

Jazz Pharmaceuticals plc  
Form 10-Q  
May 07, 2013  
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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 March 31, 2013

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 (I.R.S. Employer  
incorporation or organization) 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Name of each exchange on which registered  
Ordinary shares, nominal value \$0.0001 per share The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

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

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As of April 22, 2013, 58,850,434 ordinary shares of the registrant, nominal value \$0.0001 per share, were outstanding.

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QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2013

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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 non-U.S. countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Xyrem Success Program®, FazaClo® (clozapine, USP), Luvox CR® (fluvoxamine maleate) Extended-Release Capsules, Luvox® (fluvoxamine maleate), Versacloz™ (clozapine, USP) oral suspension, Prialt® (ziconotide) intrathecal infusion, Niravam® (orally disintegrating tablet presentation of alprazolam), Parcopa® (orally disintegrating tablet presentation of carbidopa/levodopa), Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase®, Asparec® (mPEG-r-crisantaspase), Leukotac® (inolimomab), ProstaScint® (capromab pendetide), Quadramet® (samarium sm 153 lexidronam injection), Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (Escherichia coli L-asparaginase), Xenazine® (tetrabenazine), Custodiol® (solution HTK) and NAVIGATOR Reimbursement and Access Program™. This report also includes trademarks, service marks, and trade names of other companies.



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## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

## JAZZ PHARMACEUTICALS PLC

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	March 31, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$450,511	\$387,196
Accounts receivable, net	93,833	75,480
Inventories	22,830	26,525
Prepaid expenses	11,286	7,445
Deferred tax assets, net	47,517	35,813
Other current assets	21,395	19,113
Total current assets	647,372	551,572
Property and equipment, net	7,795	7,281
Intangible assets, net	835,003	869,952
Goodwill	436,355	442,600
Deferred tax assets, net, non-current	62,933	74,850
Deferred financing costs	15,686	16,576
Other long-term assets	4,546	3,662
Total assets	\$2,009,690	\$1,966,493
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$31,634	\$15,887
Accrued liabilities	100,935	104,666
Current portion of long-term debt	32,656	29,688
Income taxes payable	37,803	39,884
Contingent consideration	39,300	—
Deferred tax liability, net	259	275
Deferred revenue	1,138	1,138
Total current liabilities	243,725	191,538
Deferred revenue, non-current	6,566	6,776
Long-term debt, less current portion	418,506	427,073
Contingent consideration, non-current	—	34,800
Deferred tax liability, net, non-current	169,176	178,393
Other non-current liabilities	9,817	6,621
Commitments and contingencies (Note 6)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	471	471
Additional paid-in capital	1,168,633	1,151,010
Accumulated other comprehensive income	10,606	31,046
Accumulated deficit	(17,871	) (61,296

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Total shareholders' equity	1,161,900	1,121,292
Total liabilities and shareholders' equity	\$2,009,690	\$1,966,493

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

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

	Three Months Ended March 31,	
	2013	2012
Revenues:		
Product sales, net	\$194,652	\$101,452
Royalties and contract revenues	1,585	1,078
Total revenues	196,237	102,530
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technologies)	27,220	7,744
Selling, general and administrative	70,528	44,356
Research and development	10,747	3,959
Intangible asset amortization	19,555	10,732
Total operating expenses	128,050	66,791
Income from operations	68,187	35,739
Interest income (expense), net	(7,399	) 13
Foreign currency gain	271	—
Income from continuing operations before income tax provision	61,059	35,752
Income tax provision	17,634	5,517
Income from continuing operations	43,425	30,235
Loss from discontinued operations	—	(2,554
Net income	\$43,425	\$27,681
Basic income (loss) per ordinary share:		
Income from continuing operations	\$0.74	\$0.56
Loss from discontinued operations	—	(0.05
Net income	\$0.74	\$0.51
Diluted income (loss) per ordinary share:		
Income from continuing operations	\$0.71	\$0.52
Loss from discontinued operations	—	(0.04
Net income	\$0.71	\$0.48
Weighted-average ordinary shares used in per share computations:		
Basic	58,358	53,923
Diluted	61,511	58,084

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

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JAZZ PHARMACEUTICALS PLC  
 CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(Unaudited)

	Three Months Ended		
	March 31,		
	2013	2012	
Net income	\$43,425	\$27,681	
Other comprehensive income (loss):			
Foreign currency translation adjustments	(20,440	) —	
Available-for-sale securities:			
Net unrealized gain on available-for-sale securities, net of income taxes	—	34	
Other comprehensive income (loss)	(20,440	) 34	
Total comprehensive income	\$22,985	\$27,715	
Total comprehensive income arises from:			
Continuing operations	\$22,985	\$30,269	
Discontinued operations	—	(2,554	)
Total comprehensive income	\$22,985	\$27,715	

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)

	Three Months Ended	
	March 31,	
	2013	2012
Operating activities		
Net income	\$43,425	\$27,681
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization of intangible assets	19,555	13,513
Depreciation	575	186
Loss on disposal of property and equipment	40	—
Share-based compensation	8,757	3,281
Excess tax benefit from share-based compensation	(889)	(1,914)
Acquisition accounting inventory fair value step-up	1,545	2,369
Change in fair value of contingent consideration	4,500	—
Deferred income taxes	(3,874)	—
Provision for losses on accounts receivable and inventory	142	43
Other non-cash transactions	1,975	42
Changes in assets and liabilities:		
Accounts receivable	(18,911)	(8,794)
Inventories	1,231	(101)
Prepaid expenses and other current assets	(6,272)	(2,217)
Other long-term assets	(999)	(298)
Accounts payable	16,158	4,649
Accrued liabilities	(2,660)	(6,539)
Income taxes payable	(1,397)	—
Deferred revenue	(207)	(285)
Other non-current liabilities	3,196	(1)
Liability under government settlement	—	(7,320)
Net cash provided by operating activities	65,890	24,295
Investing activities		
Cash acquired from merger with Azur Pharma	—	81,751
Purchases of marketable securities	—	(30,628)
Proceeds from sale of marketable securities	—	15,082
Proceeds from maturities of marketable securities	—	17,838
Purchases of intangible assets	(1,300)	—
Purchases of property and equipment	(1,143)	(285)
Purchase of product rights	—	(1,250)
Net cash provided by (used in) investing activities	(2,443)	82,508
Financing activities		
Proceeds from exercise of share options and warrants	9,609	5,160
Payment of employee withholding taxes related to share-based awards	(1,427)	(25,299)
Excess tax benefit from share-based compensation	889	1,914
Repayment of long-term debt	(5,938)	—
Net cash provided by (used in) financing activities	3,133	(18,225)
Effect of exchange rates on cash and cash equivalents	(3,265)	—

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Net increase in cash and cash equivalents	63,315	88,578
Cash and cash equivalents, at beginning of period	387,196	82,076
Cash and cash equivalents, at end of period	\$450,511	\$170,654

The condensed consolidated statements of cash flows include the activities of discontinued operations.  
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 a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing innovative products that address unmet medical needs. Our strategy is to continue to create shareholder value by:

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

• Acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure; and

• Pursuing targeted development of a pipeline of post-discovery specialty product candidates.

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, or the Azur Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company for accounting purposes. As part of the Azur Merger, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Prior to the Azur Merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc.

On June 12, 2012, we completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, which we refer to as the EUSA Acquisition.

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, including its predecessor Jazz Pharmaceuticals, Inc. All references to "Azur Pharma" are references to Jazz Pharmaceuticals plc (f/k/a Azur Pharma Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Azur Merger on January 18, 2012. All references to "EUSA Pharma" are references to EUSA Pharma Inc. and its consolidated subsidiaries prior to the effective time of the EUSA Acquisition on June 12, 2012.

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 the annual consolidated financial statements and accompanying notes of Jazz Pharmaceuticals plc included in its Annual Report on Form 10-K for the year ended December 31, 2012. The results of operations of the acquired Azur Pharma and EUSA Pharma businesses, along with the estimated fair values of the assets acquired and liabilities assumed in each transaction, have been included in our condensed consolidated financial statements since the effective dates of the Azur Merger and the EUSA Acquisition, respectively.

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, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013, for any other interim period or for any future period.

These condensed consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our wholly-owned subsidiaries and intercompany transactions and balances have been eliminated.

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem® (sodium oxybate) oral solution. Maintaining or increasing sales of Xyrem in its approved indications is subject to a number of risks and uncertainties, including the potential introduction of generic competition, changed or increased regulatory restrictions, and continued acceptance

of Xyrem as safe and effective by physicians and patients. Two abbreviated new drug applications, or ANDAs, have been filed with the United States Food and Drug Administration, or FDA, by third parties seeking to market generic versions of Xyrem. We have sued

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both third parties for infringement of our patents, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, we are continuing our work on various regulatory matters, including our work with the FDA on updated documents that we have submitted to the FDA on our risk management and controlled distribution system for Xyrem, which we refer to as the Xyrem Risk Management Program. The updated documents are intended to conform to current formatting requirements for risk evaluation and mitigation strategies, or REMS, required by law, as well as to make other updates to the program and its documentation. While we cannot predict the timing of finalization, or the final terms, of approved REMS documents for Xyrem, we expect that the FDA will require final REMS documents that will result in, or permit, modifications to aspects of the Xyrem Risk Management Program, which may include the ability to distribute Xyrem through more than one pharmacy. We also expect that the final REMS documents will include requirements that are not currently implemented in the Xyrem Risk Management Program. 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 to enter the market and/or negatively affect sales of Xyrem.

In addition to risks related specifically to Xyrem, we are subject to risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including: the challenges of protecting our intellectual property rights; delays or problems in the supply or manufacture of our products, particularly because we maintain limited inventories of certain products, including products for which our supply demands are growing, and we are dependent on single source suppliers to continue to meet our ongoing commercial needs; the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to health care cost containment and other austerity measures in the United States and worldwide; the ongoing regulation and oversight by 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; the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors; and the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval.

**Concentrations of Risk**

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents and marketable securities. 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 hospitals, pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the United States, and to other international distributors. 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 March 31, 2013, five customers accounted for 81% of gross accounts receivable including Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, which accounted for 60% of gross accounts receivable, and Accredo Health Group, Inc., or Accredo, which accounted for 9% of gross accounts receivable. As of December 31, 2012, five

customers accounted for 78% of gross accounts receivable, including Express Scripts which accounted for 51% of gross accounts receivable and Accredo which accounted for 11% of gross accounts receivable.

We rely on single source suppliers for drug substance and single source manufacturing partners for each of our marketed products and product candidates.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the condensed consolidated financial statements and

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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 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,	
	2013	2012
Numerator:		
Income from continuing operations	\$43,425	\$30,235
Loss from discontinued operations	—	(2,554)
Net income	\$43,425	\$27,681
Denominator:		
Weighted-average ordinary shares - basic	58,358	53,923
Dilutive effect of employee equity incentive and purchase plans	1,496	1,825
Dilutive effect of warrants	1,657	2,336
Weighted-average ordinary shares - diluted	61,511	58,084
Basic income (loss) per ordinary share:		
Income from continuing operations	\$0.74	\$0.56
Loss from discontinued operations	—	(0.05)
Net income	\$0.74	\$0.51
Diluted income (loss) per ordinary share:		
Income from continuing operations	\$0.71	\$0.52
Loss from discontinued operations	—	(0.04)
Net income	\$0.71	\$0.48

Potentially dilutive ordinary shares from employee equity plans and warrants are determined by applying the treasury stock method to the assumed exercise of warrants and share options, the assumed vesting of outstanding restricted stock units, or RSUs, and the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP. The following table represents the weighted-average ordinary shares that were excluded from the computation 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,	
	2013	2012
Options to purchase ordinary shares and RSUs	2,352	498

## Recent Accounting Pronouncements

In March 2013, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2013-05, "Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity," or ASU No. 2013-05. The objective of ASU No. 2013-05 is to resolve the diversity in practice regarding the release into net income of the cumulative translation adjustment upon derecognition of a subsidiary or group of assets within a foreign entity. ASU No. 2013-05 will be effective for us beginning January 1, 2014. We do not anticipate that the adoption of this standard will have a material impact on our results of operations or financial position, absent any material transactions involving the derecognition of subsidiaries or groups of assets within a foreign entity.





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## 2. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2013	December 31, 2012
Raw materials	\$4,989	\$9,179
Work in process	1,081	1,210
Finished goods	16,760	16,136
Total inventories	\$22,830	\$26,525

As of March 31, 2013 and December 31, 2012, the fair value of inventories acquired included a step-up in the value of inventories of \$2.4 million and \$4.0 million, respectively.

## 3. Fair Value Measurement

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

	March 31, 2013					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	\$422,742	\$—	\$—	\$422,742	\$422,742	\$—
Money market funds	27,769	—	—	27,769	27,769	—
Totals	\$450,511	\$—	\$—	\$450,511	\$450,511	\$—

	December 31, 2012					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	\$343,548	\$—	\$—	\$343,548	\$343,548	\$—
Money market funds	43,648	—	—	43,648	43,648	—
Totals	\$387,196	\$—	\$—	\$387,196	\$387,196	\$—

Cash equivalents are considered available-for-sale. We use the specific-identification method for calculating realized gains and losses on securities sold and include them in interest (expense) income, net in the condensed consolidated statements of income. All available-for-sale securities held as of March 31, 2013 and December 31, 2012 were cash equivalents.

The following table summarizes, by major security type, our available-for-sale securities and liabilities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	March 31, 2013			December 31, 2012		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)	Total Estimated Fair Value
Assets:						
Available-for-sale securities:						
Money market funds	\$27,769	\$—	\$27,769	\$43,648	\$—	\$43,648
Liabilities:						
Contingent consideration	\$—	\$39,300	\$39,300	\$—	\$34,800	\$34,800

As of March 31, 2013 and December 31, 2012, our available-for-sale securities included money market funds and their carrying values were approximately equal to their fair values. There were no transfers between the different levels of the fair value hierarchy in 2013 or in 2012.

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As part of the EUSA Acquisition, we agreed to make an additional contingent payment of \$50.0 million in cash if Erwinaze® (asparaginase Erwinia chrysanthemi) achieves U.S. net sales of \$124.5 million or greater in 2013. The fair value measurement of this contingent consideration obligation is determined using unobservable Level 3 inputs. These inputs include the probability of 2013 U.S. net sales of Erwinaze equaling or exceeding the \$124.5 million threshold and the discount rate. A significant increase or decrease in the estimated probability of meeting the milestone threshold would result in a significantly higher or lower fair value measurement, respectively. The range of the estimated contingent payment is from zero if 2013 U.S. net sales of Erwinaze are less than \$124.5 million to \$50.0 million if 2013 U.S. net sales of Erwinaze equal or exceed \$124.5 million.

The change in fair value of the contingent consideration payable was estimated as follows (in thousands):

	Level 3
Balance at December 31, 2012	\$34,800
Fair value adjustment recorded within selling, general and administrative expenses	4,500
Balance at March 31, 2013	\$39,300

In 2013, the fair value adjustment reflects a change in the estimated probability of meeting the milestone threshold and the impact of discounting as a result of the passage of time.

As of March 31, 2013, the estimated fair value of our \$475.0 million term loan was \$463.5 million and the carrying amount was \$451.2 million. The fair value was determined using quotes from the administrative agent of our credit facility that are based on the bid/ask prices of our term loan (Level 2).

#### 4. Certain Balance Sheet Items

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

	March 31, 2013	December 31, 2012
Computer software	\$4,334	\$4,292
Leasehold improvements	3,980	3,899
Computer equipment	3,800	3,687
Furniture and fixtures	1,934	1,953
Construction-in-progress	1,982	1,135
Machinery and equipment	94	94
Subtotal	16,124	15,060
Less accumulated depreciation and amortization	(8,329	) (7,779
Property and equipment, net	\$7,795	\$7,281

Accrued liabilities consisted of the following (in thousands):

	March 31, 2013	December 31, 2012
Rebates and other sales deductions	\$33,252	\$29,235
Sales returns reserve	26,794	26,385
Employee compensation and benefits	18,087	24,900
Royalties	2,928	3,271
Professional fees	3,701	2,163
Other	16,173	18,712
Total accrued liabilities	\$100,935	\$104,666

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## 5. Goodwill and Intangible Assets

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

Balance at December 31, 2012	\$442,600
Foreign exchange	(6,245 )
Balance at March 31, 2013	\$436,355

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

	March 31, 2013			December 31, 2012			
	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	12.1	\$916,321	\$ (115,867 )	\$800,454	\$930,834	\$ (97,578 )	\$833,256
Trademarks	1.8	2,600	(2,122 )	478	2,600	(2,054 )	546
Total finite-lived intangible assets		918,921	(117,989 )	800,932	933,434	(99,632 )	833,802
Acquired IPR&D assets		34,071	—	34,071	36,150	—	36,150
Total intangible assets		\$952,992	\$ (117,989 )	\$835,003	\$969,584	\$ (99,632 )	\$869,952

Based on finite-lived intangible assets recorded as of March 31, 2013, and assuming the underlying assets will not be impaired in the future and that we will not change the expected lives of the assets, future amortization costs were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2013 (remainder)	\$57,789
2014	76,859
2015	70,821
2016	66,491
2017	66,399
Thereafter	462,573
Total	\$800,932

## 6. 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 have not recognized any liabilities relating to these obligations as of March 31, 2013 and December 31, 2012. 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.

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## 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 at March 31, 2013 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2013 (remainder)	\$4,920
2014	5,832
2015	5,323
2016	4,126
2017	2,587
Thereafter	154
Total	\$22,942

In April 2013, we entered into a new operating lease agreement for additional office space in Palo Alto for a term of three years with an option to extend for one additional year. We are obligated to make lease payments totaling \$6.9 million from April 2013 through April 2016. These lease payments are not included in the above table.

As of March 31, 2013, we had \$55.1 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 Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification 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 Paragraph IV Certification 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 Paragraph IV Certification in the United States District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. Two additional method of use patents covering the distribution system for Xyrem were issued in December 2010 and February 2011, respectively, and were listed in the Orange Book, and we filed lawsuits against Roxane in February 2011 and again in May 2011 to include these additional patents in the litigation in response to Roxane's Paragraph IV Certifications against each of these patents, and also to include another issued patent in the litigation which is not listed in the Orange Book. These additional lawsuits were subsequently consolidated with the action filed on November 22, 2010. On April 26, 2012, the District Court held a Markman hearing, a pretrial hearing following which the trial judge construes the claims of the patents at issue in a lawsuit, and the District Court issued a Markman order construing the claims of the patents then involved in the litigation in September 2012. Two new patents, one covering a formulation of Xyrem and the other covering use of Xyrem for treatment of narcolepsy (Patent Nos. 8,263,650 and 8,324,275), or the '650 patent and the '275 patent, were issued in September 2012 and December 2012, respectively, and were listed in the Orange Book. In October 2012, we filed a new lawsuit in the District Court against Roxane in response to Roxane's Paragraph IV Certification against the '650 patent, or the '650 case, and in December 2012, we filed a lawsuit in the District Court against Roxane alleging infringement of the '275 patent, or the '275 case. In April 2013, the District Court issued an order consolidating the three lawsuits and an order scheduling discovery and other deadlines for the consolidated case. Under the scheduling order, fact discovery concerning the '650 and '275 patents will remain open until September 2013, with Markman briefing concerning the '650 and '275 patents scheduled to occur between July and October 2013. Expert discovery involving all ten of the patents involved in the consolidated case is scheduled to begin following the issuance of any Markman order, and is expected to last approximately five and a half months. Although no trial date for the consolidated case has been scheduled, based on the scheduling order, we anticipate that trial in the consolidated case could occur as early as mid-2014. However, the

actual timing of events in this litigation may be significantly earlier or later than contemplated by the scheduling order, and we cannot predict the timing or outcome of events in this litigation. In accordance with the the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA had been stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification, but that stay has expired.

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On December 10, 2012, we received a 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. Amneal's Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal's proposed generic product. Amneal's Paragraph IV Certification further alleged that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification alleging that a ninth patent listed in the Orange Book for Xyrem is invalid. On January 18, 2013, we filed a lawsuit against Amneal in response to Amneal's Paragraph IV Certifications in the District Court. We are seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Amneal, FDA approval of Amneal's ANDA will be stayed until the earlier of (i) June 10, 2015, which is 30 months after our receipt of Amneal's Paragraph IV Certification on December 10, 2012, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the outcome of this matter.

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem. Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, that did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's stated positions in its responses to the Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem.

FazaClo ANDA Matters: Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., 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 Laboratories, Inc. on August 21, 2008, against Novel Laboratories, Inc. on November 25, 2008, and against Mylan Pharmaceuticals, Inc. on July 23, 2010. Each case was filed in the United States District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, Inc., 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 will commence in May 2015, or earlier upon the occurrence of certain events. 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. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in the suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc.



and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

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 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 either a \$10.5 million or \$25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. On March 14, 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. We submitted a complaint in arbitration alleging that Dr. Cutler's suit had been improperly filed in Los Angeles and seeking a declaratory judgment that we have complied with all contractual obligations to Dr. Cutler. On July 25, 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the

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arbitration clause in the applicable contract. We have asked the Superior Court to vacate the arbitrator's dismissal of the arbitration and appealed the Superior Court's denial of our motion to the California Court of Appeal. In addition, on November 7, 2012, we filed challenges to the sufficiency of the complaint in the Superior Court, but the Superior Court case has been stayed pending the outcome of our appeal. This matter, like all litigation, carries certain risks, and there can be no assurance of the outcome.

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.

## 7. Shareholders' Equity

The following table presents a summary of ordinary shares issued and related cash proceeds and payments (in thousands):

	Three Months Ended March 31, 2013		Three Months Ended March 31, 2012	
	Shares	Cash	Shares	Cash
Azur Merger	—	\$—	12,360	\$—
Employee withholding taxes related to share-based awards (1)	—	(1,427)	—	(25,299)
Exercises of share options and warrants and vested RSUs	826	9,609	1,722	5,160
Directors' deferred compensation plan	—	—	29	—
Totals	826	\$8,182	14,111	\$(20,139)

During the three months ended March 31, 2013, we paid \$1.4 million of income tax withholdings on behalf of employees related to the net share settlement of vested RSUs. During the three months ended March 31, 2012, we (1) paid \$25.3 million of income tax withholdings on behalf of certain employees of Jazz Pharmaceuticals, Inc. related to the net share settlement of exercised share options in connection with the Azur Merger. The income tax withholdings paid were recorded as a reduction to additional paid-in capital.

## Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income as of March 31, 2013 and December 31, 2012 were as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Income
Balance at December 31, 2012	\$31,046	\$31,046
Other comprehensive loss	(20,440)	(20,440)
Balance at March 31, 2013	\$10,606	\$10,606

During the three months ended March 31, 2013, other comprehensive loss reflects foreign currency translation adjustments which are primarily due to the strengthening of the U.S. dollar against the Euro.

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## 8. Share-Based Compensation

Share-based compensation expense related to share options, RSUs, ordinary shares credited to the directors' phantom share accounts and grants under our ESPP was as follows (in thousands):

	Three Months Ended	
	March 31,	
	2013	2012
Selling, general and administrative	\$7,005	\$2,405
Research and development	1,043	515
Cost of product sales	709	361
Total share-based compensation expense, pre-tax	8,757	3,281
Tax benefit from share-based compensation expense	(2,853	) —
Total share-based compensation expense, net of tax	\$5,904	\$3,281

## 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,			
	2013	2012		
Shares underlying options granted (in thousands)	1,011	825		
Grant date fair value	\$27.75	\$27.89		
Black-Scholes option pricing model assumption information:				
Volatility	59	% 63		%
Expected term (years)	4.4	5.2		
Range of risk-free rates	0.6-0.7%	1.0		%
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,	
	2013	2012
RSUs granted (in thousands)	447	405
Grant date fair value	\$58.93	\$51.83

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

As of March 31, 2013, compensation cost not yet recognized related to unvested share options and RSUs was \$63.2 million and \$48.0 million, respectively, which is expected to be recognized over a weighted-average period of 3.0 years and 3.4 years, respectively.

## 9. Related Party Transactions

In March 2013, we entered into an underwriting agreement with an underwriter and certain selling shareholders, pursuant to which the selling shareholders sold to the underwriter 5.4 million of our ordinary shares, resulting in aggregate gross proceeds to the selling shareholders of approximately \$314.4 million, before deducting underwriting discounts, commissions and other offering expenses. The selling shareholders included entities affiliated with certain members of our board of directors and one of our directors. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the



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offering and, consistent with our obligations under existing registration rights agreements, we paid expenses of approximately \$0.5 million in connection with this offering.

## 10. Segment and Other Information

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 development and commercialization of specialty pharmaceutical products. The following table presents a summary of total revenues (in thousands):

	Three Months Ended	
	March 31,	
	2013	2012
Xyrem® (sodium oxybate) oral solution	\$117,526	\$73,437
Erwinaze® (asparaginase Erwinia chrysanthemi)/Erwinase®	41,816	—
Prialt® (ziconotide) intrathecal infusion	4,986	9,522
Psychiatry	17,650	17,698
Other	12,674	795
Product sales, net	194,652	101,452
Royalties and contract revenues	1,585	1,078
Total revenues	\$196,237	\$102,530

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

	Three Months Ended	
	March 31,	
	2013	2012
United States	\$176,911	\$96,270
Europe	14,362	5,914
All other	4,964	346
Total revenues	\$196,237	\$102,530

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

	Three Months Ended			
	March 31,			
	2013	2012		
Express Scripts	60	% 67		%
Accredo	17	% —		%

The following table presents total long-lived assets by location (in thousands):

	March 31,	December 31,
	2013	2012
Ireland	\$2,554	\$2,437
United States	4,884	4,451
Other	357	393
Total long-lived assets (1)	\$7,795	\$7,281

(1) Long-lived assets consist of property and equipment.

## 11. Restructuring

In June 2012, we initiated a restructuring plan to re-align certain support functions across the company following the Azur Merger and the EUSA Acquisition. In connection with this restructuring, we incur costs of severance for

terminated employees as well as retention bonus costs for certain employees retained to assist with the transition process, which is estimated to be completed by the second quarter of 2013. The one-time termination benefits are being recorded over the

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remaining service period where employees are required to stay through their termination date to receive the benefits. During the three months ended March 31, 2013, we recorded \$0.9 million of costs related to these one-time termination benefits, which are recorded within selling, general and administrative expenses in our condensed consolidated statements of income. We expect to incur approximately \$0.1 million in additional one-time termination benefit costs in connection with this plan. There were no restructuring activities during the three months ended March 31, 2012.

The following table summarizes the amounts related to one-time termination benefits for the three months ended March 31, 2013 (in thousands):

	Total Termination Benefits
Balance at December 31, 2012	\$ 1,227
Costs incurred during the period	949
Cash payments	(714)
Balance at March 31, 2013	\$ 1,462

The balance for termination benefits at March 31, 2013 is included within accrued liabilities in our condensed consolidated balance sheet.

## 12. Discontinued Operations

In 2012, we sold the women's health business, a component of the acquired Azur Pharma business, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl, or collectively, Meda. As part of the transaction, Meda purchased six women's health products from us and offered positions to approximately 60 of our employees who directly supported the women's health business.

Net revenue and loss from discontinued operations were as follows (in thousands):

	Three Months Ended March 31, 2012
Product sales, net	\$5,884
Loss from discontinued operations (1)	\$(2,554)

(1) There was no income tax on the loss from discontinued operations.

## 13. Income Taxes

Our income tax provision was \$17.6 million for the three months ended March 31, 2013 compared to \$5.5 million for the same period in 2012. Our effective tax rate from continuing operations was 28.9% for the three months ended March 31, 2013 compared to 15.4% for the same period in 2012. The increase in the effective tax rate was primarily due to a higher level of profits subject to U.S. federal and state income taxes in 2013, the release of a valuation allowance against substantially all of our U.S. federal and state deferred tax assets in the fourth quarter of 2012 and a provision for income taxes on operations we acquired as part of the EUSA Acquisition. The effective tax rate for 2013 is higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, certain uncertain tax positions, current year losses in some jurisdictions for which no tax benefit is available, and various expenses not deductible for tax purposes, partially offset by benefits from certain originating income tax credits. No provision for income tax in Ireland has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

Our deferred tax assets are composed primarily of U.S. federal and state net operating loss carryforwards and tax credit carryforwards, foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain U.S. state and foreign deferred tax assets. Each reporting period, we evaluate the

need for a valuation allowance on our deferred tax assets by jurisdiction.

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 established a liability for certain tax benefits which we judge may not be sustained upon examination. We file income tax returns in Ireland, in the U.S. (both at the federal level and in various state jurisdictions) and in certain other foreign jurisdictions, all of which typically have three to four tax years open at any point in time. Because of our net operating loss carryforwards and tax credit carryforwards, substantially



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all of our tax years remain open to federal, state, and foreign tax examination. We are currently under examination by the French tax authorities for fiscal years 2010 and 2011. We do not anticipate that the amount of our existing liability for unrecognized tax benefits will significantly change within the next 12 months.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that could impact our business. In particular, we encourage you to review the risks and uncertainties described in Part II, Item 1A "Risk Factors" included elsewhere in this report. 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 their date (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

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, including its predecessor Jazz Pharmaceuticals, Inc. All references to "Azur Pharma" are references to Jazz Pharmaceuticals plc (f/k/a Azur Pharma Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Azur Merger on January 18, 2012. All references to "EUSA Pharma" are references to EUSA Pharma Inc. and its consolidated subsidiaries prior to the effective time of the EUSA Acquisition on June 12, 2012.

Overview

We are a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing innovative products that address unmet medical needs. Our strategy is to continue to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying new growth opportunities;
- Acquiring additional marketed specialty products or products close to regulatory approval to leverage our existing expertise and infrastructure; and
- Pursuing targeted development of a pipeline of post-discovery specialty product candidates.

We have made substantial progress in the execution of our strategy. Sales of our lead product, Xyrem® (sodium oxybate) oral solution, increased 60% in the three months ended March 31, 2013 compared to the same period in 2012. Sales of Erwinaze® (asparaginase *Erwinia chrysanthemi*), called Erwinase® in markets outside the United States, a product added to our portfolio as a result of the EUSA Acquisition, increased 27% in the three months ended March 31, 2013 compared to the same period in 2012 on a pro forma basis. Through the Azur Merger and the EUSA Acquisition, we significantly increased the number of products that we market and added products in therapeutic areas that were new to us, such as oncology and pain. We also enhanced our commercial platform, adding EUSA Pharma's specialty commercial infrastructure in the United States and Europe and its international distribution network to our existing U.S. specialty product platform.

Our marketed products address medical needs in the following therapeutic areas and include the following products: Narcolepsy: Xyrem, the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy;

Oncology: Erwinaze/Erwinase, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed sensitivity to *E. coli*-derived asparaginase, and other products, including products for oncology supportive care;

Pain: Prialt® (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for the management of severe chronic pain for patients who are intolerant of or refractory to other treatments; and

Psychiatry & Other: A portfolio of products, including FazaClo® (clozapine, USP) LD and FazaClo HD, orally disintegrating clozapine tablets indicated for treatment-resistant schizophrenia, and Luvox CR® (fluvoxamine maleate) Extended-Release Capsules marketed for the treatment of obsessive compulsive disorder. A generic version of Luvox CR was launched by Par Pharmaceutical Companies, Inc. in March 2013 and we have stopped marketing the product.

In addition, in February 2013 the FDA approved a new drug application for Versacloz™ (clozapine, USP) oral suspension for treatment-resistant schizophrenia, which we have exclusive rights to market in the United States. We expect to launch Versacloz in the second half of 2013.

Our international division, based in Europe, commercializes Erwinase as well as a portfolio of other products outside of the United States. These products are primarily in the oncology, critical care and oncology supportive care therapeutic areas and include Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (Escherichia coli L-asparaginase) and Xenazine® (tetrabenazine).

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Our worldwide footprint includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 640 employees in eleven countries. We intend that our operations will function as a platform for further growth, leveraging our commercial, medical and scientific experience to seek to maximize the potential of our existing products and expand our product portfolio through a combination of internal development, acquisition and in-licensing.

In 2013, we continue to focus on executing our business strategy. In the three months ended March 31, 2013, our total net product sales increased by 92% compared to the same period in 2012. We expect total product sales will increase in 2013 over 2012 primarily due to growth in sales of Xyrem and Erwinaze/Erwinase.

Our development pipeline projects currently include line extensions for existing products, the generation of additional clinical data for existing products and clinical development of new product candidates. These projects include two clinical trials involving Erwinaze: an ongoing clinical trial evaluating the intravenous administration of Erwinaze in North America; and a planned clinical trial to further evaluate the use of Erwinaze in adolescents and young adults with ALL who are hypersensitive to E. coli-derived asparaginase, which is expected to begin in the second half of 2013. In addition, we are developing two clinical product candidates, including a Phase I clinical trial in Europe of Asparec® (mPEG-r-crisantaspase), a pegylated recombinant Erwinia asparaginase being developed for the treatment of patients with ALL with E. coli asparaginase hypersensitivity; and a Phase III clinical trial in Europe of Leukotac® (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease. We submitted an investigational new drug application, or IND, to conduct studies relating to Asparec to the FDA in November 2012, and received FDA confirmation in December 2012 that we may proceed with the initial clinical study. We obtained a worldwide exclusive license for JZP-386 (formerly known as C-10323), a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem, from Concert Pharmaceuticals, Inc. in February 2013. Pre-clinical research and development work has been initiated on JZP-386 for potential use in patients with narcolepsy. We plan to submit an IND to the FDA in 2013 to conduct studies related to JZP-386. We expect that research and development expenses will be higher in 2013 compared to 2012 due to an expected increase in development activities and due to the inclusion of a full year of expense from the acquired Azur Pharma and EUSA Pharma businesses.

We anticipate that we will continue to face a number of challenges and risks to our business and our ability to execute our strategy. For example, while we now have a more diversified product portfolio than in the past, our financial results remain significantly influenced by sales of Xyrem, which accounted for 60% of our net product sales in the three months ended March 31, 2013 and 65% for the year ended December 31, 2012. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product. We are also focusing on the lifecycle management of Xyrem, including seeking to enhance and enforce our intellectual property rights.

Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, including those discussed in Part II, Item 1A of this Quarterly Report on Form 10-Q. In particular, there are two ANDAs submitted to the FDA by third parties seeking to market generic versions of Xyrem. We have sued both third parties for infringement of our patents, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are continuing our work on various regulatory matters, including our work with the FDA on updated documents that we have submitted to the FDA on our Xyrem Risk Management Program. The updated documents are intended to conform to current formatting requirements for REMS required by law, as well as to make other updates to the program and its documentation. While we cannot predict the timing of finalization, or the final terms, of approved REMS documents for Xyrem, we expect that the FDA will require final REMS documents that will result in, or permit, modifications to aspects of the Xyrem Risk Management Program, which may include the ability to distribute Xyrem through more than one pharmacy. We also expect that the final REMS documents will include requirements that are not currently implemented in the Xyrem Risk Management Program. 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 to enter the market and/or negatively affect sales of Xyrem.

The implementation of our strategy is also 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. In addition to risks related to Xyrem, other key challenges and risks that we face include risks and uncertainties related to:

- the challenges of protecting our intellectual property rights;

- delays or problems in the supply or manufacture of our products, particularly because we maintain limited inventories

- of certain products, including products for which our supply demands are growing, and we are dependent on single source suppliers to continue to meet our ongoing commercial needs;

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the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to health care cost containment and other austerity measures in the United States and worldwide;

the ongoing regulation and oversight by the FDA, the 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;

the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors; and

the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval.

All of these risks are discussed in greater detail, along with other risks, in Part II, Item 1A of this Quarterly Report on Form 10-Q.

## Results of Operations

The following discussions of our results of continuing operations exclude the results related to the women's health business sold in 2012 (see "Loss from Discontinued Operations" below for more information). This business has been segregated from continuing operations and reflected as a discontinued operation. The following table presents revenues and expenses from continuing operations for the three months ended March 31, 2013 and 2012 (amounts in thousands):

	Three Months Ended		Increase/ (Decrease)
	March 31, 2013	2012 (1)	
Product sales, net	\$ 194,652	\$ 101,452	92%
Royalties and contract revenues	1,585	1,078	47%
Cost of product sales (excluding amortization of acquired developed technologies)	27,220	7,744	251%
Selling, general and administrative	70,528	44,356	59%
Research and development	10,747	3,959	171%
Intangible asset amortization	19,555	10,732	82%
Interest income (expense), net	(7,399)	) 13	N/A(2)
Foreign currency gain	271	—	N/A(2)
Income tax provision	17,634	5,517	220%

(1) Our financial results include the financial results of the historic Azur Pharma business since the completion of the Azur Merger on January 18, 2012.

(2) Comparison to prior period is not meaningful.

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## Product Sales, Net

The following table presents product sales for the three months ended March 31, 2013 and 2012 (amounts in thousands):

	Three Months Ended		Increase/ (Decrease)
	March 31, 2013	2012	
Xyrem	\$ 117,526	\$ 73,437	60%
Erwinaze/Erwinase	41,816	—	N/A(1)
Prialt	4,986	9,522	(48)%
Psychiatry	17,650	17,698	—%
Other	12,674	795	N/A(1)
Product sales, net	194,652	101,452	92%
Royalties and contract revenues	1,585	1,078	47%
Total revenues	\$ 196,237	\$ 102,530	91%

(1) Comparison to prior period is not meaningful.

Xyrem product sales increased in the three months ended March 31, 2013 compared to the same period in 2012, primarily due to a higher average net selling price in the 2013 period, and to a lesser extent, increases in sales volume. Price increases were instituted in 2012 and February 2013 based on market analysis. Sales volumes increased by 15% in the three months ended March 31, 2013 compared to the same period in 2012. The sales volume increase was driven by an increase in the average number of patients on Xyrem and by a greater number of Xyrem patients who refilled their Xyrem prescriptions on schedule and who remained on therapy, which we believe resulted from our efforts to increase physician knowledge about Xyrem and to improve patient support services. The sales volume increase was also impacted by our dedicated Xyrem sales force which increased physician awareness of narcolepsy and its diagnosis and, more recently, by a higher number of prescriptions from new or previously infrequent physician prescribers who treat narcolepsy. Sales of Erwinaze/Erwinase were \$41.8 million in the three months ended March 31, 2013, an increase of 27% compared to the same period in 2012 on a pro forma basis, primarily due to increases in sales volume. We acquired Erwinaze/Erwinase in the EUSA Acquisition in June 2012. Prialt product sales decreased by \$4.5 million compared to the same period in 2012, primarily due to sales of \$4.6 million to Eisai Co. Limited for distribution and sale of Prialt in Europe under a supply agreement in the three months ended March 31, 2012, but not in the same period in 2013. Psychiatry product sales decreased slightly in the three months ended March 31, 2013 compared to the same period in 2012, primarily due to the launch of a generic version of Luvox CR in March 2013. We expect total product sales will increase in 2013 over 2012 primarily due to growth in sales of Xyrem and Erwinaze/Erwinase, partially offset by decreases in sales of some of our other products. Achievement of increased product sales is subject to various risks, including the risk that we experience supply shortages for Erwinaze and are unable to meet product demand. See the discussion regarding Erwinaze supply issues in Part II, Item 1A of this Quarterly Report on Form 10-Q under the heading “We depend on single source suppliers and manufacturers for each of our products, product candidates and their active pharmaceutical ingredients. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects.”

## Royalties and Contract Revenues

Royalties and contract revenues increased in the three months ended March 31, 2013 compared to the same period in 2012 due to royalties from the acquired EUSA Pharma business. We expect royalty and contract revenue to increase slightly in 2013 as compared to 2012 primarily due to the inclusion of a full year of royalties from the acquired EUSA Pharma business.

## Cost of Product Sales

Cost of product sales increased in the three months ended March 31, 2013 compared to the same period in 2012 primarily due to increased sales. Gross margin as a percentage of net product sales was 86.0% in the three months ended March 31, 2013 compared to 92.4% for the same period in 2012. The decrease in our gross margin percentage was primarily due to a change in product mix with lower gross margins earned on products acquired in 2012. We expect our gross margin percentage to increase slightly in 2013 compared to 2012 primarily driven by a decrease in the amount of acquisition accounting inventory fair value step-up adjustments and also the different product mix in 2013.



Table of Contents**Selling, General and Administrative Expenses**

Selling, general and administrative expenses were higher in the three months ended March 31, 2013 compared to the same period in 2012 primarily due to an increase in salary and benefit related expenses (including share-based compensation) of \$14.8 million driven primarily by increased headcount from the EUSA Acquisition and the expansion of our business. In addition, we recorded a charge of \$4.5 million in the three months ended March 31, 2013 related to the change in fair value of the contingent consideration payable. Sales and promotional expenses increased by \$3.2 million and travel, facility and maintenance expenses increased by \$3.0 million in the three months ended March 31, 2013 compared to the same period in 2012. Transaction, integration and restructuring expenses decreased by \$4.1 million in the three months ended March 31, 2013 compared to the same period in 2012. We expect that selling, general and administrative expenses will be higher in 2013 than in 2012 due to the inclusion of a full year of expense with respect to the acquired EUSA Pharma business, increased headcount to support our larger, global organization and an increase in direct marketing spend on key products.

**Research and Development Expenses**

Research and development expenses consist primarily of personnel expenses, costs related to clinical studies and outside services, and other research and development costs. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Clinical study and outside services costs relate primarily to clinical studies performed by clinical research organizations, materials and supplies, and other third-party fees. 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 what 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 in a manner that we believe will best support the future growth of our business.

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

	Three Months Ended March 31,	
	2013	2012
Personnel expenses	\$4,470	\$2,302
Clinical studies and outside services	5,507	1,358
Other	770	299
Total	\$10,747	\$3,959

Research and development expenses increased by \$6.8 million in the three months ended March 31, 2013 compared to the same period in 2012 primarily due to increased clinical studies and outside services costs including upfront license fees of \$4.0 million, and, to a lesser extent, costs incurred to develop new product candidates that we acquired in the EUSA Acquisition and the Azur Merger. In addition, personnel expenses increased by \$2.2 million in the three months ended March 31, 2013 compared to the same period in 2012.

A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of 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 report.

**Intangible Asset Amortization**

We acquired finite-lived intangible assets in connection with the Azur Merger and the EUSA Acquisition that are expected to be amortized over their useful economic lives of two to 15 years. The increase in the amortization expense in the three months ended March 31, 2013 compared to the same period in 2012 was primarily due to amortization relating to the intangible assets acquired in the EUSA Acquisition. We expect amortization expense in 2013 to increase substantially from 2012 due to the inclusion of a full year of amortization expense related to the intangible

assets we acquired in the EUSA Acquisition.

Interest Income (Expense), Net

Interest expense in the three months ended March 31, 2013 resulted from the term loan we obtained under a credit agreement in June 2012. As of March 31, 2013, \$457.2 million principal amount was outstanding on our term loan and the

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interest rate on the term loan was 5.25%. We expect interest expense in 2013 to increase significantly from 2012 due to a higher average debt balance.

**Foreign Currency Gain**

Foreign currency gain in the three months ended March 31, 2013 related to the translation of foreign currency net monetary assets, including intercompany balances.

**Income Tax Provision**

Our income tax provision was \$17.6 million for the three months ended March 31, 2013 compared to \$5.5 million for the same period in 2012. Our effective tax rate from continuing operations was 28.9% for the three months ended March 31, 2013 compared to 15.4% for the same period in 2012. The increase in the effective tax rate was primarily due to a higher level of profits subject to U.S. federal and state income taxes in 2013, the release of a valuation allowance against substantially all of our U.S. federal and state deferred tax assets in the fourth quarter of 2012 and a provision for income taxes on operations we acquired as part of the EUSA Acquisition. The effective tax rate for 2013 is higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, certain uncertain tax positions, current year losses in some jurisdictions for which no tax benefit is available, and various expenses not deductible for tax purposes, partially offset by benefits from certain originating income tax credits. No provision for income tax in Ireland has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

**Loss from Discontinued Operations**

In 2012, we sold our women's health business. Net revenue and loss from discontinued operations were as follows (in thousands):

	Three Months Ended March 31, 2012
Product sales, net	\$5,884
Loss from discontinued operations (1)	\$(2,554 )

(1) There was no income tax on the loss from discontinued operations.

**Non-GAAP Financial Measures**

To supplement our financial results presented on a GAAP basis, we use certain non-GAAP adjusted financial measures as shown in the table and footnotes below. We believe that these non-GAAP financial measures are helpful in understanding our past financial performance and potential future results, particularly in light of the effect of various acquisition and divestiture transactions effected by us during 2012. They are not meant to be considered in isolation or as a substitute for comparable GAAP measures, and should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP. Our management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate our business and make operating decisions. Compensation of our executives is based in part on the performance of our business based on certain of these non-GAAP measures. In addition, we believe that the use of these non-GAAP measures enhances the ability of investors to compare our results from period to period. The adjusted financial measures, as used by us in this report, may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by our competitors and other companies. Adjusted net income measures exclude from continuing operations intangible asset amortization, share-based compensation expense, acquisition accounting inventory fair value step-up adjustments, transaction and integration costs, restructuring charges, change in fair value of contingent consideration, upfront license fees, depreciation and other non-cash expense, and adjust the income tax provision to the estimated amount of taxes payable in cash.



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A reconciliation of GAAP income from continuing operations to adjusted net income, a non-GAAP financial measure, and related per share amounts is as follows (in thousands, except per share amounts):

	Three Months Ended	
	March 31,	
	2013	2012
GAAP income from continuing operations	\$43,425	\$30,235
Intangible asset amortization	19,555	10,732
Share-based compensation expense	8,757	3,281
Acquisition accounting inventory fair value step-up	1,545	1,308
Transaction and integration costs	1,022	6,095
Restructuring charges	949	—
Change in fair value of contingent consideration	4,500	—
Upfront license fees	4,000	—
Depreciation	575	—
Other non-cash expense	1,229	42
Income tax adjustments (1)	(1,132)	) —
Adjusted net income (2)	\$84,425	\$51,693
GAAP income from continuing operations per diluted share	\$0.71	\$0.52
Adjusted net income per diluted share (2)	\$1.37	\$0.89
Shares used in computing GAAP income from continuing operations and adjusted net income per diluted share amounts	61,511	58,084

(1) Tax adjustments to convert the income tax provision to the estimated amount of taxes payable in cash.

(2) Adjusted net income and adjusted net income per diluted share as used in this report exclude the impact of discontinued operations.

### Liquidity and Capital Resources

As of March 31, 2013, we had cash and cash equivalents of \$450.5 million and borrowing availability under the revolving credit facility of \$100.0 million. We generated cash flows from operations of \$65.9 million during the three months ended March 31, 2013, and we expect to continue to generate positive cash flow from operations. We believe that our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future, including our obligations under the credit agreement and a potential contingent payment of \$50.0 million which we agreed to in connection with the EUSA Acquisition if Erwinaze achieves U.S. net sales of \$124.5 million or greater in 2013. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses as well as the other factors set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q under the headings “Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects,” “If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected,” “The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem,” and “To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.” Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse

effect on our business.

As of March 31, 2013, \$457.2 million principal amount was outstanding on our term loan, which is repayable in quarterly installments. As of March 31, 2013, the interest rate on the term loan was 5.25%. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. We are required to make mandatory prepayments of borrowings under the term loan (without payment of a premium) with net cash proceeds from certain non-ordinary course asset sales, issuances of debt (other than certain permitted debt) and

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casualty proceeds and condemnation awards; and, beginning with the fiscal year ending December 31, 2013, with 50% of our excess cash flow, as defined in the credit agreement (subject to increase to 75% if our secured leverage ratio exceeds 2.25 to 1.0, or decrease to 25% or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.0 or 0.75 to 1.0, respectively). We may make voluntary prepayments of principal without premium or penalty, except that a 1% premium would apply to a repayment via a repricing of the loan under the term loan effected on or prior to June 12, 2013.

Borrowings under the credit agreement are guaranteed by Jazz Pharmaceuticals plc and certain of its subsidiaries and are secured by substantially all of our assets. Our failure to comply with any of the operating and financial covenants contained in the credit agreement would constitute an event of default under the credit agreement. The credit agreement contains other customary events of default. If one or more events of default occurs and continues beyond any applicable cure period, the administrative agent may, with the consent of the lenders holding a majority of the loans and commitments under the facilities, or will, at the request of such lenders, terminate the commitments of the lenders to make further loans and declare all of the obligations under the credit agreement to be immediately due and payable. In such event, we would not have sufficient cash resources to repay the full amount of the obligations. We are currently in compliance with the covenants under the credit agreement.

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

We may also use our available cash resources to fund repurchases of our ordinary shares through open market purchases, privately negotiated purchases or a combination of these transactions. In May 2013, our board of directors authorized the use of up to \$200 million for a share repurchase program. The timing and amount of repurchases will depend on a variety of factors, including the price of the our ordinary shares, alternative investment opportunities, restrictions under the existing credit agreement, corporate and regulatory requirements and market conditions.

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

	Three Months Ended	
	March 31,	
	2013	2012
Net cash provided by operating activities	\$65,890	\$24,295
Net cash provided by (used in) investing activities	(2,443	) 82,508
Net cash provided by (used in) financing activities	3,133	(18,225
Effect of foreign currency exchange rates on cash and cash equivalents	(3,265	) —
Net increase in cash and cash equivalents	\$63,315	\$88,578

Net cash from operating activities increased by \$41.6 million in 2013 primarily due to an increase in net income of \$15.7 million, adjustments for non-cash items primarily related to intangible asset amortization and share-based compensation, and changes in working capital.

Net cash from investing activities in 2012 primarily related to cash received in connection with the Azur Merger.

Net cash from financing activities in 2013 primarily related to proceeds from exercises of share options and warrants of \$9.6 million partially offset by the principal repayment of our long-term debt of \$5.9 million. Net cash used in financing activities in 2012 primarily related to payments totaling \$25.3 million of income tax withholdings on behalf of certain employees related to the net share settlement of exercised share options in connection with the Azur Merger partially offset by proceeds from exercise of share options and warrant exercises of \$5.2 million.





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## Contractual Obligations

The table below presents a summary of our contractual obligations as of March 31, 2013 (in thousands):

Contractual Obligations (1)	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Term loan—principal	\$457,188	\$32,656	\$92,031	\$136,563	\$195,938
Term loan—interest (2)	96,373	23,877	41,102	29,280	2,114
Purchase obligations (3)	57,047	55,087	400	400	1,160
Operating lease obligations (4)	22,942	6,248	11,046	5,648	—
Revolving credit facility (5)	2,131	507	1,015	609	—
Contingent consideration obligation (6)	50,000	50,000	—	—	—
Total	\$685,681	\$168,375	\$145,594	\$172,500	\$199,212

This table does not include potential future milestone payment or royalty obligations to third parties under asset purchase, product development and license agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable.

Potential future milestone payments to third parties under these agreements could be up to an aggregate of \$284 million, of which up to \$120 million will become due and payable to Elan in tiered contingent payments, with the first such payment becoming due if net sales of Prialt of at least \$75 million are achieved in a calendar year. The remainder would become due and payable to other third parties upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones, the timing and likelihood of which are not known. We are also obligated under these agreements to pay royalties on net sales of certain products at specified rates, which royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.

In June 2012, we entered into a credit agreement that provides for a term loan in an aggregate principal amount of \$475.0 million, which matures in June 2018, and a \$100.0 million revolving credit facility, which matures in June 2017. In June 2012, we borrowed \$475.0 million under the term loan, and we have repaid principal of \$17.8 million as of March 31, 2013. The interest rate was 5.25% at March 31, 2013, which we used to estimate interest owed on the term loan until the final maturity date.

(3) Consists primarily of non-cancelable commitments to third party manufacturers.

Includes the minimum lease payments for our office buildings and automobile lease payments for our sales force.

(4) In April 2013, we entered into a new operating lease agreement for additional office space in Palo Alto for a term of three years with an option to extend for one additional year. We are obligated to make lease payments totaling \$6.9 million from April 2013 through April 2016 which are not included in the above table.

(5) The revolving credit facility described in note (2) has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.50% and assumed undrawn amounts of \$100.0 million to estimate commitment fees owed. No amount was borrowed under the revolving credit facility as of March 31, 2013.

(6) This amount represents a contingent payment of \$50.0 million that we agreed to make if Erwinaze achieves U.S. net sales of \$124.5 million or greater in 2013. The amount set forth in the table has not been probability adjusted or discounted. The fair value of this contingent consideration as of March 31, 2013 was \$39.3 million and was recorded as a current liability on our condensed consolidated balance sheet.

No provision for income tax in Ireland has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. In addition, our liability for unrecognized tax benefits has been excluded from the above contractual obligations table as the nature and timing of future payments, if any, cannot be reasonably estimated. We do not anticipate that the amount of our existing liability for unrecognized tax benefits will significantly change in the next 12 months.

### Critical Accounting Estimates

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in determining the amounts to be deducted from gross revenues, in particular estimates of government rebates, which include Medicaid and TRICARE rebates, and estimated product returns. Significant estimates and assumptions are also required to determine whether to capitalize intangible assets, the amortization periods for identifiable intangible assets, the potential

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impairment of goodwill and other intangible assets, income taxes, contingent consideration and share-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable. Although we believe our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2012. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

### Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created by those sections. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “intend,” “potential” and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under Part II, Item 1A “Risk Factors.” Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

### Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2013, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2012.

### Item 4. Controls and Procedures

**Evaluation of Disclosure Controls and Procedures.** We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2013.

**Limitations on the Effectiveness of Controls.** A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if

any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

**Changes in Internal Control over Financial Reporting.** Management determined that, as of March 31, 2013, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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## PART II – OTHER INFORMATION

## Item 1. Legal Proceedings

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

**Xyrem ANDA Matters:** On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it had submitted an abbreviated new drug application, or ANDA, to the United States Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem® (sodium oxybate) oral solution. Roxane’s Paragraph IV Certification 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 Paragraph IV Certification 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 Paragraph IV Certification in the United States District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. Two additional method of use patents covering the distribution system for Xyrem were issued in December 2010 and February 2011, respectively, and were listed in the Orange Book, and we filed lawsuits against Roxane in February 2011 and again in May 2011 to include these additional patents in the litigation in response to Roxane’s Paragraph IV Certifications against each of these patents, and also to include another issued patent in the litigation which is not listed in the Orange Book. These additional lawsuits were subsequently consolidated with the action filed on November 22, 2010. On April 26, 2012, the District Court held a Markman hearing, a pretrial hearing following which the trial judge construes the claims of the patents at issue in a lawsuit, and the District Court issued a Markman order construing the claims of the patents then involved in the litigation in September 2012. Two new patents, one covering a formulation of Xyrem and the other covering use of Xyrem for treatment of narcolepsy (Patent Nos. 8,263,650 and 8,324,275), or the ’650 patent and the ’275 patent, were issued in September 2012 and December 2012, respectively, and were listed in the Orange Book. In October 2012, we filed a new lawsuit in the District Court against Roxane in response to Roxane’s Paragraph IV Certification against the ’650 patent, or the ’650 case, and in December 2012, we filed a lawsuit in the District Court against Roxane alleging infringement of the ’275 patent, or the ’275 case. In April 2013, the District Court issued an order consolidating the three lawsuits and an order scheduling discovery and other deadlines for the consolidated case. Under the scheduling order, fact discovery concerning the ’650 and ’275 patents will remain open until September 2013, with Markman briefing concerning the ’650 and ’275 patents scheduled to occur between July and October 2013. Expert discovery involving all ten of the patents involved in the consolidated case is scheduled to begin following the issuance of any Markman order, and is expected to last approximately five and a half months. Although no trial date for the consolidated case has been scheduled, based on the scheduling order, we anticipate that trial in the consolidated case could occur as early as mid-2014. However, the actual timing of events in this litigation may be significantly earlier or later than contemplated by the scheduling order, and we cannot predict the timing or outcome of events in this litigation. In accordance with the the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane’s ANDA had been stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane’s Paragraph IV Certification, but that stay has expired. On December 10, 2012, we received a 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. Amneal’s Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal’s proposed generic product. Amneal’s Paragraph IV Certification further alleged that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification alleging that a ninth patent listed in the Orange Book for Xyrem is invalid. On January 18, 2013, we filed a lawsuit against Amneal in response to Amneal’s Paragraph IV Certifications in the District Court. We are seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Amneal, FDA approval of Amneal’s ANDA will be stayed until the earlier of (i) June 10, 2015, which is 30 months after our receipt of Amneal’s

Paragraph IV Certification on December 10, 2012, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the outcome of this matter.

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem. Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by

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law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, that did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's stated positions in its responses to the Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem.

FazaClo ANDA Matters: Azur Pharma Public Limited Company, or Azur Pharma, received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo<sup>®</sup> (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 Laboratories, Inc. on August 21, 2008, against Novel Laboratories, Inc. on November 25, 2008, and against Mylan Pharmaceuticals, Inc. on July 23, 2010. Each case was filed in the United States District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, Inc., 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 will commence in May 2015, or earlier upon the occurrence of certain events. 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. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in the suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

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 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 either a \$10.5 million or \$25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. On March 14, 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. We submitted a complaint in arbitration alleging that Dr. Cutler's suit had been improperly filed in Los Angeles and seeking a declaratory judgment that we have complied with all contractual obligations to Dr. Cutler. On July 25, 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. We have asked the Superior Court to vacate the arbitrator's dismissal of the arbitration and appealed the Superior Court's denial of our motion to the California Court of Appeal. In addition, on November 7, 2012, we filed challenges to the sufficiency of the complaint in the Superior Court, but the Superior Court case has been stayed pending the outcome of our appeal. This matter, like all litigation, carries certain risks, and there can be no assurance of the outcome.

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.

Item 1A. Risk Factors

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

We have marked with an asterisk (\*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2012.



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Risks Relating to Xyrem and the Significant Impact of Xyrem Sales

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

Xyrem is our largest selling product and our financial results are significantly influenced by sales of Xyrem, which accounted for 60% of our net product sales for the three months ended March 31, 2013 and 65% of our net product sales for the year ended December 31, 2012. Our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2010 to 2011 and from 2011 to 2012, 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 February 2013, and we cannot assure you that price adjustments we have taken or may take in the future have not already negatively affected, or will not in the future negatively affect, Xyrem sales volumes.

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

• the potential introduction of a generic version of Xyrem;

• changed or increased regulatory restrictions, including changes to our risk management program and the terms of the final risk evaluation and mitigation strategy, or REMS, documents, for Xyrem, or regulatory actions by the FDA as a result of, or related to the matters raised in, the warning letter we received from the FDA in October 2011 or the Form FDA 483 we received in May 2012, as discussed in more detail in the risk factors below;

• our manufacturing partners' ability to obtain sufficient quota from the U.S. Drug Enforcement Administration, or the DEA, to satisfy our needs for Xyrem;

• any supply, manufacturing or distribution problems arising with any of our manufacturing and distribution partners, all of whom are sole source providers for us;

• the availability of reimbursement from third party payors;

• changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement and coverage by federal healthcare programs;

• continued acceptance of Xyrem as safe and effective by physicians and patients, even in the face of negative publicity that surfaces from time to time; and

• changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem.

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

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

If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.\*

Although Xyrem is covered by patents covering its formulation, distribution system and method of use, two third parties have filed ANDAs seeking FDA approval of generic versions of Xyrem, and additional third parties may also seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if such company or companies decide to launch generic versions of Xyrem before applicable ongoing patent litigation is concluded at risk of potentially being held liable for damages for patent infringement.

On October 18, 2010, we received notice from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem before expiration of the Orange-Book-listed patents relating to Xyrem. On December 10, 2012, we received notice from Amneal that Amneal has submitted an ANDA to the FDA seeking regulatory approval to market a generic version of Xyrem before expiration of the Orange-Book-listed patents relating to Xyrem. We have sued both Roxane and Amneal seeking to prevent them from introducing a generic

version of Xyrem that would infringe our patents, but we cannot assure you that any of the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. Additional ANDAs could also be filed requesting approval to market generic versions of Xyrem. If an ANDA is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. In April 2013, the District Court issued an order consolidating our three lawsuits against Roxane and an order scheduling discovery and other

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deadlines for the consolidated case. Although no trial date for the consolidated case has been scheduled, based on the scheduling order, we anticipate that trial in the consolidated case could occur as early as mid-2014. However, the actual timing of events in this litigation may be significantly earlier or later than contemplated by the scheduling order, and we cannot predict the timing or outcome of events in this litigation. In accordance with the Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA had been stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification, but that stay has expired. We do not know the status of Roxane's ANDA and cannot predict what actions the FDA or Roxane may take with respect to Roxane's ANDA. With the expiration of the 30-month stay, if Roxane's ANDA is approved by the FDA, Roxane may seek to launch a generic version of Xyrem prior to a District Court, or potential appellate court, decision in our ongoing patent litigation. While, in the event of such commercialization, Roxane would be liable to us for damages in the event we ultimately prevail in the patent litigation, we expect that the introduction of generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem. Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, which did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition.

We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's stated positions in its responses to the Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem. See the next risk factor in this Item 1A entitled "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

A generic manufacturer would need to obtain quota from the DEA in order to manufacture both the active pharmaceutical ingredient and the finished product for a generic version of Xyrem. The DEA publishes an annual aggregate quota for the active pharmaceutical ingredient of Xyrem, and our supplier is required to request and justify allocation of sufficient annual manufacturing quota as well as additional manufacturing quota if needed throughout the year. Until 2011, our active pharmaceutical ingredient supplier obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for each of 2012 and 2013, our supplier has been allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. As a result, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In addition, our supplier has been allocated only a portion of the requested quota for 2013 to make the active pharmaceutical ingredient of Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, both our active pharmaceutical ingredient

supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013. We cannot assure you sufficient quotas will be received from the DEA to meet our needs, and if we and our supplier and manufacturer cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

After any introduction of a generic competitor, a significant percentage of the prescriptions written for Xyrem may be filled with the generic version, resulting in a loss in sales of Xyrem. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. We expect that generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.\*

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management and controlled distribution system, which we refer to as the Xyrem Risk Management Program, that was implemented at the time Xyrem was approved, which includes parts of the Xyrem Success Program, to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. Our Xyrem Risk Management Program includes a number of elements including patient and physician education, a database of information so that we may track and report certain information, and the use of a single central pharmacy to distribute Xyrem. It also includes unique features that provide more extensive information about adverse events, including deaths, than is generally available for other products that are not subject to similar risk management programs. As required by the FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to the FDA and could result in the FDA requiring changes to the Xyrem label or taking or requiring us to take other actions that could have an adverse effect on Xyrem's commercial success.

Elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The Xyrem Risk Management Program, however, is not in the form that is now required for REMS documents. FDAAA requires that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. We have submitted updated REMS documents to the FDA, which are intended to conform the elements of the Xyrem Risk Management Program, our deemed REMS, to the current REMS formatting requirements, as well as to make other updates to the program and its documents. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem. While we cannot predict the timing of finalization, or the final terms, of approved REMS documents for Xyrem, we expect that the FDA will require final REMS documents that will result in, or permit, modifications to aspects of the Xyrem deemed REMS, which may include the ability to distribute Xyrem through more than one pharmacy. We also expect that the final REMS documents will include requirements that are not currently implemented in the Xyrem Risk Management Program. 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 to enter the market and/or negatively affect sales of Xyrem.

Section 505-1(i)(1) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA, generally provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same elements as the referenced drug, such as a medication guide, a patient package insert and other "elements to assure safe use," or ETASUs, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and permit the ANDA holder to submit a different, comparable aspect of the ETASUs in its REMS documents if the FDA either determines that the burden of creating a single shared system outweighs its benefit, or if the ANDA applicant certifies that it has been unable to obtain a license to an aspect of the ETASUs for the referenced drug product that are covered by a patent or a trade secret. The FDCA provides that the FDA may seek to negotiate a license between the ANDA sponsor and the sponsor of the listed product before granting a waiver of the single shared system requirement. In its December 13, 2012 response denying the Citizen Petition we filed in July 2012, the FDA stated that when the new drug application, or NDA, holder has a deemed REMS, the FDA directs the ANDA applicant to work with the NDA holder to create a single shared system to implement the ETASUs that will be approved as a final REMS.

Accordingly, from time to time we may face pressure to license or share our Xyrem Risk Management Program, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that may be taken by a third party to seek to license or share our REMS, or the FDA's response to a certification that a third party has been unable to obtain a license. We also cannot predict the outcome or impact on our business of any discussions with any ANDA applicant with respect to the potential creation of a single shared system. Furthermore, if

we do not share our REMS with a generic competitor within a time frame that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to allow the generic competitor to market a generic drug with a REMS that does not include the same elements in our Xyrem deemed REMS or, when approved, in our final REMS documents.

The Federal Trade Commission, or the FTC, has been paying increasing attention to the use of REMS by companies selling branded products, in particular to whether REMS may be deliberately being used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner. The FDCA further states that a REMS shall not be used by an NDA holder to block or delay generic drugs from entering the market. It is also possible that the FDA may take the position that a potential generic competitor does not need a REMS that has the same ETASUs as our Xyrem deemed REMS in order to obtain approval of its ANDA. In the denial of our Citizen Petition described above, the FDA stated that if the FDA determines that an ANDA may be ready for approval before final approval of

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the REMS of a sponsor holding a deemed REMS, the FDA will direct the ANDA applicant to submit a proposed risk management plan with ETASUs that are comparable to the ETASUs that are approved for the referenced drug in order to have adequate risk management elements in place for the ANDA until the final REMS is approved. The legal basis for this position is uncertain. However, it is possible that the FDA may rely on this position as a basis to grant approval of an ANDA with a risk management plan rather than a final REMS. The 30-month stay of FDA approval of Roxane's ANDA expired on April 18, 2013, and we have not yet received approval of final REMS documents for Xyrem. Accordingly, it is possible that, consistent with the position that the FDA articulated in its denial of our Citizen Petition, the FDA could approve Roxane's ANDA with a risk management plan that is separate from our Xyrem deemed REMS, rather than with a final REMS or a shared REMS for both the generic and Xyrem. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects. See the risk factor in this Item 1A entitled "We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products." Currently, our Xyrem deemed REMS requires that all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under our program is cumbersome. While we have an exclusive agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or ESSDS, through June 2015, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem and our sales would be adversely affected. If we change our central pharmacy, new contracts might be required with government and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under our Xyrem Risk Management Program or any REMS that we are subject to in the future. Transitioning to a new pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the United States, 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 April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us, as required. We reported these cases to the FDA when we discovered them, investigated the related data from ESSDS, as well as additional data we gathered, and submitted an analysis of the data to the FDA. In July 2012, we held a telephonic meeting with the FDA with respect to our analysis. Based in part on this meeting and our agreement with the FDA on a revised Xyrem label in December 2012, we believe that the FDA will not require any further data or analysis with respect to mortality during the historical period that was covered by our investigation and evaluation, and that no further action is required by us. However, there can be no assurance that the FDA will agree with our assessment, and the FDA may ultimately take, or require us to take, actions that may be costly or time consuming and/or that negatively affect the commercial success of Xyrem.

In October 2011, we received a warning letter from the FDA regarding certain aspects of our adverse event reporting system for Xyrem and drug safety procedures related to the unreported deaths uncovered in April 2011. In May 2012, we received a Form FDA 483 after a follow-up inspection in May 2012, which noted the FDA's observations with respect to incomplete review of information from ESSDS related to potential Xyrem-related adverse events prior to 2011 and determination of whether there are additional adverse events that are required to be reported to the FDA based on such review; the investigation of serious unexpected adverse drug experiences, including insufficient documentation to demonstrate the past investigation; and lack of a written procedure relating to one administrative aspect of our current drug safety monitoring procedures. We have completed the actions that we believe are required to address the observations in the May 2012 Form FDA 483, and we believe that we have submitted the data and completed the actions that are necessary to fully address the matters raised in the 2011 warning letter. Accordingly, we have submitted a request to the FDA to close out the warning letter, but we do not know whether the FDA will require further information or actions. In any event, we expect that the FDA will conduct a re-inspection before

closing out the warning letter. We cannot predict either the timing or the final outcome of the FDA's regulatory compliance review. We do not know whether the FDA will take further action, or require us to take further action, with respect to our adverse event reporting, or whether the FDA will ultimately conclude we have not taken all appropriate corrective actions with respect to the May 2012 Form FDA 483 or the warning letter.

Regulatory authorities in other countries where Xyrem is sold may take similar actions. Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the FDA's or any other regulatory authority's satisfaction could have a material and adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth prospects. See also the risk factor in this Item 1A entitled "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."

The FDA has required that Xyrem's label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product



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cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. In addition, Xyrem's FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. We cannot predict whether the FDA will require additional warnings, including boxed warnings, to be included on Xyrem's label. For example, in December 2012, we updated our Xyrem label in consultation with the FDA to include a new contraindication for the use of alcohol with Xyrem. Warnings in the Xyrem label and any limitations on our ability to advertise and promote Xyrem may have affected, and could in the future negatively affect, Xyrem sales and therefore our business, financial condition, results of operations and growth prospects.

**Risks Relating to Our Business**

While Xyrem remains our largest product, our success also depends on our ability to effectively commercialize our other marketed products, and our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.\*

In addition to Xyrem, we have a portfolio of marketed products, including Erwinaze<sup>®</sup> (asparaginase *Erwinia chrysanthemi*) (called Erwinase<sup>®</sup> in markets outside the United States) and Prialt<sup>®</sup> (ziconotide) intrathecal infusion. Erwinaze, a biologic product, is used in conjunction with chemotherapy to treat patients with acute lymphoblastic leukemia, or ALL, with hypersensitivity to *E. coli*-derived asparaginase. Erwinaze is exclusively licensed to us, and manufactured for us, by the U.K. Health Protection Agency, now part of Public Health England, an executive agency of the U.K. Department of Health, or PHE, and was approved by the FDA under a biological license application, or BLA, in November 2011 and launched in the U.S. market in the same month. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere.

Erwinaze represents an important part of our strategy to grow sales of our existing products. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of challenges, including the limited population of patients with 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 maintenance of current sales level and continued growth is our need to assure sufficient supply of Erwinaze on a timely basis. See the discussion regarding Erwinaze supply issues in the next risk factor in this Item 1A entitled "We depend on single source suppliers and manufacturers for each of our products, product candidates and their active pharmaceutical ingredients. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects."

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

Prialt, an intrathecally administered infusion of ziconotide, was approved by the FDA in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. We face many challenges in maintaining and growing sales of Prialt, including acceptance of intrathecal administration by patients and physicians and challenges for physicians with timely reimbursement for use of Prialt. In addition, the FDA has required that the label for Prialt include a boxed warning regarding the risk of psychiatric symptoms and neurological impairment. We cannot predict whether the FDA will require additional warnings, or place any additional limitations on our ability to advertise and promote Prialt, which could negatively impact Prialt sales. In the fourth quarter of

2012, we began the roll-out of the NAVIGATOR Reimbursement and Access Program<sup>TM</sup>, a centralized program to provide a single point of access to Prialt, in anticipation of a transition to a centralized distribution system for Prialt in 2013. In connection with the transition to and implementation of the new distribution system, we could experience disruptions that could negatively affect product sales.

Failure to maintain or increase prescriptions and revenue from sales of our marketed products, including Erwinaze and Prialt, could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We may choose to increase the price of our marketed products, and we cannot assure you that price adjustments will not negatively affect our sales volumes. In addition, sales of Erwinaze may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the dosing requirements of treated patients and other factors, and it may be difficult for us or investors to estimate Erwinaze revenue until we have more experience selling the product. The market price of our

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ordinary shares may decline if the sales of our products do not continue or grow at the rates anticipated by financial analysts or investors.

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

We depend on single source suppliers and manufacturers for each of our products, product candidates and their active pharmaceutical ingredients. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects.\*

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredient and the finished product in sufficient quantities that meet detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. If we or any of our third party suppliers or manufacturers encounter these or any other manufacturing, quality or compliance difficulties with respect to any of our products, we may be unable to meet the commercial demand for such products, which could adversely affect our business, financial condition, results of operations and growth prospects.

We do not have our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. The availability of our products for commercial sale depends upon our ability to procure the ingredients, raw materials, packaging materials and finished products we need from third parties. In part due to the limited market size for our products and product candidates, we have entered into supply and manufacturing agreements with suppliers and manufacturers, each of which is currently our single source for each of our marketed products and for the active pharmaceutical ingredients used in some of these products.

We maintain very limited inventories of certain of our products, including Xyrem and Erwinaze, as well as the ingredients or raw materials used to make our products. Our limited inventory puts us at significant risk of not being able to meet product demand. During 2013, our supply of Erwinaze has been nearly completely absorbed by demand for the product. While we have been able to resolve potential supply shortages and meet product demand to date, the most recent batch that was manufactured does not meet certain related specifications for the product. We believe that the cause of the failure of the most recent batch to meet these specifications can be addressed to avoid a similar problem in future batches, and we are working with our manufacturer to evaluate potential steps that could be taken to avoid or minimize a disruption in the availability of Erwinaze to patients. However, if our efforts are not successful, we expect that we could experience a temporary supply interruption later this year. In addition, other difficulties or delays in production, such as those described elsewhere in this risk factor, could result in additional supply interruptions in the future. If our suppliers and manufacturers, including any new suppliers without a track record of meeting our supply needs, for any reason do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, if one of our suppliers or manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or manufacturers could require us to obtain regulatory clearance in the form of a "prior approval supplement" and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take up to two years, or longer in certain cases, to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an

active pharmaceutical ingredient supplier or a finished product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA or similar international regulatory body approval of a new supplier or manufacturer.

Our current supplier of sodium oxybate, Siegfried (USA) Inc., or Siegfried, was approved by the FDA in late 2011 and became our sole supplier in 2012. While we expect Siegfried will continue to be our sole supplier of sodium oxybate for the foreseeable future, we cannot assure you that Siegfried can or will continue to supply on a timely basis, or at all, sufficient quantities of active pharmaceutical ingredient to enable the manufacture of the quantities of Xyrem that we need.

Erwinaze is licensed to us, and manufactured for us, by PHE, which is our sole supplier for Erwinaze. During the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma Inc., or EUSA Pharma, agreed to a number of post-marketing commitments related to the manufacture of Erwinaze by PHE. In the past, there has been a disruption of supply of

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Erwinase in the European market due to manufacturing challenges. Failure by PHE to comply with regulatory requirements, including follow through on manufacturing-related post-marketing commitments that are monitored by the FDA, could adversely affect its ability to supply Erwinase to us and could result in FDA approval being revoked or product recalls, either of which could have a material adverse effect on our sales of and revenues from Erwinase and limit our potential future maintenance and growth of the market for this product. In addition, if the FDA or any non-U.S. regulatory authority mandates any changes to the specifications for Erwinase, we may face challenges having product produced to meet such specifications, and PHE may charge us more to supply Erwinase meeting such specifications, which may result in additional costs to us and may decrease any profit we would otherwise achieve with Erwinase.

We cannot assure you that PHE will be able to continue to supply our ongoing commercial needs of Erwinase in a timely manner, or at all, especially if our demand for product continues to increase. We have limited inventory of Erwinase. If PHE experiences a disruption in supply or capacity constraints as a result of increased demand or otherwise, we do not have the right to engage a backup supplier for Erwinase except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach by PHE or the cessation of PHE's business. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming, might not be successful and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinase. Any failure of PHE to supply sufficient quantities of Erwinase to meet commercial needs at historic levels or higher could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are in the process of changing our supplier for ziconotide, the active ingredient in Prialt, and have commenced the transfer to the new supplier. We are also in the process of changing our finished product manufacturer for Prialt. There can be no assurance that the new supplier of ziconotide will be approved by the FDA or non-U.S. regulatory authorities or that the new manufacturer of Prialt will be approved by non-U.S. regulatory authorities, or that our commercial supplies of such products will be sufficient until such approvals have been obtained. Any failure to obtain and maintain sufficient commercial supplies could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

For FazaClo LD and FazaClo HD orally disintegrating clozapine tablets, we have single sources of supply for both the active pharmaceutical ingredient and finished product, and should it become necessary to change suppliers, the process could take two years or longer. Pursuant to our license and supply agreement, Douglas Pharmaceuticals America Limited has agreed to supply Versacloz™ (clozapine, USP) oral suspension finished product to us.

The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem, sodium oxybate, is a Schedule I controlled substance, our supplier of sodium oxybate, as well as our finished product manufacturer, must each obtain separate DEA quotas in order to supply us with sodium oxybate and Xyrem. Since the DEA typically grants quotas on an annual basis, our sodium oxybate supplier and Xyrem manufacturer are required to request and justify allocation of sufficient annual DEA quotas as well as additional DEA quotas if our commercial or clinical requirements exceed the allocated quotas throughout the year. In the past, we have had to engage in lengthy legal and other efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2013, our supplier has been allocated only a portion of the requested quota to make the active pharmaceutical ingredient of Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, both our active pharmaceutical ingredient supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013. We cannot assure you sufficient quotas will be received from the DEA to meet our needs, and if we and our supplier and manufacturer cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

In addition, the FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. If there are delays in qualifying new

manufacturers or facilities or a new manufacturer is unable to obtain a sufficient quota from the DEA, if required, or to otherwise meet FDA or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, particularly since we do not have secondary sources for supply and manufacture of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates.

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products or ingredients to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA's current Good Manufacturing Practices, or cGMP, requirements. In complying with cGMP requirements, our suppliers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. DEA regulations also govern facilities where controlled substances such as sodium oxybate are manufactured. Manufacturing facilities of our suppliers have been and are subject to periodic

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unannounced inspection by the FDA, the DEA and other regulatory authorities, including state authorities and similar authorities in non-U.S. jurisdictions. Failure to comply with applicable legal requirements subjects the suppliers to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need.

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

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

We intend to grow our business over the long term by acquiring or in-licensing and developing additional products and product candidates that we believe have significant commercial potential. Future growth through acquisition or in-licensing will depend upon the availability of suitable products and product candidates for acquisition or in-licensing on acceptable prices, terms and conditions. Any growth through development will depend upon our identifying and obtaining product candidates, our ability to develop those product candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialize these product candidates. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities.

We cannot assure you that we will be able to successfully manage these risks or other anticipated and unanticipated problems in connection with an acquisition or in-licensing. We may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate proves not to be safe or effective in later clinical trials, a product fails to reach its forecasted commercial potential or the integration of a product or product candidate gives rise to unforeseen difficulties and expenditures. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business.

We may not realize the anticipated financial and strategic benefits from the EUSA Acquisition or be able to successfully integrate the acquired business.\*

Our acquisition of EUSA Pharma in June 2012, which we refer to as the EUSA Acquisition, has required, and will continue to require, significant efforts and expenditures, including with respect to integrating the acquired business with our historical business. We may encounter unexpected difficulties, or incur unexpected costs, in connection with our integration efforts, which include:

- the risk that our lack of experience in the oncology market will not allow us to sustain growth in, or maintain current levels of, sales of our products in such market;
- the strain on, and need to continue to expand, our existing operational, technical, financial and administrative infrastructure, including our financial controls and reporting systems and procedures and disaster recovery procedures;
- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisition, including professional fees to comply with corporate and tax laws and financial reporting requirements in a number of countries in Europe, and additional costs we may incur going forward as a result of our corporate structure that includes an increased number of subsidiaries in multiple additional countries; and
- any unanticipated liabilities for activities of or related to EUSA Pharma or any of its operations, products or product candidates that occurred prior to the closing of the acquisition or before adequate risk mitigation could be accomplished.

If any of these factors impairs our ability to integrate successfully, we may be required to spend time or money on integration activities that otherwise would be spent on the development and expansion of our business. If we fail to

integrate or otherwise manage the acquired business successfully and in a timely manner, resulting operating inefficiencies could increase costs and expenses more than we planned, could negatively impact the market price of our ordinary shares and could otherwise distract us from execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures could also impact our ability to produce timely and accurate financial statements.

We have grown rapidly, and our business and corporate structure has become substantially more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control



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deficiencies. Significant management time and effort is required to effectively manage the increased complexity of our company and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, as a result of the transactions we completed in 2012, our financial statements and results of operations in prior years may not provide meaningful guidance to form an assessment of the prospects or potential success of our future business operations.

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

We are headquartered in Dublin, Ireland and have multiple offices in the United States, the United Kingdom, and other countries in Europe. Our headcount has grown from approximately 260 employees at the end of 2011 to approximately 640 in April 2013. This includes employees in ten countries in Europe, a European commercial presence, and a complex distribution network for products in Europe and additional territories. In addition, we may expand our international operations into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, because we are conducting a larger portion of our business outside of the United States, we are now subject to a variety of risks and complexities that may materially and adversely affect our business, results of operations and financial condition, including, among other things:

- the increased complexity and costs inherent in managing international operations;
  - diverse regulatory, financial and legal requirements, and any changes to such requirements in one or more countries where we are located or do business;
  - country-specific tax, labor and employment laws and regulations;
  - complying with applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions and any changes to them;
  - challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
  - changes in currency rates; and
  - regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.
- Failure to effectively manage these risks could have a material adverse effect on our business.

In recent years, the global economy has been impacted by the effects of an ongoing global financial crisis, including the European sovereign debt crisis, which has caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe, could adversely affect our revenues, financial condition or results of operations, if, for example, our customers in Europe fail to pay or delay payments owed to us for our products. The commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.

Physicians may not prescribe our products, in which case we would not generate the revenues we anticipate from product sales. Market acceptance of any of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved, including any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and
- the availability of adequate reimbursement by third parties.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other

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companies could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, from time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Patients, physicians and regulators may therefore view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of its connection to GHB. Xyrem's label includes information about adverse events from GHB.

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

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

In addition, many of our competitors are able to deploy more personnel to market and sell their products than we do.

We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of our products. If our specialty sales forces and sales organization is not appropriately sized to adequately promote any current or potential future products, the commercial opportunity for our current or potential future products may be diminished.

In 2012 we added Erwinaze, as well as other smaller products in the oncology supportive care market, to our product portfolio. We compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in the oncology and oncology supportive care markets, and our failure to compete effectively in this area could negatively affect our sales of Erwinaze and other products.

Conducting clinical trials is costly and time consuming, and the outcomes are uncertain. A failure to prove that our product candidates are safe and effective in clinical trials would require us to discontinue their development, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.\*

We expect to increase our research and development organization to pursue targeted development activities in 2013.

We have several development pipeline projects, including the development of two clinical product candidates: Asparec® (mPEG-r-crisantaspase), which is in a Phase I clinical trial in Europe; and Leukotac® (inolimomab), which is in a Phase III clinical trial also in Europe. We obtained a worldwide exclusive license for JZP-386 (formerly known as C-10323), a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem, from Concert Pharmaceuticals, Inc. in February 2013. Pre-clinical research and development work has been initiated on this compound for potential use in patients with narcolepsy. We also intend to pursue clinical development of other product candidates that we may acquire or in-license in the future. Significant clinical, development and financial resources will be required to progress these product candidates to obtain necessary regulatory approvals and to

develop them into commercially viable products. We have not been successful in developing any product candidates that received FDA approval in the past. If a product candidate fails at any stage of development, it will not receive regulatory approval, we will not be able to commercialize it, or potentially even to continue to receive modest revenue being generated as a result of sales under a named patient program, such as in the case of Leukotac, and we will not receive any return on our investment from that product candidate.

As a condition to regulatory approval, each drug product candidate must undergo extensive and expensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. Clinical testing can take many years to complete and failure can occur any time during the clinical trial process. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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Clinical trials can be delayed or halted for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA's Good Clinical Practices;
- unforeseen safety issues, including negative results from ongoing preclinical studies and adverse events associated with product candidates;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- failure of our third-party clinical trial managers to satisfy their contractual duties, comply with regulations or meet expected deadlines; or
- insufficient funds to complete the trials.

The results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. In that case, the FDA or the equivalent in jurisdictions outside of the United States may determine our data is not sufficiently compelling to warrant marketing approval, may require we engage in additional clinical trials, or provide further analysis which may be costly and time-consuming. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials.

We are currently undertaking a Phase 1 clinical trial of Asparec in Europe. Under our license agreement with Alizé Pharma II, or Alizé, under which we obtained rights to develop and commercialize Asparec, we are subject to contractual obligations to meet certain development milestones within certain timeframes. Our ability to meet each of these milestones is uncertain, and depends upon a number of factors, including our ability to obtain clinical material and to develop a clinical program meeting the development requirements of both the FDA and European regulatory authorities in a timely fashion. If our development activities are delayed for any reason and we fail to meet our licensing obligations to Alizé, we may lose our rights to develop and commercialize Asparec.

Our development pipeline projects include not only new product candidates, but also projects involving line extensions for existing products and the generation of additional clinical data for existing products. For example, we are conducting a clinical trial evaluating the intravenous administration of Erwinaze in North America, to generate support for approval for the intravenous administration of Erwinaze, which is intended to provide more convenient dosing for patients. We also plan to conduct a clinical trial to evaluate the use of Erwinaze in adolescents and young adults with ALL who are hypersensitive to E. coli-derived asparaginase, which is expected to begin in the second half of 2013. These development efforts may not be successful, and any adverse events or other information generated during the course of our studies related to existing products could result in action by the FDA or any non-U.S. regulatory agency, which may restrict our ability to sell, or sales of, currently marketed products, or such events or other information could otherwise have a material adverse effect on a related commercial product. Any failure or delay in completing clinical trials for line extensions or the generation of additional clinical data could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

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

approvals for our product candidates.

We rely on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as FDA's and non-U.S. regulatory

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agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the United States. Our failure, or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

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

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team and other critical personnel, all of whom work on many complex matters that are essential to our success. We do not carry "key person" insurance. The loss of services of one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities. Any employee may terminate his or her employment at any time without notice or with only a few months' notice and without cause or good reason. Since the completion of the Azur Pharma and EUSA Pharma transactions, several members of the former management teams of those entities, as well as other employees, have left our company to pursue other opportunities. The resulting loss of institutional knowledge may negatively impact our achievement of the anticipated benefits of those transactions.

In addition, to grow our company we will need additional personnel. Competition for qualified personnel in the pharmaceutical industry is very intense. If we lose key personnel or are unable to attract, retain and motivate quality individuals, our business, financial condition, results of operations and growth prospects could be adversely affected. We also depend on the unique abilities, industry experience and institutional knowledge of the members of our board of directors to efficiently set company strategy and effectively guide our executive management team. We cannot be certain that future board turnover will not negatively affect our business in the future.

**Risks Related to Our Intellectual Property**

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our products and product candidates and their use and the methods used to manufacture and distribute them, as well as successfully defending these patents against third party challenges, and successfully protecting our trade secrets. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. Changes in either the patent laws or in interpretations of patent laws in the United States and other

countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. Although Xyrem is covered by patents covering its formulation, distribution system and method of use, third parties are seeking to introduce generic versions of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if such company or



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companies decide to launch generic versions of Xyrem before applicable ongoing patent litigation is concluded at risk of potentially being held liable for damages for patent infringement.

On December 10, 2012, we received a Paragraph IV Certification from Amneal that it filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the Orange-Book-listed patents relating to Xyrem. Previously, on October 18, 2010, we received notice that Roxane filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the Orange-Book-listed patents relating to Xyrem. If either of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Additional ANDAs could also be filed requesting approval to market generic versions of Xyrem; if those applications for generics were approved and the generics were launched, sales of Xyrem would decrease. We have sued both Roxane and Amneal to prevent either from introducing a generic version of Xyrem that would infringe our patents, but we cannot assure you that the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. See the risk factor in this Item 1A entitled "If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected." Azur Pharma received Paragraph IV certifications from three generic manufacturers, two in 2008 and one in 2010, relating to generic versions of FazaClo LD. Azur Pharma and CIMA, our licensor and whose drug-delivery technology is incorporated into FazaClo LD, filed lawsuits in response to each certification. In July 2011, Azur Pharma, CIMA, Barr Laboratories (one of the three generic manufacturers) and Teva, which had acquired Barr Laboratories, entered into an agreement settling the patent litigation and granting a license of our rights to have manufactured, market and sell a generic version of FazaClo LD and FazaClo HD. The sublicenses for FazaClo LD commenced in July 2012; the sublicense for FazaClo HD will commence in May 2015 or earlier upon the occurrence of certain events. In August 2011, Azur Pharma received a Paragraph IV certification notice from Teva advising that Teva had filed an ANDA with the FDA seeking approval to market a generic version of FazaClo HD. As noted above, FazaClo HD was covered under the July 2011 settlement agreement with Teva. In the July 2011 settlement agreement, 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. 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, which is having a negative impact on our sales of FazaClo LD and may have a negative impact on our sales of FazaClo HD in future periods.

The two formulation patents covering FazaClo LD and FazaClo HD that we license from CIMA are under re-examination by the U.S. Patent and Trademark Officer, or the USPTO, and both of the re-examination proceedings have proceeded to appeal at the USPTO. It is currently not possible to predict whether these re-examination proceedings will result in one or both of the patents being fully or partly invalidated. Any decision on the part of the USPTO that results in one or both of the patents being fully or partly invalidated could accelerate the entry of additional generic competitors for FazaClo LD and FazaClo HD.

The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The final substantive provisions of the Leahy-Smith Act, including the first to file system, became effective on March 16, 2013. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to invent or file, as appropriate, subject matters covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;

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• others may independently develop similar or alternative products without infringing our intellectual property rights;

• our pending patent applications may not result in issued patents;

• our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

• our issued patents and the issued patents of our licensors or partners may be vulnerable to legal challenges as a result of changes in applicable law;

• we may not develop additional proprietary products that are patentable; or

• the patents of others may have an adverse effect on our business.

We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures.

If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. For example, Erwinaze has no patent protection, and we therefore must rely on trade secrets and other unpatented proprietary information in order to obtain a competitive advantage, which we may be unable to do. Erwinaze, as a biologic product approved under a BLA, is subject to the U.S. Biologics Price Competition and Innovation Act, or the BPCIA. The BPCIA establishes a period of twelve years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a twelve-year period. The FDA is in the process of implementing the BPCIA and has not established final guidelines for administering the review and approval of applications for data exclusivity. Although we expect that Erwinaze would receive data exclusivity in the United States through 2023 under the BPCIA, we cannot assure you that it will receive this exclusivity. While Erwinaze has orphan drug marketing exclusivity for a seven-year period from its FDA approval in the United States until November 2018, and is expected to receive data exclusivity in the United States through 2023 under the BPCIA, it is possible that a potential competitor might obtain earlier approval from the FDA based upon an approval application that does not rely on or refer to data in our BLA for Erwinaze. In the European Union, the regulatory data protection and thus regulatory exclusivity period for Erwinaze has lapsed. This also means that any new marketing authorizations for Erwinaze in other European Union, or EU, member states will not receive any regulatory data protection. If a biosimilar product to Erwinaze is approved in the future in the United States or in other countries where it is sold, a significant percentage of the prescriptions written for Erwinaze may be filled with the biosimilar version, resulting in a loss in sales of Erwinaze, and there may be a decrease in the price at which Erwinaze can be sold. Competition from a biosimilar product to Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, although there are patent applications for Asparec pending in the United States and many other countries, Asparec is not yet covered by any issued patents. Asparec was granted orphan drug designation by the FDA subject to certain conditions. In addition, the FDA has not yet clarified whether Asparec is eligible to receive data exclusivity under the BPCIA. If we fail to obtain orphan drug marketing exclusivity and/or data exclusivity, and if we also fail to successfully execute on other strategies to protect our intellectual property with respect to Asparec, including protection by one or more issued patents, Asparec would be subject to competition from a biosimilar product, which could have a material adverse effect on our ability to recognize any return on our investment in the development of this product as well as on our future growth prospects.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our research and development collaborators over the ownership of rights to jointly developed intellectual property. Such disputes, if

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not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products.\*

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and non-U.S. counterparts, and may file additional U.S. and non-U.S. patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, in part because of prior research performed and patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop a third party from infringing our patents, our licensed patents or our partners' patents, that third party has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that a court will decide that these patents are not valid or infringed and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld and infringement of these patents found, the court will refuse to stop the other party on the grounds that it is in the public interest to permit the infringing activity. We are prosecuting lawsuits against the generic manufacturers who delivered Paragraph IV certifications to us with respect to Xyrem and FazaClo LD. See Item 1 "Legal Proceedings." We cannot assure you that these, or other lawsuits we may file in the future, will be successful in stopping the infringement of our patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for us.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights, or that we or such partners are infringing, misappropriating or otherwise violating other intellectual property rights, and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Such lawsuits are costly and could affect our results of operations and divert the attention of management and development personnel. There is a risk that a court could decide that we or our partners are infringing, misappropriating or otherwise violating third party patent or other intellectual property rights, which could be very costly to us and have a material adverse effect on our business.

The pharmaceutical and life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, and we may not be able to do this.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many non-U.S. jurisdictions are typically not published until 18 months after their priority date, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors' or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Patent interferences will be limited or unavailable for applications filed after March 16, 2013.

Some of our competitors may be able to sustain the costs of complex patent and other intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We own patents that cover the formulation and method of use covering the administration for Xyrem, as well as method of use patents and trade secrets that cover elements of the Xyrem deemed REMS. As a result of the implementation of the FDAAA, we have submitted updated REMS documents to the FDA, which are intended to conform the elements of the Xyrem Risk Management Program, our deemed REMS, to the current REMS formatting requirements, as well as to make other updates to the program and its documents. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem. While we cannot predict the timing of finalization, or the final terms, of approved REMS

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documents for Xyrem, we expect that the FDA will require final REMS documents that will result in, or permit, modifications to aspects of the Xyrem deemed REMS, which may include the ability to distribute Xyrem through more than one pharmacy. We also expect that the final REMS documents will include requirements that are not currently implemented in the Xyrem Risk Management Program. 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 to enter the market and/or negatively affect sales of Xyrem. In particular, depending on the extent to which certain provisions of our Xyrem deemed REMS which are currently protected by our method of use patents covering the distribution of Xyrem are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced. Certain claims of our patents may not provide as much protection in the context of a modified REMS structure. In addition, the extent of protection provided by our method of use patents covering the distribution of Xyrem depends on the nature of the distribution system that may be used by any generic competitor, including whether the distribution system is as restricted as the current Xyrem deemed REMS. If a generic competitor is able to obtain ANDA approval for a generic version of Xyrem based on a risk management plan or REMS that does not fall within the scope of any of the claims of our distribution patents, those patents will not be a barrier to the generic version's entry into the market. We cannot be certain whether our existing distribution patents or patents that may be granted in the future will be construed to cover any generic REMS or risk management plan that might be approved by the FDA. The interpretation of intellectual property protections and the effect of these protections are extremely complex, and we cannot predict the impact of any changes to our REMS documents on our business.

**Risks Related to Our Industry**

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our partners from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, advertising and promotion, distributing and exporting of pharmaceutical products are subject to extensive regulation, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. We are not permitted to market our product candidates in the United States or countries in Europe until we receive approval from the FDA or the competent European authorities, respectively, generally of an NDA, a BLA or a marketing authorization application. The application must contain information on the drug or biological candidate, including data from the preclinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability. Submission of an application does not assure approval for marketing in any jurisdiction, and we may encounter significant difficulties or costs in our efforts to obtain approval to market products. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

If the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks, we may be required to include a proposed REMS as part of an NDA or otherwise, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide information to consumers about the drug's risks and benefits. For example, the FDA requires a REMS for Xyrem, discussed in detail under the risk factor "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem" above, and other products that we sell are or may become subject to a REMS specific to our product or shared with other products in the same class of drug. We cannot predict the impact that any new REMS requirements applicable to any of our products would have on our business.

Healthcare law and policy changes, including those based on recently enacted legislation, 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.

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Healthcare Reform Act. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

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Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. The Healthcare Reform Act also makes changes to the Medicaid Drug Rebate program, discussed further herein, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014 and thereafter, and their details will be shaped significantly by implementing regulations that have yet to be finalized. In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, the Supreme Court struck down a provision in the Healthcare Reform Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall, which could impact our sales, business and financial condition.

While the constitutionality of key provisions of the Healthcare Reform Act was upheld by the Supreme Court, legislative changes to it remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates or could limit or eliminate our future spending on development projects.

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Likewise, in the countries in the EU, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to health care cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third-party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem free product voucher program and co-pay coupon programs for certain products. The co-pay coupon programs of other pharmaceutical manufacturers are the subject of ongoing class action lawsuits, first filed in 2012, challenging their legality under a variety of federal and state laws, and our co-pay coupon programs could become the target of similar lawsuits. In addition, co-pay coupon programs, including our program for Xyrem, have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives. It is possible that the outcome of the pending litigation against other manufacturers and/or the introduction and enactment of new legislation could restrict or otherwise negatively affect these programs, which could result in fewer patients using affected products and therefore could have a material adverse effect on our sales, business and financial condition.

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.\*

Oversight by FDA and Equivalent Non-U.S. Regulatory Authorities

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of our products are, and any of our product candidates that may be approved by the FDA or European and other non-U.S. regulatory authorities will be, subject to extensive and ongoing regulatory requirements. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. Failure by us or any of our third party partners, including suppliers, manufacturers and distributors and our central pharmacy for Xyrem, to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, withdrawal of product approval, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall or seizure, total or partial suspension of production or distribution, interruption of

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manufacturing or clinical trials, operating restrictions, injunctions; suspension of licenses, civil penalties and/or criminal prosecution, any of which could have a significant impact on our sales, business and financial condition. If we receive regulatory approvals to sell our products, the FDA and other non-U.S. regulatory authorities in Europe or other countries where our products are approved may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the commercial potential of the product. If we become aware of problems with any of our products in the United States or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us. In such an instance, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits. Under regulations in Europe related to pharmacovigilance, or the assessment and monitoring of the safety of drugs, we may be required to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and may be required to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time consuming and expensive and could impact our profitability.

The FDA approved the BLA for Erwinaze in the United States in November 2011, subject to certain post marketing requirements, including developing and validating assays and conducting certain non-clinical studies. In addition, the BLA approval for Erwinaze is subject to compliance with numerous post marketing commitments, including certain commitments which must be met by PHE with respect to product manufacturing, which are outside of our control. While activities are underway to complete the post marketing requirements and to comply with the post marketing commitments, if we or PHE fail to do so within the timeframe established by the FDA, or if the results of the non-clinical studies raise concerns or other issues for the FDA, our approval to market Erwinaze in the United States may be withdrawn or otherwise jeopardized.

For a patient to be prescribed Prialt, the patient must have a surgically implanted infusion pump and the FDA has approved Prialt for use with Medtronic's SynchroMed® II Drug Infusion System. Any regulatory action involving the pumps or delivery of Prialt via the pumps could materially adversely impact sales of Prialt.

In June 2009, the FDA posted an announcement regarding a potential safety signal associated with FazaClo. The posting stated that FazaClo had been found to exhibit a higher proportion of adverse events with a fatal outcome versus total adverse events compared to other clozapine products. The posting also stated that the reported events in the cases with fatal outcome are similar for FazaClo and other clozapine products. Although Azur Pharma investigated and we believe that the difference in the cited ratio between FazaClo and other marketed clozapine products does not reflect an underlying adverse safety signal, we cannot assure you that additional information we may learn will not modify our current assessment, that the FDA will agree with this assessment or that the FDA will not take further actions related to the potential safety signal, any of which could have a material adverse effect on our results of operations.

We have not obtained marketing authorizations and/or may not currently have updated the marketing authorization approval dossiers for Erwinase and several other medicinal products in every international market in which those products are being sold. For example, in some EU countries where we do not have a marketing authorization, Erwinase is being provided to patients on the basis of government-approved named patient programs or temporary use authorizations. While we believe we have satisfied the regulations regarding our communications and medical affairs activities in those countries, if any such country's regulatory authorities determine that we are promoting Erwinase without a marketing authorization in place, we could be found to be in violation of pharmaceutical advertising law or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties.

The FDA requires advertising and promotional labeling to be truthful and not misleading, and that products be marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA routinely provides its interpretations of that authority in informal communications and also in more formal communications such as untitled letters or warning letters, and although such communications are not final agency

decisions, companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful. For example, in September 2012, we received a warning letter from the FDA related to a direct-to-consumer patient brochure for FazaClo. We were no longer using the allegedly violative promotional materials at the time we received the letter, but reviewed all of our other promotional materials for FazaClo in accordance with the letter. We agreed with the FDA on plans for correcting the promotional materials and disseminating the corrective messages to healthcare providers, patients and consumers and began implementation of the corrective actions in accordance with the agreed-upon plans in February 2013. We believe that we have taken necessary actions required to fully address the agency's concerns. However, there can be no assurance that the FDA will agree with our assessment. The FDA could take further action, could require us to take further action, with respect to our FazaClo promotional materials, or could otherwise conclude we have not taken all appropriate corrective actions with respect to the warning letter. The FDA or other regulatory authorities may disagree with our response to the warning letter or challenge other of our promotional materials or activities in the future, through additional enforcement action, which may have a negative impact on our sales and/or may subject us to financial or other penalties.

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The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. For example, a predecessor company to Jazz Pharmaceuticals, Inc. was investigated for off-label promotion of Xyrem, and, while Jazz Pharmaceuticals, Inc. was not prosecuted, as part of the settlement Jazz Pharmaceuticals, Inc. entered into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services, which extended through mid-2012. The investigation resulted in significant fines and penalties, which Jazz Pharmaceuticals, Inc. has paid, and the corporate integrity agreement required us to maintain a comprehensive compliance program. For all of our products, it is important that we maintain a comprehensive compliance program. Failure to maintain a comprehensive and effective compliance program, and to integrate the operations of EUSA Pharma into a combined comprehensive and effective compliance program on a timely basis, could subject us to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products.

Various U.S. state agencies traditionally oversee pharmaceutical compounding activities. Compounded drugs are made by certain pharmacies, typically by combining, mixing or altering ingredients of a drug to make a formulation that is not readily available to patients and/or approved by the FDA. A number of problems have been associated with the making and use of compounded drugs, including product contamination, product toxicity, product instability and impaired performance of medical devices used to deliver drugs. Improperly compounded products can pose serious public health issues, as evidenced by the October 2012 fungal meningitis outbreak in the United States which was traced to compounded drugs from the New England Compounding Center. Pharmaceutical products administered intrathecally, such as Prialt, are frequently compounded by pharmacies for off-label use, a process over which we have no control. If any of our products are used in compounded drugs, we may have exposure to claims by patients treated with compounded formulations containing our products and to regulatory action by relevant government agencies. Any such claims or regulatory actions could result in harm to our reputation and have a negative effect on our business. In addition, since late 2012, there have been increased legislative and enforcement activities on the federal level, including proposed federal legislation to give the FDA greater authority over compounding operations. We cannot predict impact on our business of any such new legislation.

**Other Regulatory Authorities**

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the Department of Justice, the FTC, the U.S. Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those non-U.S. countries in which we commercialize our products. In addition to the FDCA, other federal, state and non-U.S. statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our partners, including our suppliers, manufacturers and distributors and the central pharmacy for Xyrem, are subject to many of the same requirements.

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition to quota requirements, the DEA imposes various registration, importing, exporting, recordkeeping and reporting requirements, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the Controlled Substance Act, or the CSA. The states also impose similar requirements for handling controlled substances. The United States is a party to the Convention on Psychotropic Substances (1971), or the 1971 Convention. In October 2012, the World Health Organization, or the WHO, sent a recommendation to the United Nations Commission on Narcotic Drugs, or the CND, to reschedule GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. In March 2013, the CND voted to reschedule GHB from Schedule IV to Schedule II under the 1971 Convention. While the DEA imposes its own

scheduling requirements in the United States under the CSA, the United States is obligated as a signatory to the 1971 Convention to ensure that drug scheduling in the United States is consistent with its obligations under the international treaties. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, the international rescheduling of GHB means that Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements in Europe and certain other countries than the restrictions currently in place. In the United States, under DEA regulations, the Xyrem finished product is currently classified as a Schedule III controlled substance, with sodium oxybate, classified as a Schedule I controlled substance. Although the U.S. Department of Health and Human Services, or the HHS, has taken the position in the past that the United States would not be required to alter the domestic control of GHB should it be rescheduled to Schedule II under the 1971 Convention, we cannot guarantee that international rescheduling of GHB from Schedule IV to Schedule II will not impact restrictions on Xyrem in the United States. Failure by us or any of our partners, including suppliers, manufacturers and

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distributors, to comply with such requirements could result in, among other things, additional operating costs to us, delays in shipments outside or into the United States and adverse regulatory actions.

In addition, pursuant to the Export Administration Regulations, we are required to obtain a license from the U.S. Department of Commerce prior to the exportation of certain materials and technical information related to Prialt, a synthesized conotoxin, which is a designated controlled biological toxin.

The U.S. federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

The U.S. Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. In addition, in recent years the government has pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Additional states are considering or recently have considered similar proposals. Non-U.S. governments often have similar regulations which we also will be subject to in those countries where we market and sell products.

Our business activities outside of the United States are subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act of 2010, or the UK Bribery Act. The FCPA generally prohibits the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. The UK Bribery Act prohibits companies which do business with the United Kingdom and their employees and representatives from giving, offering, or promising bribes to any person, including non-UK government officials, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies may be held liable for failing to prevent employees and persons associated with the company from violating the Act. As described above, our business is

heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. We have ongoing efforts that are designed to ensure our compliance with these laws, including training, policies, procedures, and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third party agents, although we may be liable for their actions. Any violation of these laws may result in civil and criminal penalties, and could have a material adverse impact on our business.

We are also subject to laws and regulations covering data privacy and the protection of health-related and other personal



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information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU member states may interpret the legislation differently, which adds to its complexity, and guidance on implementation and compliance practices are often updated or otherwise revised. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration and, if adopted, could lead to additional and stricter requirements and penalties in the event of non-compliance.

The number and complexity of both federal and state laws continue to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations and the Physician Payment Sunshine provisions. The Physician Payment Sunshine provisions will require extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. The Centers for Medicare and Medicaid Services, or CMS, recently issued a final rule implementing the Physician Payment Sunshine provisions and clarified the scope of the reporting obligations. The final rule also provided that manufacturers must begin tracking on August 1, 2013 and must begin reporting payment data to CMS by March 31, 2014. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Compliance with the various federal and state laws that apply to pharmaceutical manufacturers is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and, in some cases, the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. For example, the FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner. Such a challenge or any challenge that we or our business partners have failed to comply with applicable laws and regulations could have a material adverse effect on our business, financial condition, results of operations and growth prospects. If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid supplemental rebate and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug. Such data previously have not been submitted for our two radiopharmaceutical products, ProstaScint<sup>®</sup> (capromab pendetide) and Quadramet<sup>®</sup> (samarium sm 153 lexidronam injection). We have been engaged in interactions with CMS and a trade group regarding the reporting of Medicaid pricing data and paying Medicaid rebates on these and other radiopharmaceutical products and expect to begin

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making any required reports and paying required rebates on our products later this year. Any additional rebate liability resulting from this reporting will negatively impact our financial results.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organizations. With regard to the amount of the rebates owed, the Healthcare Reform Act increased the minimum Medicaid rebate for all drugs; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Healthcare Reform Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a new branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of \$2.8 billion in 2013 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

CMS has issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act and subsequent legislation but has not yet issued final regulations. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The Healthcare Reform Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts "orphan drugs" – those designated under section 526 of the FDCA – from the ceiling price requirements for these newly-eligible entities. The Health Resources and Services Administration, or HRSA, which administers the 340B program, has issued proposed regulations to implement the orphan drug exception, but has not yet issued final regulations. The issuance of final regulations will continue to increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law also requires that a company that participates in the Medicaid rebate program report average sales price, or ASP, information to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed

each quarter based on our submission to CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for prior quarters was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the price that we are required to charge certain safety-net providers under the 340B drug discount program.

In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, average sales price, or best price information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Our failure to submit monthly/quarterly

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average manufacturer price, average sales price, and best price data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the submission is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

In September 2010, CMS and the Office of the Inspector General indicated that they intend more aggressively to pursue companies who fail to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to sell to covered entities if the manufacturer sells to any other purchaser and to report to the government the ceiling prices for its drugs. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule, or FSS, pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator “covered drugs” available to the “Big Four” federal agencies – the VA, the Department of Defense, or DoD, the Public Health Service, and the Coast Guard – at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the “non-federal average manufacturer price,” or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of \$100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed “tracking customer.” Further, in addition to the “Big Four” agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies “negotiated pricing” for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor’s commercial “most favored customer” pricing. We offer one single FCP-based FSS contract price to all FSS purchasers for all products.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, or TMA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, we have entered into a Section 703 Agreement with TMA under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the Annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our

business, financial condition, results of operations and growth prospects.

Reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.\*

In both U.S. and non-U.S. markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for

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example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with such studies, our products may be considered less safe, less effective or less cost-effective than other products, and third party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because some of our products compete in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only at limited levels, we may not be able to effectively commercialize our products.

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover products appropriately under our DoD pricing agreements, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the Federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In various European countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. We have periodically increased the price of Xyrem, most recently in February 2013, and we have made and may in the future make similar price increases on our other products. We cannot assure you that such price adjustments will not negatively affect our ability to secure and maintain reimbursement coverage for our products, which could negatively impact our sales volumes.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologicals, have been reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25, or BCA, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, or ATRA. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs, because Congress failed to enact legislation by January 15, 2012, to reduce federal deficits by \$1.2 trillion over ten years. The BCA caps the cuts to Medicare payments or items and services at 2%, and requires the cuts to be implemented on the first day of the first month following the issuance of a sequestration order. The ATRA delayed implementation of sequestration from January 2, 2013, to March 1, 2013, and as a result, the Medicare cuts took effect April 1, 2013. These cuts could adversely impact payment for our products, which could negatively impact our revenue.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products are associated with significant risks of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Some of our products, including Xyrem, have boxed warnings in their labels. Further, another product, Luvox CR<sup>®</sup> (fluvoxamine maleate) Extended-Release Capsules, is a selective serotonin reuptake inhibitor, and products by other manufacturers in that class are currently involved in product liability litigation.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class of injured patients. Further, third party payors, either individually or as a putative class, may bring actions seeking to recover monies spent on one of products. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. The risk of product liability claims may also increase if a company receives a warning letter from a regulatory agency. We cannot predict the frequency,



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outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully. In addition, defending a product liability lawsuit is expensive and can divert the attention of key employees from operating our business.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval. Similarly, any such regulatory action by the FDA could lead to product liability lawsuits as well.

**Risks Relating to Our Financial Condition**

We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position.\*

As of March 31, 2013, we had approximately \$457.2 million in secured debt outstanding, all of which was incurred under our credit agreement entered into in connection with the EUSA Acquisition. Our debt may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

Our ability to meet our debt service obligations will depend on our future performance, which will be subject to financial, business, and other factors affecting our operations, many of which are beyond our control. If we do not have sufficient funds to meet our debt service obligations, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner or at all.

Covenants in our credit agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.

In June 2012, we entered into a credit agreement which provides for a six-year \$475.0 million term loan and a five-year \$100.0 million revolving credit facility. The credit agreement contains various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;

sell assets and capital stock of our subsidiaries;  
enter into certain transactions with affiliates; and

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consolidate or merge with or into, or sell substantially all of our assets to, another person.

The credit agreement also includes, among other financial covenants, a financial covenant that requires us to maintain a maximum secured leverage ratio. Our ability to comply with this financial covenant may be affected by events beyond our control. Our failure to comply with any of the covenants could result in a default under the credit agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the revolving credit facility, which could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. In addition, if we are unable to repay those amounts, the lenders under our credit agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business.

To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business.

The scope of our business and operations grew substantially in 2012 through the combination of Jazz Pharmaceuticals, Inc. and Azur Pharma in a merger transaction completed in January 2012, or the Azur Merger, and the EUSA Acquisition. To continue to grow our business over the longer-term, we will need to commit substantial additional resources to in-licensing and/or acquiring new products and product candidates, and to costly and time-consuming product development and clinical trials of our product candidates. We also intend to continue to invest in our commercial operations in an effort to grow sales of our current products. Our future capital requirements will depend on many factors, including many of those discussed above, such as:

- the revenues from our commercial products, which may be affected by many factors, including the extent of generic competition for our products;
- the costs of our commercial operations;
- the costs of integration activities related to any future strategic transactions we may engage in;
- the cost of acquiring and/or licensing any new products and product candidates;
- the scope, rate of progress, results and costs of our development and clinical activities;
- the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost of investigations, litigation and/or settlements related to regulatory oversight and third-party claims; and
- changes in laws and regulations, including, for example, healthcare reform legislation.

One of our corporate goals is to continue to expand our business through the licensing, acquisition and/or development of additional marketed or close to approval products and specialty product candidates. We cannot assure you that we will continue to identify attractive opportunities or that our funds will be sufficient to fund these activities if opportunities arise. We may be unable to expand our business if we do not have sufficient capital or cannot borrow or raise additional capital on attractive terms. In particular, the debt under our credit agreement may limit our ability to borrow additional funds for acquisitions or to use our cash flow or obtain additional financing for future acquisitions. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

During the past several years, domestic and international financial markets have experienced extreme disruption from time to time, including, among other things, high volatility and significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. We may decide to access the capital or credit markets to supplement our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility to satisfy our needs for working capital, capital expenditures and debt service requirements or to continue to grow our business over the longer term through product acquisition and in-licensing, product development and clinical trials of product candidates, and expansion of our commercial operations. In the event of adverse capital and credit market conditions, we may not be able to obtain capital market financing or credit on favorable terms, or at all, which could have a material adverse effect on our business and results of operations. Changes in our credit ratings issued by nationally recognized credit rating agencies could adversely

affect our cost of financing and have an adverse effect on the market price of our securities.

We may not be able to successfully maintain our tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.

We are incorporated in Ireland and maintain subsidiaries in the United States, a number of other European jurisdictions and Bermuda. Azur Pharma was able to achieve a low average tax rate through the performance of certain functions and

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ownership of certain assets in tax-efficient jurisdictions, including Ireland and Bermuda, together with intra-group service and transfer pricing agreements, each on an arm's length basis. We are continuing to use a substantially similar structure and arrangements. Taxing authorities, such as the U.S. Internal Revenue Service, or the IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. The IRS or other taxing authority may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes.

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because Azur Pharma was, and we continue to be, an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. Because we indirectly acquired all of Jazz Pharmaceuticals, Inc.'s assets through the acquisition of the shares of Jazz Pharmaceuticals, Inc. common stock in the Azur Merger at the closing, we could be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874.

For us to be treated as a foreign corporation for U.S. federal tax purposes under Section 7874 of the Code, either (1) the former stockholders of Jazz Pharmaceuticals, Inc. must have owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Jazz Pharmaceuticals, Inc., or (2) we must have substantial business activities in Ireland after the Azur Merger (taking into account the activities of our expanded affiliated group). The Jazz Pharmaceuticals, Inc. stockholders owned less than 80% of our share capital immediately after the Azur Merger by reason of their ownership of shares of Jazz Pharmaceuticals, Inc. common stock. As a result, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes.

It is possible that the IRS could disagree with the position that the ownership test is satisfied and assert that Section 7874 of the Code applies to treat us as a U.S. corporation following the Azur Merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. The IRS continues to scrutinize transactions that are potentially subject to Section 7874, and issued new final and temporary regulations under Section 7874 in June 2012. These regulations apply only to acquisitions completed on or after June 7, 2012, and therefore should not apply to the Azur Merger. Nevertheless, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have retroactive application to us, Jazz Pharmaceuticals, Inc., our respective shareholders, and/or the Azur Merger.

Section 7874 of the Code limits Jazz Pharmaceuticals, Inc. and its U.S. affiliates' ability to utilize their U.S. tax attributes to offset certain U.S. taxable income, if any, generated by certain taxable transactions.\*

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, this limitation applies to us. As a result, after the Azur Merger, Jazz Pharmaceuticals, Inc. or its U.S. affiliates have not been able and will continue to be unable, for a period of time, to utilize their U.S. tax attributes to offset their U.S.

taxable income, if any, resulting from certain taxable transactions. Notwithstanding this limitation, we plan to fully utilize Jazz Pharmaceuticals, Inc.'s U.S. net operating losses, or NOLs, prior to their expiration. As a result of this limitation, however, it may take Jazz Pharmaceuticals, Inc. longer to use its NOLs. Moreover, contrary to these plans, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Jazz Pharmaceuticals, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Jazz Pharmaceuticals, Inc. does not generate sufficient taxable income.

Our U.S. affiliates' ability to use their net operating losses to offset potential taxable income and related income taxes that would otherwise be due could be subject to further limitations if we do not generate taxable income in a timely manner or if the "ownership change" provisions of Sections 382 and 383 of the Code result in further annual limitations. Our U.S. affiliates have a significant amount of NOLs. Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, our U.S. affiliates will generate

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sufficient taxable income to use all of the NOLs. In addition, realization of NOLs to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the “ownership change” provisions of Sections 382 and 383 of the Code and similar state provisions, which may result in the expiration of additional NOLs before future utilization. In general, an “ownership change” occurs if, during a three-year rolling period, there is a change of 50% or more in the percentage ownership of a company by 5% shareholders (and certain persons treated as 5% shareholders), as defined in the Code and Treasury Regulations. In this regard, we currently estimate that, as a result of these ownership change provisions, we have an annual limitation on the utilization of certain NOLs of \$29 million for each of the years 2013 to 2016, \$12 million for 2017, and a combined total of \$3 million for 2018 to 2026. However, Sections 382 and 383 of the Code are extremely complex provisions with respect to which there are many uncertainties, and we have not requested a ruling from the IRS to confirm our analysis of the ownership change limitations related to the NOLs generated by our U.S. affiliates. Therefore, we have not established whether the IRS would agree with our analysis regarding the application of Sections 382 and 383 of the Code. If the IRS were to disagree with our analysis, or if our U.S. affiliates were to experience additional ownership changes in the future, our U.S. affiliates could be subject to further annual limitations on the use of the NOLs to offset potential taxable income and related income taxes that would otherwise be due.

We have significant intangible assets and goodwill. Consequently, the potential impairment of our intangible assets and goodwill may significantly impact our profitability.

As of March 31, 2013, we had recorded \$1.3 billion of intangible assets and goodwill related to our past acquisitions. Intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of intangible assets and goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of intangible assets or goodwill occur.

Our financial results could be adversely affected by foreign exchange fluctuations.

We have significant operations in Europe as well as in the United States, but we report revenues, costs and earnings in U.S. dollars. Our primary currency translation exposures relate to our subsidiaries that have functional currencies denominated in the Euro and the British Pound Sterling, or GBP. Exchange rates between the U.S. dollar and each of the Euro and GBP are likely to fluctuate from period to period. Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the local currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. If we continue to expand our international operations, we will conduct more transactions in currencies other than the U.S. dollar. To the extent that non-U.S. revenue and expense transactions are not denominated in the local currency, we are also subject to the risk of transaction losses. Given the volatility of exchange rates, there is no assurance that we will be able to effectively manage currency transaction and/or conversion risks. We have not entered into derivative instruments to offset the impact of foreign exchange fluctuations. Fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations and financial condition.

**Risks Relating to Our Ordinary Shares**

The market price of our ordinary shares has been volatile and may continue to be volatile in the future, and the value of your investment could decline significantly.

Investors who hold our ordinary shares may not be able to sell their shares at or above the price at which they purchased their ordinary shares (or the price at which they purchased their shares of Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger). The price of our ordinary shares has fluctuated significantly from time to time since the completion of the Azur Merger in January 2012, and the price of Jazz Pharmaceuticals, Inc.’s common stock historically fluctuated significantly. The risk factors described above relating to our business and products could cause the price of our ordinary shares to continue to fluctuate significantly. In addition, the stock market in general, including the market for life sciences companies, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and

industry factors may seriously harm the market price of our ordinary shares, regardless of our operating performance. Our share price may be dependent upon the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, the market price of our ordinary shares could decline. In the past, following periods of volatility in the market or significant price decline, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.



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In addition, the market price of our ordinary shares may decline if the effect of the Azur Merger and/or the EUSA Acquisition on the financial results of our combined company is not consistent with the expectations of financial analysts or investors.

Future sales of our ordinary shares in the public market could cause our share price to fall.\*

Sales of a substantial number of our ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity or equity-related securities. As of April 22, 2013, we had 58,850,434 ordinary shares outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144.

In addition, we have in the past and may in the future grant rights to some of our shareholders that require us to register the resale of our ordinary shares on behalf of these shareholders and/or facilitate offerings of ordinary shares held by these shareholders, including in connection with potential future acquisitions of additional products, product candidates, or companies. For example, consistent with our obligations under existing registration rights agreements, we entered into underwriting agreements with certain underwriters and selling shareholders pursuant to which selling shareholders sold an aggregate of approximately 13 million ordinary shares in two separate registered public offerings in March 2012 and in March 2013. In addition, in connection with the Azur Merger, we registered for resale all of the ordinary shares held by the historic Azur Pharma shareholders that permitted such shareholders to resell those ordinary shares immediately following the closing of the Azur Merger. If current or potential future holders of registration rights, by exercising their registration rights or otherwise, sell a large number of shares, the sale could adversely affect the market price of our ordinary shares. We have also filed registration statements to register the sale of our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and intend to file additional registration statements to register any shares automatically added each year to the share reserves under these plans.

Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities. It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Acts, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

Provisions of our articles of association could delay or prevent a takeover of us by a third party.\*

Our articles of association could delay, defer or prevent a third party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. For example, our articles of association:

- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes;
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association; and

- permit our board of directors to issue one or more series of preferred shares with rights and preferences, as our shareholders may determine by ordinary resolution.

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors other than the candidates nominated by our board.

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We have never declared or paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.\*

We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs, acquire or in-license additional products and product candidates, and pursue other opportunities. If we propose to pay dividends in the future, we must do so in accordance with Irish law, which provides that distributions including dividend payments, share repurchases and redemptions be funded from “distributable reserves.” In addition, our ability to pay cash dividends on or repurchase our ordinary shares is restricted under the terms of our credit agreement. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our credit agreement and other factors our board of directors deems relevant. Holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future.

A transfer of our ordinary shares may be subject to Irish stamp duty.

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer. This duty is currently charged at the rate of 1.0% of the price paid or the market value of the shares acquired, if higher. Because our ordinary shares are traded on a recognized stock exchange in the United States, an exemption of this stamp duty is available to transfers by shareholders who hold our ordinary shares beneficially through brokers which in turn hold those shares through the Depositary Trust Company, or DTC, to holders who also hold through DTC. However, a transfer by a record holder who holds our ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Irish Companies Acts or any other applicable law permit, may, or may provide that a subsidiary of ours will, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of our ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of our subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

Dividends paid by us may be subject to Irish dividend withholding tax.

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the United States, European Union countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

Our auditor, like other independent registered public accounting firms operating in Ireland and a number of other European countries, is not currently permitted to be subject to inspection by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, our investors currently do not have the benefits of PCAOB oversight. As an auditor of companies that are publicly-traded in the United States and as a firm registered with the PCAOB, our independent registered public accounting firm is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and the professional standards of the PCAOB. However, because our auditor is located in Ireland, a jurisdiction where the PCAOB is currently unable to conduct inspections, our auditor is not currently inspected by the PCAOB. Inspections of other auditors conducted by the PCAOB outside of Ireland have at times identified deficiencies in those auditor’s audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in Ireland prevents the PCAOB from regularly evaluating our auditor’s audits

and its quality control procedures. In addition, the inability of the PCAOB to conduct auditor inspections in Ireland makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors located outside of Ireland that are subject to regular PCAOB inspections. As a result, our investors are deprived of the benefits of PCAOB inspections, and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On February 26, 2013, we issued 470,836 of our ordinary shares pursuant to the cash exercise of a warrant held by an institutional investor. This warrant was originally issued by Jazz Pharmaceuticals, Inc. in 2005, and we assumed the warrant upon the closing of the Azur Merger. This warrant had an exercise price of \$9.34 per share, resulting in gross proceeds to us upon exercise of approximately \$4.4 million. In issuing the above-mentioned shares, we relied on the exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering.

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Item 6. Exhibits.

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Public Limited Company (formerly Azur Limited Company), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan as Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
2.5	Asset Purchase Agreement, dated as of September 5, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals International II Limited, Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 15, 2012).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K

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4.3 (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012). Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

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Exhibit Number	Description of Document
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.6 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.5A	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.5B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.28E in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.2+	Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.28H in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.3+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.30B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.4+	Jazz Pharmaceuticals plc Cash Bonus Plan (U.S. Affiliates) (incorporated herein by reference to Exhibit 10.32B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.5+	Jazz Pharmaceuticals Cash Bonus Plan (International Affiliates) (Calendar Year 2013) (incorporated herein by reference to Exhibit 10.32C in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.6+	Jazz Pharmaceuticals plc 2013 Executive Officer Compensation Arrangements.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS++	XBRL Instance Document
101.SCH++	XBRL Taxonomy Extension Schema Document
101.CAL++	XBRL Taxonomy Extension Calculation Linkbase Document



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101.DEF++ XBRL Taxonomy Extension Definition Linkbase Document  
101.LAB++ XBRL Taxonomy Extension Labels Linkbase Document  
101.PRE++ XBRL Taxonomy Extension Presentation Linkbase Document

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The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. \*Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

+Indicates management contract or compensatory plan.

Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under ++ any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the

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submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 7, 2013

Jazz Pharmaceuticals Public Limited Company  
(Registrant)

/s/ Bruce C. Cozadd  
Bruce C. Cozadd  
Chairman and Chief Executive Officer and Director  
(Principal Executive Officer)

/s/ Kathryn E. Falberg  
Kathryn E. Falberg  
Executive Vice President and Chief Financial Officer  
(Principal Financial Officer)

/s/ Karen J. Wilson  
Karen J. Wilson  
Senior Vice President, Finance  
(Principal Accounting Officer)

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## EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Public Limited Company (formerly Azur Limited Company), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan as Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
2.5	Asset Purchase Agreement, dated as of September 5, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals International II Limited, Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 15, 2012).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K

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4.3

(File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012). Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

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