in the second quarter of 2018 in the U.S. and other countries. We cannot predict whether the required remediation activities in connection with the FDA warning letter or the MHRA report will further strain manufacturing capacity and adversely affect Erwinaze supply. As capacity constraints and supply disruptions continue, whether as a result of continued quality, manufacturing or regulatory issues or otherwise, we will be unable

to build a desired excess level of product inventory, our ability to supply the market may continue to be compromised and physicians' decisions to use Erwinaze have been, and in the future may continue to be, negatively impacted. If we fail to obtain a sufficient supply of Erwinaze, our sales of and revenues from Erwinaze, 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 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 2018. We cannot predict whether the term of the agreement will be extended or, if extended, the terms of any such extension.

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.

Table of Contents

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 months ended March 31, 2018 and for the year ended December 31, 2017. We seek to increase sales of Defitelio through sales 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. We made a significant investment in Vyxeos through the acquisition of Celator Pharmaceuticals, Inc., or the Celator Acquisition. 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 shipping 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 6% of our net product sales for the three months ended March 31, 2018 and 2% of our net product sales for the year ended December 31, 2017. In the fourth quarter of 2017, we submitted an MAA for Vyxeos in the European Union, or EU, for the treatment of t-AML or AML-MRC. We expect to launch Vyxeos, if approved, in the EU on a rolling basis shortly following approval, which could occur as early as mid-2018. We cannot predict whether we will be able to obtain approval in the EU in a timely manner, or at all.

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 availability of adequate coverage, pricing and reimbursement approvals and potential competition from products in development. If sales of Vyxeos do not reach the levels we expect, or we are unable to obtain regulatory approval for Vyxeos in the EU in a timely manner, or at all, 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 ES associated with OSA and narcolepsy. In the first quarter of 2018, the FDA accepted the NDA for filing with a standard review. The FDA has 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. 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 has 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

Table of Contents

related to the role of REMS programs in delaying approval of generic products. 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 documents concerning the provision of financial assistance to Medicare patients taking drugs sold by us. 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 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 could also 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 9, 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 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;

Table of Contents

- 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 March 31,		Increase/ (Decrease)	
	2018	2017		
Product sales, net	$440,847	$373,678	18	%
Royalties and contract revenues	3,766	2,375	59	%
Cost of product sales (excluding amortization of intangible assets)	33,919	25,065	35	%
Selling, general and administrative	207,213	144,255	44	%
Research and development	62,667	44,928	39	%
Intangible asset amortization	53,007	25,665	107	%
Interest expense, net	20,605	18,844	9	%
Foreign exchange loss	1,728	1,464	18	%
Income tax provision	19,146	29,160	(34	)%
Equity in loss of investees	337	161	109	%

Revenues

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

	Three Months Ended March 31,		Increase/ (Decrease)	
	2018	2017		
Xyrem	$316,777	$272,326	16	%
Erwinaze/Erwinase	50,627	51,388	(1	)%
Defitelio/defibrotide	35,061	35,900	(2	)%
Vyxeos	26,228	—	N/A(1)	
Prialt® (ziconotide) intrathecal infusion	6,126	7,717	(21	)%
Other	6,028	6,347	(5	)%
Product sales, net	440,847	373,678	18	%
Royalties and contract revenues	3,766	2,375	59	%
Total revenues	$444,613	$376,053	18	%

(1) Comparison to prior period not meaningful.

Product Sales, Net

Xyrem product sales increased in the three months ended March 31, 2018 compared to the same period in 2017 due to an increase in sales volume and a higher average net selling price. Xyrem product sales volume increased by 9% in the

three

33

Table of Contents

months ended March 31, 2018 compared to the same period 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 product sales for the three months ended March 31, 2018 were consistent with the same period in 2017. The company experienced supply challenges in the three months ended March 31, 2018, which resulted in fluctuations in inventory levels and temporary disruptions in the company's ability to supply certain markets. Defitelio/defibrotide product sales for the three months ended March 31, 2018 were consistent with the same period in 2017. Vyxeos product sales in the three months ended March 31, 2018 were $26.2 million. Vyxeos launched in the U.S. in August 2017. Prialt product sales decreased in the three months ended March 31, 2018 compared to the same period in 2017, primarily due to a change in the relative mix of vial sizes sold. Other product sales decreased in the three months ended March 31, 2018 compared to the same period in 2017, primarily due to a decrease in sales of our psychiatry products due to generic competition, partially offset by an increase in sales of other products. 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 months ended March 31, 2018 compared to the same period in 2017 primarily due to higher contract revenues from out-licensing agreements. We do not expect royalties and contract revenues to change materially in 2018 compared to 2017.

Cost of Product Sales

Cost of product sales increased in the three months ended March 31, 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 92.3% in the three months ended March 31, 2018 compared to 93.3% for the same period in 2017. The decrease in the gross margin percentage in the three months ended March 31, 2018 was primarily due to a change in product mix. We do not expect our gross margin as a percentage of net product sales to change materially in 2018 compared to 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in the three months ended March 31, 2018 compared to the same period in 2017, primarily due to an accrued estimated loss contingency of $57.0 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 9, 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 three months ended March 31, 2018 also included an increase in compensation-related expenses of $5.2 million, driven by higher headcount, and higher marketing and promotional expenses, primarily due to pre-launch promotional costs for the potential U.S. commercial launch of solriamfetol and EU launch of Vyxeos, 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 and 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, continuation of the U.S launch of Vyxeos and the potential EU commercial launch of Vyxeos.

Research and Development Expenses

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

allocating resources accordingly. We also continually review our development pipeline projects and the status of their development and, as necessary, reallocate resources among our development pipeline projects that we believe will best support the future growth of our business.

Table of Contents

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

	Three Months Ended March 31,	
	2018	2017
Clinical studies and outside services	$28,189	$22,931
Personnel expenses	17,204	16,655
Milestone expenses	11,000	—
Other	6,274	5,342
Total	$62,667	$44,928

Research and development expenses increased by $17.7 million in the three months ended March 31, 2018 compared to the same period in 2017. Clinical studies and outside services costs increased in the three months ended March 31, 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 and regulatory activities, partially offset by lower clinical trial costs following the completion of three Phase 3 clinical trials for solriamfetol. Milestone expense of $11.0 million in the three months ended March 31, 2018 related to milestone payments following FDA acceptance of our NDA for solriamfetol in March 2018.

For 2018 and beyond, we expect that our research and development expenses will continue to increase from historical levels, particularly as we prepare for a number of anticipated regulatory submissions, initiate additional clinical trials and related development work and potentially acquire rights to additional product candidates. A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of and regulatory submissions for our product candidates, and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Intangible Asset Amortization

Intangible asset amortization increased by $27.3 million in the three months ended March 31, 2018 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 due to the full year of amortization of the Vyxeos intangible asset.

Interest Expense, Net

Interest expense, net increased by $1.8 million in the three months ended March 31, 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 the third quarter of 2017 and higher interest rates on our term loan borrowings, partially offset by 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.

Income Tax Provision

Our income tax provision was $19.1 million in the three months ended March 31, 2018 compared to $29.2 million for the same period in 2017. The effective tax rate was 29.2% in the three months ended March 31, 2018 compared to 25.2% for the same period in 2017. The increase in the effective tax rate for the three months ended March 31, 2018 compared to the same period in 2017 was primarily due to the impact of the estimated loss contingency and a decrease in originating tax credits, partially offset by a decrease in U.S corporate income tax rate. The effective tax rate for the three months ended March 31, 2018 was higher than the Irish statutory rate of 12.5% primarily due to various expenses not deductible for income tax purposes, income taxable at a rate higher than the Irish statutory rate and unrecognized tax benefits.

35

Table of Contents

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.