

Jazz Pharmaceuticals plc  
Form 10-Q  
August 05, 2015  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the quarterly period ended June 30, 2015

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.)

Fourth Floor, Connaught House,  
One Burlington 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  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  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of July 31, 2015, 61,339,267 ordinary shares of the registrant, nominal value \$0.0001 per share, were outstanding.

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JAZZ PHARMACEUTICALS PLC  
 QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2015

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We own or have rights to various copyrights, trademarks and trade names used in our business in the United States and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase® (asparaginase Erwinia chrysanthemi), Defitelio® (defibrotide), Prialt® (ziconotide) intrathecal infusion, FazaClo® (clozapine, USP) and Leukotac™ (inolimomab). This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

## JAZZ PHARMACEUTICALS PLC

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	June 30, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$921,643	\$684,042
Accounts receivable, net of allowances	193,647	186,371
Inventories	30,781	30,037
Prepaid expenses	26,250	12,800
Deferred tax assets, net	50,604	48,440
Other current assets	21,985	21,322
Assets held for sale	—	32,833
Total current assets	1,244,910	1,015,845
Property and equipment, net	80,428	58,363
Intangible assets, net	1,282,955	1,437,435
Goodwill	664,015	702,713
Deferred tax assets, net, non-current	73,280	75,494
Deferred financing costs	25,188	33,174
Other non-current assets	22,498	15,931
Total assets	\$3,393,274	\$3,338,955
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$26,409	\$25,126
Accrued liabilities	146,053	164,091
Current portion of long-term debt	28,478	9,428
Income taxes payable	13,456	7,588
Deferred tax liability, net	9,438	9,430
Deferred revenue	1,330	1,138
Total current liabilities	225,164	216,801
Deferred revenue, non-current	3,930	4,499
Long-term debt, less current portion	1,337,986	1,333,000
Deferred tax liability, net, non-current	326,707	375,054
Other non-current liabilities	52,664	38,393
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Jazz Pharmaceuticals plc shareholders' equity		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	471	471
Additional paid-in capital	1,512,450	1,458,005
Accumulated other comprehensive loss	(248,042)	(122,097)
Retained earnings	181,828	34,704

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Total Jazz Pharmaceuticals plc shareholders' equity	1,446,768	1,371,144
Noncontrolling interests	55	64
Total shareholders' equity	1,446,823	1,371,208
Total liabilities and shareholders' equity	\$3,393,274	\$3,338,955

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

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JAZZ PHARMACEUTICALS PLC  
 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Revenues:				
Product sales, net	\$332,106	\$289,100	\$639,141	\$534,086
Royalties and contract revenues	1,641	2,130	3,909	4,063
Total revenues	333,747	291,230	643,050	538,149
Operating expenses:				
Cost of product sales (excluding amortization and impairment of intangible assets)	21,813	30,692	50,111	61,616
Selling, general and administrative	107,132	100,556	219,520	206,919
Research and development	27,833	20,090	55,014	38,199
Acquired in-process research and development	—	—	—	127,000
Intangible asset amortization	23,668	32,795	48,345	63,977
Impairment charges	—	32,806	—	32,806
Total operating expenses	180,446	216,939	372,990	530,517
Income from operations	153,301	74,291	270,060	7,632
Interest expense, net	(15,812)	(11,429)	(32,057)	(21,505)
Foreign currency gain (loss)	(1,914)	74	331	197
Loss on extinguishment and modification of debt	(16,815)	—	(16,815)	—
Income (loss) before income tax provision	118,760	62,936	221,519	(13,676)
Income tax provision	30,647	19,350	62,706	36,377
Net income (loss)	88,113	43,586	158,813	(50,053)
Net loss attributable to noncontrolling interests, net of tax	(1)	(73)	(1)	(1,062)
Net income (loss) attributable to Jazz Pharmaceuticals plc	\$88,114	\$43,659	\$158,814	\$(48,991)
Net income (loss) attributable to Jazz Pharmaceuticals plc per ordinary share:				
Basic	\$1.44	\$0.73	\$2.60	\$(0.83)
Diluted	\$1.40	\$0.70	\$2.52	\$(0.83)
Weighted-average ordinary shares used in calculating net income (loss) attributable to Jazz Pharmaceuticals plc per ordinary share:				
Basic	61,190	59,519	60,998	59,025
Diluted	63,090	62,378	63,028	59,025

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

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

(In thousands)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Net income (loss)	\$88,113	\$43,586	\$158,813	\$(50,053)
Other comprehensive income (loss):				
Foreign currency translation adjustments	30,544	(11,220)	(125,953)	3,796
Other comprehensive income (loss)	30,544	(11,220)	(125,953)	3,796
Total comprehensive income (loss)	118,657	32,366	32,860	(46,257)
Comprehensive income (loss) attributable to noncontrolling interests, net of tax	1	(347)	(9)	(1,059)
Comprehensive income (loss) attributable to Jazz Pharmaceuticals plc	\$118,656	\$32,713	\$32,869	\$(45,198)

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

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JAZZ PHARMACEUTICALS PLC  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended	
	June 30,	
	2015	2014
Operating activities		
Net income (loss)	\$ 158,813	\$(50,053 )
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Intangible asset amortization	48,345	63,977
Share-based compensation	44,119	32,367
Impairment charges	—	32,806
Depreciation	4,595	3,169
Acquired in-process research and development	—	127,000
Loss on disposal of property and equipment	46	—
Excess tax benefit from share-based compensation	—	(792 )
Acquisition accounting inventory fair value step-up adjustments	—	10,477
Deferred income taxes	(16,873 )	(18,598 )
Provision for losses on accounts receivable and inventory	610	1,925
Loss on extinguishment and modification of debt	16,815	—
Other non-cash transactions	7,938	2,907
Changes in assets and liabilities:		
Accounts receivable	(8,479 )	(21,889 )
Inventories	(1,849 )	(3,302 )
Prepaid expenses and other current assets	(13,676 )	936
Other long-term assets	(6,658 )	(3,365 )
Accounts payable	2,129	(31,555 )
Accrued liabilities	(18,135 )	(821 )
Income taxes payable	6,497	5,454
Deferred revenue	(382 )	(557 )
Contingent consideration	—	(14,900 )
Other non-current liabilities	13,271	8,461
Net cash provided by operating activities	237,126	143,647
Investing activities		
Net proceeds from sale of business	33,703	—
Purchases of property and equipment	(27,432 )	(14,660 )
Acquisitions, net of cash acquired	—	(828,676 )
Acquisition of in-process research and development	—	(127,000 )
Net cash provided by (used in) investing activities	6,271	(970,336 )
Financing activities		
Net proceeds from issuance of debt	901,003	636,355
Proceeds from employee equity incentive and purchase plans and exercise of warrants	26,730	31,642
Repayments of long-term debt	(895,402 )	(4,804 )
Payment of employee withholding taxes related to share-based awards	(16,679 )	(10,551 )
Share repurchases	(11,690 )	(23,487 )
Excess tax benefit from share-based compensation	—	792

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Acquisition of noncontrolling interests	—	(136,640	)
Payment of contingent consideration	—	(35,100	)
Net cash provided by financing activities	3,962	458,207	
Effect of exchange rates on cash and cash equivalents	(9,758	) 233	
Net increase (decrease) in cash and cash equivalents	237,601	(368,249	)
Cash and cash equivalents, at beginning of period	684,042	636,504	
Cash and cash equivalents, at end of period	\$921,643	\$268,255	

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



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

1. The Company and Summary of Significant Accounting Policies

Jazz Pharmaceuticals plc, a public limited company formed under the laws of Ireland, 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. In these areas, we market Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase Erwinia chrysanthemi) in the United States, and we market Erwinase® and Defitelio® (defibrotide) in countries outside the United States. Our strategy is to create shareholder value by:

• Growing sales of the existing products in our portfolio, including by identifying new growth opportunities;

• Acquiring additional differentiated products that are on the market or product candidates that are in late-stage development; and

• Pursuing focused development of a pipeline of post-discovery differentiated product candidates.

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 Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or 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, 2014.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three and six months ended June 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015, for any other interim period or for any future period.

These condensed consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our subsidiaries and intercompany transactions and balances have been eliminated. We record noncontrolling interests in our condensed consolidated financial statements which represent the ownership interest of minority shareholders in the equity of Gentium S.p.A., or Gentium. Our condensed consolidated financial statements include the results of operations of businesses we have acquired from the date of each acquisition for the applicable reporting periods.

Significant Risks and Uncertainties

Our financial results remain significantly influenced by sales of Xyrem. In the three and six months ended June 30, 2015, net product sales of Xyrem were \$247.8 million and \$460.5 million, respectively, which represented 74.6% and 72.1% of total net product sales, respectively. Our ability to maintain or increase sales of Xyrem in its approved indications is subject to a number of risks and uncertainties, including the potential introduction of generic competition or an alternative sodium oxybate product that competes with Xyrem, changed or increased regulatory restrictions, continued acceptance of Xyrem by physicians and patients, and any increase in restrictive conditions for reimbursement required by, and the availability of reimbursement from, third party payors. Seven abbreviated new drug applications, or ANDAs, have been filed with the U.S. Food and Drug Administration, or FDA, by third parties seeking to market generic versions of Xyrem. We have filed lawsuits seeking to prevent the introduction of a generic version of Xyrem that would infringe our patents, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. Although no trial date has been set in any of the ANDA suits, we anticipate

that trial on some of the patents in the case against the first ANDA filer, Roxane Laboratories, Inc., or Roxane, could occur as early as the first quarter of 2016. In addition, certain of the ANDA filers have challenged the validity of six patents covering the distribution system for Xyrem by filing petitions for inter partes review, or IPR, by the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office. In July 2015, the PTAB issued decisions instituting IPR trials with respect to these petitions, and we expect the PTAB to issue final decisions on the validity of the

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patents within a year of institution. Furthermore, in April 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs III LLC) filed an IPR petition challenging the validity of one of our Xyrem distribution patents that is already the subject of one of the IPR petitions proceeding to trial before the PTAB. The PTAB has not yet determined whether to institute proceedings with respect to this IPR petition. 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 IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate products that compete with Xyrem, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are in the process of implementing the necessary systems, processes, procedures and activities to transition to the final risk evaluation and mitigation strategy, or REMS, for Xyrem approved by the FDA in late February 2015. While we expect to implement the Xyrem REMS by late August 2015 and to submit ongoing assessments, in each case as set forth in the FDA's Xyrem REMS approval notice, we cannot guarantee that we will be able to do so in a timely manner, that our implementation of the approved Xyrem REMS will meet FDA requirements, that the assessments will be satisfactory to the FDA, or that the Xyrem REMS will satisfy FDA's expectations in their anticipated evaluation of the Xyrem REMS on an ongoing basis. Any failure to transition to the Xyrem REMS in a timely manner and to the satisfaction of the FDA or to comply with the REMS obligations could negatively affect sales of Xyrem, result in additional costs and expenses for us, and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, we cannot predict whether the FDA will seek to require or ultimately require modifications to the Xyrem REMS, including with respect to the distribution system, or seek to otherwise impose or ultimately impose additional requirements to the Xyrem REMS, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

We also expect to continue to face pressure to develop a single shared REMS with potential generic competitors for Xyrem or to license or share intellectual property pertinent to the Xyrem REMS, which is the subject of multiple issued patents, or elements of the Xyrem REMS, with generic competitors. In January 2014, the FDA held an initial meeting with us and the then-current sodium oxybate ANDA applicants to facilitate the development of a single shared REMS for sodium oxybate. The parties have had regular interactions with respect to developing a single shared REMS since the initial meeting, and we expect the interactions to continue. If we do not develop a single shared REMS or license or share intellectual property pertinent to our Xyrem REMS with generic competitors within a time frame or on terms that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to allow one or more generic competitors to market a generic drug with a separate REMS that includes different, but comparable, elements to assure safe use, than those in our approved Xyrem REMS. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared REMS for sodium oxybate, licensing or sharing intellectual property pertinent to our Xyrem REMS, or the FDA's response to a certification that a third party had been unable to obtain a license. In addition, the Federal Trade Commission, other governmental authorities or others could claim or determine that we are using the Xyrem REMS in an anticompetitive manner (including in light of the FDA's statement in the Xyrem REMS approval notice that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the Federal Food, Drug and Cosmetic Act) or have engaged in other anticompetitive practices.

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), were \$46.2 million and \$96.5 million, respectively, in the three and six months ended June 30, 2015, which represented 13.9% and 15.1% of total net product sales, respectively. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing sales and marketing and research and development activities. However, our ability to successfully and sustainably maintain

or grow sales of Erwinaze is subject to a number of risks and uncertainties, including the limited population of patients with acute lymphoblastic leukemia, or ALL, and the incidence of hypersensitivity reactions to E. coli-derived asparaginase within that population, as well as our need to apply for and receive marketing authorizations, through the European Union's mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries. Another significant challenge to our ability to maintain current sales levels and to increase sales is our need to avoid supply interruptions of Erwinaze due to capacity constraints, production delays, quality challenges or other manufacturing difficulties. We have limited inventory of Erwinaze, which puts us at significant risk of not being able to meet product demand. Erwinaze is licensed from and manufactured by a single source, which was Public Health England, or PHE, through March 31, 2015. As of April 1, 2015, the facility at which Erwinaze is manufactured was transferred to Porton BioPharma Limited, or PBL, a limited liability company that is wholly-owned by the U.K. Secretary of State for Health. We are now working with PBL on matters related to Erwinaze supply. The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product.

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As a consequence of constrained manufacturing capacity, we have had an extremely limited ability to build an excess level of product inventory that could be used to absorb disruptions to supply resulting from any quality or other issues. If we continue to be subject to capacity constraints or experience quality or other manufacturing challenges in the future, we may be unable to build a desired excess level of product inventory, and our ability to supply the market may be compromised. Although we are taking steps to improve the Erwinaze manufacturing process, if our ongoing efforts are not successful, we could experience additional Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. In addition, while we continue to work with the manufacturer of Erwinaze to evaluate potential steps to expand production capacity to increase the supply of Erwinaze over the longer term to address worldwide demand, our ability to maintain or increase sales of Erwinaze may be limited by our ability to obtain a sufficient supply of the product.

In furtherance of our growth strategy, we have made a significant investment in Defitelio/defibrotide. We added the product to our portfolio as a result of our acquisition of Gentium that closed in January 2014, or the Gentium Acquisition, and secured worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. Our ability to realize the anticipated benefits from this investment is subject to a number of risks and uncertainties, including our ability to successfully maintain or grow sales of Defitelio in Europe, or obtain marketing approval in other countries, including the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. During 2014, Defitelio was launched in a number of European countries. We have launched and expect to continue to launch Defitelio in additional European countries on a rolling basis in 2015 and are in the process of making pricing and reimbursement submissions with respect to Defitelio, and discussing them with regulatory authorities, in those European countries where Defitelio is not yet launched, including in countries where pricing and reimbursement approvals are required for launch. A key challenge to our success in maintaining or growing sales of Defitelio in Europe is our ability to obtain appropriate pricing and reimbursement approvals in those European countries where Defitelio is not yet launched. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected countries would be delayed, or, if we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

We are also engaged in activities related to the potential approval of defibrotide in the United States. In July 2015, we completed a rolling submission of a new drug application, or NDA, to the FDA for defibrotide for the treatment of hepatic veno-occlusive disease, or VOD, with evidence of multi-organ dysfunction following hematopoietic stem cell transplantation, or HSCT. We cannot predict whether our NDA will be accepted for filing or approved in a timely manner, if at all. It is possible that the FDA may ask an Oncologic Drugs Advisory Committee, or ODAC, which provides the FDA with independent expert advice and recommendations, to review our NDA. The ODAC may recommend against approval of our NDA, may recommend conditioning approval on our conducting one or more potentially time-consuming and costly clinical trials to provide supporting data either before approval or as a post-marketing commitment, or may recommend more narrow or restricted labeling than we have proposed. We also face other challenges that could impact the anticipated value of Defitelio/defibrotide, including the limited size of the population of VOD patients who are indicated for treatment with Defitelio/defibrotide (particularly if the FDA requires more narrow or restricted labeling than we have proposed), the need to establish U.S. pricing and reimbursement support for the product in the event we are able to obtain U.S. marketing approval for defibrotide, the possibility that we may be required to conduct time-consuming and costly clinical trials as a condition of any U.S. marketing approval for the product, the lack of experience of U.S. physicians in diagnosing and treating VOD, and challenges to our ability to develop the product for additional indications. If sales of Defitelio/defibrotide do not reach the levels we expect, our anticipated revenue from the product would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to risks specifically related to Xyrem, Erwinaze and Defitelio/defibrotide, we are subject to other challenges and risks specific to our business, as well as risks and uncertainties common to companies in the

pharmaceutical industry with development and commercial operations, including: the challenges of protecting and enhancing our intellectual property rights; delays or problems in the supply or manufacture of our products, particularly with respect to certain products as to which we maintain limited inventories, including products for which our supply demands are growing, and our dependence on single source suppliers to continue to meet our ongoing commercial demand or our requirements for clinical trial supplies; 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 other austerity measures in the United States and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the United States in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by third party payors; and the challenges of compliance with the requirements of the FDA, the U.S. Drug Enforcement Administration, or DEA, and non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, adverse event reporting and product recalls or withdrawals.

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Other risks and uncertainties related to our ability to execute on our strategy include: the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance and support of our products by patients, physicians and payors; the risks and costs associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historic business, the increase in geographic dispersion among our centers of operation, taking on the operation of a manufacturing plant as a result of the Gentium Acquisition 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; 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 that we are conducting or that we plan to conduct for our product candidates; the inherent uncertainty associated with the regulatory approval process, especially as we continue to undertake increased activities and make growing investment in our product pipeline development projects; our potential inability to identify and acquire, in-license or develop additional products or product candidates to grow our business; and possible restrictions on our ability and flexibility to pursue certain future corporate development and other 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 and cash equivalents. 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 marketable securities and issuers of investments to the extent recorded on the balance sheet.

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 United States, 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 we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of June 30, 2015, five customers accounted for 88% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliates, or Express Scripts, which accounted for 70% of gross accounts receivable and IDIS Limited, or IDIS, which accounted for 8% of gross accounts receivable. As of December 31, 2014, five customers accounted for 86% of gross accounts receivable, including Express Scripts, which accounted for 66% of gross accounts receivable, and IDIS, which accounted for 11% of gross accounts receivable.

We depend on single source suppliers and manufacturers for each of our products, product candidates and their active pharmaceutical ingredients.

**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.

**Net Income (Loss) Attributable to Jazz Pharmaceuticals plc per Ordinary Share**

Basic net income (loss) attributable to Jazz Pharmaceuticals plc per ordinary share is based on the weighted-average number of ordinary shares outstanding. Diluted net income (loss) attributable to Jazz Pharmaceuticals plc per ordinary

share is based on the weighted-average number of ordinary shares outstanding and potentially dilutive ordinary shares outstanding.

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

	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Numerator:				
Net income (loss) attributable to Jazz Pharmaceuticals plc	\$88,114	\$43,659	\$158,814	\$(48,991)
Denominator:				
Weighted-average ordinary shares used in calculating net income (loss) attributable to Jazz Pharmaceuticals plc per ordinary share - basic	61,190	59,519	60,998	59,025
Dilutive effect of employee equity incentive and purchase plans	1,900	2,293	2,030	—
Dilutive effect of warrants	—	566	—	—
Weighted-average ordinary shares used in calculating net income (loss) attributable to Jazz Pharmaceuticals plc per ordinary share - diluted	63,090	62,378	63,028	59,025

Net income (loss) attributable to Jazz Pharmaceuticals plc per ordinary share:

Basic	\$1.44	\$0.73	\$2.60	\$(0.83)
Diluted	\$1.40	\$0.70	\$2.52	\$(0.83)

For the six months ended June 30, 2014, potentially dilutive ordinary shares from employee equity incentive and purchase plans and warrants were not included in the diluted net loss attributable to Jazz Pharmaceuticals plc per ordinary share because the inclusion of such shares would have an anti-dilutive effect.

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans, warrants and our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, are determined by applying the treasury stock method to the assumed exercise of share options and warrants, 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 2021 Notes. The potential issue of approximately 2.9 million ordinary shares issuable upon exchange of the 2021 Notes had no effect on diluted net income attributable to Jazz Pharmaceuticals plc per ordinary share because the average price of our ordinary shares for the three and six months ended June 30, 2015 did not exceed the effective exchange price of \$199.77 per ordinary share.

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

	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
1.875% exchangeable senior notes due 2021	2,878	—	2,878	—
Options to purchase ordinary shares and RSUs	1,586	1,088	1,453	5,526
Warrants to purchase ordinary shares	—	—	—	928
Ordinary shares under ESPP	—	—	—	137

## Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2015-03, "Interest - Imputation of Interest", or ASU No. 2015-03. ASU No. 2015-03 requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt

liability instead of as an asset. ASU No. 2015-03 does not affect the recognition and measurement guidance for debt issuance costs. ASU No. 2015-03 will be effective for us beginning January 1, 2016 and requires retrospective application. ASU-2015-03 will represent a change in accounting principle in 2016, the year of adoption. We are currently evaluating the impact of ASU 2015-03 on the presentation of our consolidated financial statements.

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In April 2015, the FASB issued ASU No. 2015-05, “Intangibles-Goodwill and Other-Internal-Use Software”, or ASU No. 2015-05. ASU No. 2015-05 provides guidance on whether a cloud computing arrangement contains a software license to be accounted for as internal-use software to assist in the evaluation of the accounting for fees paid by a customer in the arrangement. ASU No. 2015-05 will be effective for us beginning January 1, 2016 and may be applied either prospectively to new cloud computing arrangements or retrospectively. We are currently evaluating the impact of ASU 2015-05 on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers”, or ASU No. 2014-09, which 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. In July 2015, the FASB decided to defer by one year the effective date of ASU No. 2014-09 which will now be effective for us beginning January 1, 2018 and can be adopted on a full retrospective basis or on a modified retrospective basis. We are currently assessing our approach to the adoption of this standard and the potential impact on our results of operations and financial position.

## 2. Disposition

In March 2015, we sold certain products and the related business that we originally acquired as part of our acquisition of EUSA Pharma Inc. The purchase price for the products and related business was \$34.0 million, subject to pre- and post-closing purchase price adjustments. We received approximately \$33 million in cash after purchase price adjustments were made.

We recognized a loss on disposal of \$0.2 million in the six months ended June 30, 2015 within selling, general and administrative expenses in our condensed consolidated statements of operations. The related assets met the assets held for sale criteria and were reclassified to assets held for sale as of December 31, 2014. Goodwill was allocated to these assets using the relative fair value method. We have determined that the disposition of these assets did not qualify for reporting as a discontinued operation, because the sale does not represent a strategic shift that has or will have a major effect on our operations and financial results.

## 3. Fair Value Measurement

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

	June 30, 2015				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents
Cash	\$243,964	\$—	\$—	\$243,964	\$243,964
Time deposits	677,679	—	—	677,679	677,679
Totals	\$921,643	\$—	\$—	\$921,643	\$921,643
	December 31, 2014				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents
Cash	\$338,262	\$—	\$—	\$338,262	\$338,262
Time deposits	345,780	—	—	345,780	345,780
Totals	\$684,042	\$—	\$—	\$684,042	\$684,042

Cash equivalents 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 operations.

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The following table summarizes, by major security type, our available-for-sale securities as of June 30, 2015 and December 31, 2014 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	June 30, 2015		December 31, 2014	
	Other Observable Inputs (Level 2)	Total Estimated Fair Value	Other Observable Inputs (Level 2)	Total Estimated Fair Value
Time deposits	\$677,679	\$677,679	\$345,780	\$345,780

As of June 30, 2015, our available-for-sale securities included time deposits which were measured at fair value using Level 2 inputs and their carrying values were approximately equal to their fair values. 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. There were no transfers between the different levels of the fair value hierarchy in 2015 or in 2014.

As of June 30, 2015, the estimated fair value of our 2021 Notes was approximately \$672 million. The fair value of the 2021 Notes was estimated using quoted market prices obtained from brokers (Level 2). The estimated fair value of our borrowings under our term loan and revolving credit facility and other borrowings were approximately equal to their respective book values based on the borrowing rates currently available for variable rate loans (Level 2).

As of December 31, 2014, assets measured at fair value on a non-recurring basis subsequent to initial recognition included assets classified as held for sale on the condensed consolidated balance sheet. The carrying amount of \$32.8 million for assets held for sale was equal to estimated fair value, which was based on the sales price agreed less costs to sell, and represented a Level 3 input. We completed the sale of these assets in March 2015.

## 4. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Raw materials	\$4,079	\$3,570
Work in process	13,759	9,870
Finished goods	12,943	16,597
Total inventories	\$30,781	\$30,037

## 5. Goodwill and Intangible Assets

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

Balance at December 31, 2014	\$702,713	
Foreign exchange	(38,698	)
Balance at June 30, 2015	\$664,015	

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

	June 30, 2015			December 31, 2014			
	Remaining Weighted-Average Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies	12.4	\$ 1,337,015	\$ (280,529 )	\$ 1,056,486	\$ 1,450,606	\$ (259,889 )	\$ 1,190,717
Manufacturing contracts	2.6	11,879	(4,279 )	7,600	13,012	(3,060 )	9,952
Trademarks	—	2,887	(2,887 )	—	2,914	(2,896 )	18
Total finite-lived intangible assets		1,351,781	(287,695 )	1,064,086	1,466,532	(265,845 )	1,200,687
Acquired IPR&D assets		218,869	—	218,869	236,748	—	236,748
Total intangible assets		\$ 1,570,650	\$ (287,695 )	\$ 1,282,955	\$ 1,703,280	\$ (265,845 )	\$ 1,437,435

The decrease in the gross carrying amount of intangible assets as of June 30, 2015 compared to December 31, 2014 reflects the negative impact of foreign currency translation adjustments, primarily due to the strengthening of the U.S. dollar against the euro.

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

Based on finite-lived intangible assets recorded as of June 30, 2015, 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
2015 (remainder)	\$47,863
2016	91,548
2017	91,548
2018	88,698
2019	88,477
Thereafter	655,952
Total	\$ 1,064,086

#### 6. Certain Balance Sheet Items

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

	June 30, 2015	December 31, 2014
Construction-in-progress	\$57,876	\$37,145
Computer software	12,839	10,634
Computer equipment	10,332	7,670
Leasehold improvements	8,735	7,931
Machinery and equipment	5,750	6,408

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Furniture and fixtures	2,350	2,220	
Land and buildings	1,693	1,547	
Subtotal	99,575	73,555	
Less accumulated depreciation and amortization	(19,147	) (15,192	)
Property and equipment, net	\$80,428	\$58,363	

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Accrued liabilities consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Rebates and other sales deductions	\$61,230	\$51,899
Employee compensation and benefits	28,062	46,143
Royalties	10,293	7,964
Sales returns reserve	8,650	14,039
Professional fees	5,622	3,295
Accrued interest	4,656	10,327
Accrued construction-in-progress	3,387	4,931
Other	24,153	25,493
Total accrued liabilities	\$146,053	\$164,091

## 7. Debt

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

	June 30, 2015	December 31, 2014
1.875% exchangeable senior notes due 2021	\$575,000	\$575,000
Unamortized discount on 1.875% exchangeable senior notes due 2021	(117,119)	(124,735)
1.875% exchangeable senior notes due 2021, net	457,881	450,265
Term loans	747,087	890,479
Borrowings under revolving credit facility	160,000	—
Other borrowings	1,496	1,684
Total debt	1,366,464	1,342,428
Less current portion	28,478	9,428
Total long-term debt	\$1,337,986	\$1,333,000

## Credit Agreement

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

Under the June 2015 credit agreement, the term loan matures on June 18, 2020 and the revolving credit facility terminates, and any loans outstanding thereunder become due and payable, on June 18, 2020.

Borrowings under the June 2015 credit agreement bear interest, at our option, at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 1.50% to 2.25% per annum, based upon our secured leverage ratio, or (b) the prime lending rate, plus an applicable margin ranging from 0.50% to 1.25% per annum, based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.35% per annum based upon our secured leverage ratio.

As of June 30, 2015, the interest rate on the term loan was 2.04% and the effective interest rate was 2.38%. As of June 30, 2015, we had drawn \$160.0 million under the revolving credit facility and a further \$1.1 million was committed for an outstanding letter of credit. As of June 30, 2015, the interest rate on borrowings under the revolving credit facility was 1.94%.

Jazz Pharmaceuticals plc and certain of our wholly-owned subsidiaries are borrowers under the June 2015 credit agreement. The borrowers' obligations under the June 2015 credit agreement, and any hedging or cash management



obligations entered into with a lender, are guaranteed on a senior secured basis by Jazz Pharmaceuticals plc and certain of its subsidiaries (including the issuer of the 2021 Notes as described below) and are secured by substantially all of Jazz Pharmaceuticals plc's, the borrowers' and the guarantor subsidiaries' assets.

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We may make voluntary prepayments of principal at any time without payment of a premium. We are required to make mandatory prepayments of the term loan (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), and (3) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the term loan, which are due quarterly, will begin in December 2015 and are equal to 5.0% per annum of the original principal amount of \$750.0 million during the first two years, 7.5% per annum during the third year, 10.0% per annum during the fourth year and 12.5% per annum during the fifth year, with any remaining balance payable on the maturity date.

The June 2015 credit agreement contains financial covenants that require Jazz Pharmaceuticals plc and its restricted subsidiaries to (a) not exceed a maximum secured net leverage ratio or (b) not fall below a cash interest coverage ratio. We were, as of June 30, 2015, and are currently in compliance with these financial covenants.

In connection with our entry into the June 2015 credit agreement and termination of the 2012 credit agreement, we recorded a loss on extinguishment and modification of debt of \$16.8 million, which was comprised of \$16.0 million related to the expensing of unamortized deferred financing costs and unamortized original issue discount associated with extinguished debt and \$0.8 million related to new third party fees associated with modified debt.

Exchangeable Senior Notes

The 2021 Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of Jazz Pharmaceuticals plc. The Issuer's obligations under the 2021 Notes are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. No subsidiary of Jazz Pharmaceuticals plc guaranteed the 2021 Notes. Subject to certain local law restrictions on payment of dividends, among other things, and potential negative tax consequences, we are not aware of any significant restrictions on the ability of Jazz Pharmaceuticals plc to obtain funds from the Issuer or Jazz Pharmaceuticals plc's other subsidiaries by dividend or loan, or any legal or economic restrictions on the ability of the Issuer or Jazz Pharmaceuticals plc's other subsidiaries to transfer funds to Jazz Pharmaceuticals plc in the form of cash dividends, loans or advances. There is no assurance that in the future such restrictions will not be adopted.

As of June 30, 2015, the carrying value of the equity component of the 2021 Notes, net of equity issuance costs, was \$126.9 million.

Maturities

Scheduled maturities with respect to our long-term debt are as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2015 (remainder)	\$9,684
2016	37,855
2017	42,547
2018	61,169
2019	79,791
Thereafter	1,255,450
Total	\$1,486,496

8. Commitments and ContingenciesIndemnification

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

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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 and the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we did not recognize any liabilities relating to these obligations as of June 30, 2015 and December 31, 2014. 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**

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. Future minimum lease payments under our noncancelable operating leases as of June 30, 2015 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2015 (remainder)	\$5,631
2016	11,434
2017	12,267
2018	7,803
2019	7,192
Thereafter	73,273
Total	\$ 117,600

In January 2015, we entered into an agreement to lease office space located in Palo Alto, California in a building to be constructed by the landlord. We expect to occupy this office space by the end of 2017. The 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 five years each. We are obligated to make lease payments totaling approximately \$88 million over the initial term of the lease. In connection with this lease, the landlord is providing a tenant improvement allowance for the costs associated with the design, development and construction of tenant improvements for the leased facility. We are obligated to fund all costs incurred in excess of the tenant improvement allowance. The scope of the planned tenant improvements do not qualify as “normal tenant improvements” under the lease accounting guidance. Accordingly, for accounting purposes, we have concluded we are the deemed owner of the building during the construction period. As of June 30, 2015, we recorded project construction costs of \$2.0 million incurred by the landlord as construction-in-progress in property and equipment, net and a corresponding financing obligation in other non-current liabilities in our condensed consolidated balance sheets. We will increase the asset and financing obligation as additional building costs are incurred by the landlord during the construction period. Rent expense of \$0.5 million and \$0.9 million associated with the ground lease during construction was recognized in the condensed consolidated statements of operations in the three and six months ended June 30, 2015, respectively.

In April 2015, we amended an existing operating sublease for office space in Palo Alto, California for additional office space and extended the term of this sublease to December 2017. As a result of the amendment, we are obligated to make additional lease payments of approximately \$10 million. We also obtained an option to extend the term of the sublease twice for a period of one year each.

As of June 30, 2015, we had \$36.4 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

**Legal Proceedings**

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

**Xyrem ANDA Matters:** On October 18, 2010, we received a notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem (sodium oxybate) oral solution. Roxane’s initial notice alleged that all five patents then listed for Xyrem in the FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” or Orange Book, on the date of the notice are invalid, unenforceable or not infringed by Roxane’s proposed generic product. On

November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's initial notice in the U.S. District Court for the District of New Jersey, or the District Court, seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA was stayed for 30 months, or until April 18, 2013. That stay has expired. Additional patents covering Xyrem were issued between December 2010 and December

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2012, and, after receiving Paragraph IV Certification notices from Roxane, we filed additional lawsuits against Roxane on February 4, 2011, May 2, 2011, October 26, 2012 and December 5, 2012 to include these additional patents in the litigation. All of the lawsuits filed against Roxane between 2010 and 2012 have been consolidated by the District Court into a single case, or the Roxane consolidated case, alleging that 10 of our patents covering Xyrem are or will be infringed by Roxane's ANDA and seeking a permanent injunction to prevent Roxane from launching a generic version of Xyrem that would infringe these patents.

In December 2013, the District Court permitted Roxane to amend its answer in the Roxane consolidated case to allege additional equitable defenses, and the parties were given additional time for discovery on those new defenses. In addition, in March 2014, the District Court granted our motion to bifurcate and stay the portion of the Roxane consolidated case regarding patents related to the distribution system for Xyrem. Although no trial date has been scheduled, based on the District Court's current schedule, we anticipate that trial on the patents in the Roxane consolidated case that are not subject to the stay could occur as early as the first quarter of 2016. We do not have any estimate of a possible trial date for trial on the patents in the Roxane consolidated case that are currently subject to the stay. The actual timing of events in this litigation may be significantly earlier or later than we currently anticipate, and we cannot predict the specific timing or outcome of events in this litigation.

On April 1, 2014 and January 15, 2015, we received additional notices of Paragraph IV Certification from Roxane regarding newly issued patents for Xyrem listed in the Orange Book. On February 20, 2015, we filed a new lawsuit against Roxane in the District Court, alleging that three of our patents covering Xyrem are infringed or will be infringed by Roxane's ANDA and seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe these patents. On April 20, 2015, Roxane moved to dismiss claims involving our patent covering a part of the Xyrem label that instructs prescribers on adjusting the dose of Xyrem when it is being co-administered with divalproex sodium (also known as valproate or valproic acid) on the grounds that this patent does not cover patentable subject matter. We cannot predict the timing or outcome of events in this matter or its impact on the Roxane consolidated case.

On December 10, 2012, December 12, 2012 and August 8, 2013, we received notices of Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On January 18, 2013 and September 12, 2013, we filed lawsuits against Amneal in the District Court, alleging that nine of 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. These lawsuits against Amneal were consolidated by the District Court on November 6, 2013.

On November 21, 2013 and November 24, 2013, we received notices 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 13 of 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.

In April 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request in May 2014. The order consolidating the cases provides that Amneal's 30-month stay period will be extended to coincide with the date of Par's 30-month stay period. As a result, FDA's approval of both Amneal's and Par's ANDAs is stayed until the earlier of (i) May 20, 2016, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of events in the Amneal/Par consolidated case or their impact on other ongoing proceedings with Amneal or Par as described below.

On April 7, 2014 and January 19, 2015, we received additional notices of Paragraph IV Certification from Amneal regarding newly issued patents for Xyrem listed in the Orange Book. On May 20, 2014 and February 6, 2015, we filed additional lawsuits against Amneal in the District Court, alleging that four of 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. We cannot predict the timing or outcome of

events in these matters or their impact on other ongoing proceedings with Amneal.

On July 3, 2014, August 6, 2014 and November 25, 2014, we received additional notices of Paragraph IV Certification from Par regarding newly issued patents for Xyrem listed in the Orange Book. We filed additional lawsuits against Par in the District Court on August 15, 2014, October 2, 2014 and January 8, 2015, alleging that three of 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. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Par.

On June 4, 2014, we received a notice of Paragraph IV Certification from Ranbaxy Laboratories Limited, or Ranbaxy, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On June 6, 2014, we

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received a notice of an amended Paragraph IV Certification from Ranbaxy. On July 15, 2014, we filed a lawsuit against Ranbaxy in the District Court, alleging that 14 of our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that will infringe these patents. On August 20, 2014 and December 1, 2014, we received additional notices of Paragraph IV Certification from Ranbaxy regarding newly issued patents for Xyrem listed in the Orange Book. On October 2, 2014 and January 9, 2015, we filed additional lawsuits against Ranbaxy in the District Court, alleging that two of our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Ranbaxy.

On October 30, 2014, we received a notice of Paragraph IV Certification from Watson Laboratories, Inc., or Watson, that it has submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Watson in the District Court, alleging that 15 of our patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents. On March 23, 2015, Watson moved to dismiss the portion of the case based on our Orange Book-listed patents covering the distribution system for Xyrem on the grounds that these patents do not cover patentable subject matter. We cannot predict the timing or outcome of events in this litigation.

In January 2015, Amneal, Ranbaxy and Watson proposed the consolidation of their respective cases and a consolidated schedule to the District Court, while Par sought its own proposed schedule with the District Court, notwithstanding the prior consolidation of portions of the Par and Amneal cases. In April 2015, the District Court issued an order that consolidated all then-pending lawsuits against Amneal, Par, Ranbaxy and Watson into one case, the Amneal/Par/Ranbaxy/Watson consolidated case. Under a related scheduling order issued in March 2015, the District Court would hold a Markman hearing for the Amneal/Par/Ranbaxy/Watson consolidated case no earlier than January 2016. We cannot predict the timing or outcome of events in the Amneal/Par/Ranbaxy/Watson consolidated case or their impact on other ongoing proceedings with any ANDA filer.

On March 23, 2015, March 25, 2015, March 26, 2015 and April 16, 2015, we received an additional notice of Paragraph IV Certification from each of Par, Amneal, Ranbaxy and Roxane, respectively, regarding a newly issued method of treatment patent for Xyrem listed in the Orange Book. We filed additional lawsuits against Par, Amneal and Ranbaxy in the District Court on May 7, 2015 and against Roxane on June 1, 2015, alleging that this patent is infringed or will be infringed by Par's, Amneal's, Ranbaxy's and Roxane's ANDAs and seeking a permanent injunction to prevent each of these parties from introducing a generic version of Xyrem that would infringe this patent. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with any ANDA filer.

On May 14, 2015, we received an additional notice of Paragraph IV Certification from Watson regarding newly issued patents for Xyrem listed in the Orange Book. On June 26, 2015, we filed a lawsuit against Watson in the District Court, alleging that two of our patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in this matter or its impact on other ongoing proceedings with any ANDA filer.

On June 8, 2015, we received a Paragraph IV Certification from Wockhardt Bio AG, or Wockhardt, that it has submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Wockhardt's Paragraph IV Certification alleged that 15 patents listed in the Orange Book for Xyrem are invalid, unenforceable, and/or will not be infringed by Wockhardt's proposed generic product. On July 17, 2015, we filed a lawsuit in the District Court alleging that 17 of our patents covering Xyrem are or will be infringed by Wockhardt's ANDA and seeking a permanent injunction to prevent Wockhardt from introducing a generic version of Xyrem that would infringe our patents. We cannot predict the timing or outcome of events in this matter or its impact on other ongoing proceedings with any ANDA filer.



On July 23, 2015, we received a Paragraph IV Certification from Lupin Inc., or Lupin, that it has submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Lupin's Paragraph IV Certification alleged that 16 patents listed in the Orange Book for Xyrem are invalid, unenforceable, and/or will not be infringed by Lupin's proposed generic product. We are evaluating initiation of litigation against Lupin. We cannot predict the timing or outcome of events in this matter or its impact on other ongoing proceedings with any ANDA filer.

Also on July 23, 2015, we received an additional notice of Paragraph IV Certification from Amneal regarding a newly issued patent for Xyrem listed in the Orange Book. We expect to file a lawsuit against Amneal in the District Court alleging that our patent is 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 this patent. We cannot predict the timing or outcome of events in this matter or its impact on other ongoing proceedings with any ANDA filer.

Xyrem Post-Grant Patent Review Matters: Between June and August 2014, petitions seeking covered business method, or CBM, post-grant patent review by the PTAB were filed by certain of the ANDA filers with respect to the validity of six of

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our patents related to the distribution system for Xyrem. In the fall of 2014, we filed preliminary responses to the petitions in which, among other things, we asserted that the challenged patents should not be subject to CBM review. In early 2015, the PTAB issued decisions denying institution of CBM review for all of these petitions. In January 2015, certain of the ANDA filers filed petitions for IPR by the PTAB with respect to the validity of six patents covering the distribution system for Xyrem. In July 2015, the PTAB issued decisions instituting IPR trials with respect to these petitions, and we expect the PTAB to issue final decisions on the validity of the patents within a year of institution. In addition, in April 2015, a hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs III LLC) filed an IPR petition challenging the validity of one of our Xyrem distribution patents that is already the subject of one of the IPR petitions proceeding to trial before the PTAB. In July 2015, we filed a preliminary response to this petition, opposing the petition and stating reasons that review should not be granted. The PTAB has not yet determined whether to institute proceedings with respect to this IPR petition. 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 IPR or other proceeding, whether the PTAB will institute any petitioned IPR proceeding that has not yet been instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings or other aspects of our Xyrem business.

FazaClo ANDA Matters: Azur Pharma Public Limited Company, or Azur Pharma (prior to the business combination between Jazz Pharmaceuticals, Inc. and Azur Pharma) received notices of Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc., or Barr, Novel Laboratories, Inc., or Novel, and Mylan Pharmaceuticals, Inc., or Mylan, indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo® (clozapine, USP) LD orally disintegrating clozapine tablets. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification against Barr on August 21, 2008, against Novel on November 25, 2008 and against Mylan on July 23, 2010. Each case was filed in the U.S. District Court for the District of Delaware, or the Delaware Court. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD commenced in May 2015. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product at the end of August 2012. Teva has also exercised its option for supply of an authorized generic product for FazaClo HD. The Novel and Mylan matters had been stayed pending reexamination of the patents in the lawsuits. In September 2013 and January 2014, reexamination certificates were issued for the two patents-in-suit, and the patentability of the claims of the patents confirmed. The Delaware Court lifted the stay of litigation in the two cases in March 2014. On December 19, 2014, we and CIMA entered into an agreement with Novel settling the patent litigation against Novel, and we granted Novel a patent sublicense to manufacture, market and sell its generic version of FazaClo LD and, if applicable, FazaClo HD. Novel's launch date will be May 1, 2017, or earlier upon the occurrence of certain events. On July 13, 2015, we entered into an agreement with Mylan settling the patent litigation against Mylan, and we granted Mylan a patent sublicense to manufacture, market, and sell its generic versions of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product upon the occurrence of certain events. Mylan's launch date will be May 1, 2016 for FazaClo LD and May 1, 2017 for FazaClo HD, or earlier depending upon the occurrence of certain events.

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in the California Superior Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to a \$10.5 million and an additional \$25.0 million

contingent payment, plus unspecified punitive damages and attorneys' fees. In March 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. In July 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. That ruling was affirmed by the California Court of Appeal in January 2014, and the case was remanded to Superior Court for discovery and trial. Trial has been scheduled for October 2015. We cannot predict the specific timing or outcome of this litigation.

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.

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## Other Contingencies

We have not previously submitted pricing data for two radiopharmaceutical products, Quadramet® (samarium sm 153 lexitronam injection) and ProstaScint® (capromab pendetide), for Medicaid and the Public Health Service's 340B drug pricing discount program. We engaged in interactions with the Centers for Medicare and Medicaid Services, or CMS, and a trade group, the Council on Radionuclides and Radiopharmaceuticals, or CORAR, regarding the reporting of Medicaid pricing data and paying Medicaid rebates for radiopharmaceutical products. In addition to the discussions with CMS as part of CORAR, we have had separate discussions with CMS directly regarding Quadramet. We sold Quadramet to a third party in December 2013, but we retained any liabilities related to sales of the product during prior periods. Similarly, we sold ProstaScint to a third party in May 2015, but we retained any liabilities related to sales of the product during prior periods. We are currently unable to predict whether price reporting and rebates will be required for Quadramet and ProstaScint and, if so, for what period they will be required. The initiation of any reporting of Medicaid pricing data for Quadramet or ProstaScint could result in retroactive 340B ceiling price liability for these two products. We are currently unable to reasonably estimate an amount or range of a potential contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results.

## 9. Shareholders' Equity

The following tables present a reconciliation of our beginning and ending balances in shareholders' equity for the six months ended June 30, 2015 and 2014, respectively (in thousands):

	Attributable to:		
	Jazz Pharmaceuticals plc	Noncontrolling interests	Total Shareholders' Equity
Shareholders' equity at January 1, 2015	\$ 1,371,144	\$ 64	\$ 1,371,208
Issuance of ordinary shares in conjunction with employee equity incentive and purchase plans	26,730	—	26,730
Employee withholding taxes related to share-based awards	(16,679)	) —	(16,679)
Share-based compensation	44,394	—	44,394
Shares repurchased	(11,690)	) —	(11,690)
Other comprehensive loss	(125,945)	) (8)	(125,953)
Net income	158,814	(1)	158,813
Shareholders' equity at June 30, 2015	\$ 1,446,768	\$ 55	\$ 1,446,823
	Attributable to:		
	Jazz Pharmaceuticals plc	Noncontrolling interests	Total Shareholders' Equity
Shareholders' equity at January 1, 2014	\$ 1,295,534	\$ —	\$ 1,295,534
Noncontrolling interests from the Gentium Acquisition	—	136,578	136,578
Acquisition of noncontrolling interests	(1,517)	) (135,123)	(136,640)
Issuance of ordinary shares in conjunction with employee equity incentive and purchase plans and warrant exercises	31,642	—	31,642
Employee withholding taxes related to share-based awards	(10,551)	) —	(10,551)
Share-based compensation	32,476	—	32,476
Tax benefit from employee share options	792	—	792
Shares repurchased	(23,487)	) —	(23,487)
Other comprehensive income	3,793	3	3,796
Net loss	(48,991)	) (1,062)	(50,053)
Shareholders' equity at June 30, 2014	\$ 1,279,691	\$ 396	\$ 1,280,087

Share Repurchase Program

In May 2013, our board of directors authorized a share repurchase program pursuant to which we may repurchase a number of ordinary shares having an aggregate repurchase price of up to \$200 million, exclusive of any brokerage commissions. In the six months ended June 30, 2015, we spent a total of \$11.7 million to purchase 0.1 million of our ordinary

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shares under the share repurchase program at an average total purchase price, including commissions, of \$165.05 per share. All ordinary shares repurchased by us were canceled. As of June 30, 2015, the remaining amount authorized under the share repurchase program was \$9.7 million.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss attributable to Jazz Pharmaceuticals plc as of June 30, 2015 and December 31, 2014 were as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2014	\$(122,097	) \$(122,097 )
Other comprehensive loss	(125,945	) (125,945 )
Balance at June 30, 2015	\$(248,042	) \$(248,042