Jazz Pharmaceuticals plc
Form 10-Q
November 05, 2013
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
ý Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 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 incorporation or organization)	(I.R.S. Employer Identification No.)

Fourth Floor, Connaught House,
One Burlington Road, Dublin 4, Ireland
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	ý	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 ý

As of October 29, 2013, 57,789,719 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

Table of Contents

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2013

INDEX

		Page
PART I – FINANCIAL INFORMATION		
Item 1.	Financial Statements	3
	Condensed Consolidated Balance Sheets – September 30, 2013 and December 31, 2012	3
	Condensed Consolidated Statements of Income – Three and Nine Months Ended September 30, 2013 and 2012	4
	Condensed Consolidated Statements of Comprehensive Income – Three and Nine Months Ended September 30, 2013 and 2012	5
	Condensed Consolidated Statements of Cash Flows – Nine Months Ended September 30, 2013 and 2012	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	34
Item 4.	Controls and Procedures	34
PART II – OTHER INFORMATION		
Item 1.	Legal Proceedings	36
Item 1A.	Risk Factors	37
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	70
Item 6.	Exhibits	71

We own or have rights to various copyrights, trademarks, and trade names used in our business in the United States and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, 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.

2

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$588,462	$387,196
Accounts receivable, net	113,271	75,480
Inventories	24,868	26,525
Prepaid expenses	19,350	7,445
Deferred tax assets, net	45,565	35,813
Other current assets	18,551	19,113
Total current assets	810,067	551,572
Property and equipment, net	12,060	7,281
Intangible assets, net	823,724	869,952
Goodwill	446,823	442,600
Deferred tax assets, net, non-current	70,976	74,850
Deferred financing costs	15,458	16,576
Other non-current assets	6,391	3,662
Total assets	$2,185,499	$1,966,493
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$22,434	$15,887
Accrued liabilities	106,390	104,666
Current portion of long-term debt	5,572	29,688
Income taxes payable	19,850	39,884
Contingent consideration	47,700	—
Deferred tax liability, net	275	275
Deferred revenue	1,138	1,138
Total current liabilities	203,359	191,538
Deferred revenue, non-current	6,001	6,776
Long-term debt, less current portion	545,564	427,073
Contingent consideration, non-current	—	34,800
Deferred tax liability, net, non-current	170,127	178,393
Other non-current liabilities	16,747	6,621
Commitments and contingencies (Note 7)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	471	471
Additional paid-in capital	1,201,221	1,151,010
Accumulated other comprehensive income	44,622	31,046
Accumulated deficit	(2,674)	(61,296)

Total shareholders' equity	1,243,701	1,121,292
Total liabilities and shareholders' equity	$2,185,499	$1,966,493

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

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Product sales, net	$230,386	$174,130	$631,602	$398,585
Royalties and contract revenues	1,774	1,385	5,047	3,691
Total revenues	232,160	175,515	636,649	402,276
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	24,252	32,629	76,503	52,662
Selling, general and administrative	74,970	60,924	223,004	162,505
Research and development	12,814	6,920	32,811	13,200
Intangible asset amortization	19,564	19,742	58,518	43,444
Total operating expenses	131,600	120,215	390,836	271,811
Income from operations	100,560	55,300	245,813	130,465
Interest expense, net	(6,202)	(7,750)	(20,743)	(9,199)
Foreign currency loss	(614)	(1,099)	(728)	(1,357)
Loss on extinguishment and modification of debt	—	—	(3,749)	—
Income from continuing operations before income tax provision	93,744	46,451	220,593	119,909
Income tax provision	18,335	12,856	59,574	24,966
Income from continuing operations	75,409	33,595	161,019	94,943
Loss from discontinued operations	—	(386)	—	(6,908)
Net income	$75,409	$33,209	$161,019	$88,035
Basic income (loss) per ordinary share:				
Income from continuing operations	$1.30	$0.59	$2.76	$1.69
Loss from discontinued operations	—	(0.01)	—	(0.12)
Net income	$1.30	$0.58	$2.76	$1.57
Diluted income (loss) per ordinary share:				
Income from continuing operations	$1.23	$0.56	$2.62	$1.59
Loss from discontinued operations	—	(0.01)	—	(0.12)
Net income	$1.23	$0.55	$2.62	$1.47
Weighted-average ordinary shares used in per share computations:				
Basic	58,217	57,703	58,437	56,198
Diluted	61,519	60,883	61,532	59,846

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

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Net income	$75,409	$33,209	$161,019	$88,035
Other comprehensive income:				
Foreign currency translation adjustments	25,402	14,248	13,576	13,860
Available-for-sale securities:				
Net unrealized gain on available-for-sale securities, net of income taxes	—	—	—	8
Reclassification adjustments for gains included in earnings, net of income taxes	—	—	—	23
Other comprehensive income	25,402	14,248	13,576	13,891
Total comprehensive income	$100,811	$47,457	$174,595	$101,926
Total comprehensive income arises from:				
Continuing operations	$100,811	$47,843	$174,595	$108,834
Discontinued operations	—	(386)	—	(6,908)
Total comprehensive income	$100,811	$47,457	$174,595	$101,926

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

Table of Contents

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

	Nine Months Ended September 30,	
	2013	2012
Operating activities		
Net income	$161,019	$88,035
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization of intangible assets	58,518	51,014
Depreciation	2,065	789
Loss on disposal of property and equipment	47	146
Share-based compensation	32,139	15,151
Excess tax benefit from share-based compensation	(82)	(4,266)
Acquisition accounting inventory fair value step-up	3,143	17,822
Change in fair value of contingent consideration	12,900	1,100
Deferred income taxes	(17,962)	(8,768)
Provision for losses on accounts receivable and inventory	1,758	2,696
Loss on extinguishment and modification of debt	3,749	—
Other non-cash transactions	4,435	1,771
Changes in assets and liabilities:		
Accounts receivable	(37,649)	(17,773)
Inventories	(3,445)	1,715
Prepaid expenses and other current assets	(11,300)	(3,843)
Other long-term assets	(3,421)	(2,297)
Accounts payable	6,670	(2,543)
Accrued liabilities	1,562	(15,812)
Income taxes payable	(19,086)	28,139
Deferred revenue	(776)	(48)
Other non-current liabilities	10,125	(301)
Liability under government settlement	—	(7,320)
Net cash provided by operating activities	204,409	145,407
Investing activities		
Acquisitions, net of cash acquired	—	(542,531)
Purchases of marketable securities	—	(37,443)
Proceeds from sale of marketable securities	—	81,246
Proceeds from maturities of marketable securities	—	31,988
Acquisition of intangible assets	(1,300)	—
Purchases of property and equipment	(6,874)	(4,993)
Purchase of product rights	—	(10,750)
Net cash used in investing activities	(8,174)	(482,483)
Financing activities		
Net proceeds from issuance of debt	553,425	450,916
Proceeds from employee equity incentive and purchase plans and exercise of warrants	23,577	20,995
Share repurchases	(102,397)	—
Payment of employee withholding taxes related to share-based awards	(5,303)	(25,299)
Excess tax benefit from share-based compensation	82	4,266

Repayment of long-term debt	(464,517)	(5,938)
Net cash provided by financing activities	4,867	444,940
Effect of exchange rates on cash and cash equivalents	164	(147)
Net increase in cash and cash equivalents	201,266	107,717
Cash and cash equivalents, at beginning of period	387,196	82,076
Cash and cash equivalents, at end of period	$588,462	$189,793

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.

Table of Contents

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 and nine months ended September 30, 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.

Certain prior period amounts presented in the accompanying footnotes have been reclassified to conform to current period presentation, as described in Note 2.

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

Table of Contents

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 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.

We are continuing our efforts on various regulatory matters, including working 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, and potential modifications to this program. We are engaged in ongoing communications with the FDA with respect to our risk evaluation and mitigation strategies, or REMS, documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy. We expect that final REMS documents for Xyrem will include modifications to, and/or 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. We cannot predict whether, or on what terms, we will reach agreement with FDA on final REMS documents for Xyrem, whether we will initiate dispute resolution or other proceedings with FDA prior to finalizing the REMS documents, or, if any such proceedings are initiated, the outcome or timing thereof.

In addition, the FDA is seeking to schedule an initial meeting with us and ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). Also, we may face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any discussions with the FDA and/or any ANDA applicant with respect to the potential creation of a single shared system REMS for Xyrem, 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.

Our financial results are increasingly influenced by sales of our second largest product, Erwinaze® (asparaginase Erwinia chrysanthemi), which have continued to grow. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available through ongoing research and development activities. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of risks and uncertainties, including assuring sufficient supply of Erwinaze on a timely basis, the limited population of patients with acute lymphoblastic leukemia, or ALL, and the incidence of hypersensitivity reactions to E. coli-derived asparaginase within that population, and our need to apply for and receive marketing authorizations in certain additional countries so we can launch promotional efforts in those countries. We maintain very limited inventory of Erwinaze and, in 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. While we have been able to resolve potential supply shortages and meet product demand to date, if our continued efforts to avoid supply shortages are not successful, we could experience Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product.

In addition to risks related specifically to Xyrem and Erwinaze, we are subject to other challenges and risks specific to our business, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including: the challenges of protecting 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. Other risks and uncertainties related to our ability to execute on our strategy include: our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business; and possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents and marketable securities. Our investment policy permits investments in U.S. federal government and federal agency securities,

Table of Contents

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 September 30, 2013, five customers accounted for 88% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, which accounted for 73% of gross accounts receivable, and Accredo Health Group, Inc., or Accredo, which accounted for 7% 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 depend on single source suppliers and manufacturers for each of our products, product candidates and their active pharmaceutical ingredients.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Net Income 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):

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Numerator:				
Income from continuing operations	$75,409	$33,595	$161,019	$94,943
Loss from discontinued operations	—	(386)	—	(6,908)
Net income	$75,409	$33,209	$161,019	$88,035
Denominator:				
Weighted-average ordinary shares - basic	58,217	57,703	58,437	56,198
Dilutive effect of employee equity incentive and purchase plans	1,852	1,404	1,587	1,557
Dilutive effect of warrants	1,450	1,776	1,508	2,091
Weighted-average ordinary shares - diluted	61,519	60,883	61,532	59,846
Basic income (loss) per ordinary share:				
Income from continuing operations	$1.30	$0.59	$2.76	$1.69
Loss from discontinued operations	—	(0.01)	—	(0.12)
Net income	$1.30	$0.58	$2.76	$1.57
Diluted income (loss) per ordinary share:				
Income from continuing operations	$1.23	$0.56	$2.62	$1.59
Loss from discontinued operations	—	(0.01)	—	(0.12)
Net income	$1.23	$0.55	$2.62	$1.47

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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Options to purchase ordinary shares and RSUs	1,028	1,785	2,074	1,314

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2013-11, “Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists”, or ASU No. 2013-11, which concludes that, under certain circumstances, unrecognized tax benefits should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. ASU No. 2013-11 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 financial position.

In March 2013, the FASB issued 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.

10

Table of Contents

2. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2013	December 31, 2012
Raw materials	$4,474	$4,979
Work in process	6,523	5,410
Finished goods	13,871	16,136
Total inventories	$24,868	$26,525

Inventories of $4.2 million previously classified as raw materials as of December 31, 2012 have been reclassified to work in process to conform to current period presentation. As of September 30, 2013 and December 31, 2012, the fair value of inventories acquired included a step-up in the value of inventories of $0.8 million and $4.0 million, respectively.

3. Fair Value Measurement

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

	September 30, 2013					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	$295,970	$—	$—	$295,970	$295,970	$—
Time deposits	292,492	—	—	292,492	292,492	—
Totals	$588,462	$—	$—	$588,462	$588,462	$—

	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, net in the condensed consolidated statements of income. All available-for-sale securities held as of September 30, 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):

	September 30, 2013				December 31, 2012		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	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							

Time deposits	$—	$292,492	$—	$ 292,492	$—	$—	$ —
Money market funds	—	—	—	—	43,648	—	43,648
Totals	$—	$292,492	$—	$ 292,492	$43,648	$—	$ 43,648
Liabilities:							
Contingent consideration	$—	$—	$ 47,700	$ 47,700	$—	$ 34,800	$ 34,800

Table of Contents

As of September 30, 2013, our available-for-sale securities included time deposits and their carrying values were approximately equal to their fair values. As of December 31, 2012, our available-for-sale securities included money market funds. There were no transfers between the different levels of the fair value hierarchy in 2013 or in 2012.

As part of the EUSA Acquisition, we agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze 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	12,900
Balance at September 30, 2013	$47,700

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 September 30, 2013, the estimated fair value of the $555.8 million principal amount of our new term loans was $555.1 million and the carrying amount was $551.1 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 new term loans (Level 2). For additional information related to our new term loans, see Note 6.

4. Certain Balance Sheet Items

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

	September 30, 2013	December 31, 2012
Computer software	$7,670	$4,292
Computer equipment	5,059	3,687
Leasehold improvements	4,303	3,899
Construction-in-progress	2,638	1,135
Furniture and fixtures	1,966	1,953
Machinery and equipment	186	94
Subtotal	21,822	15,060
Less accumulated depreciation and amortization	(9,762)	(7,779)
Property and equipment, net	$12,060	$7,281

Accrued liabilities consisted of the following (in thousands):

	September 30, 2013	December 31, 2012
Rebates and other sales deductions	$37,125	$29,235
Employee compensation and benefits	26,263	24,900
Sales returns reserve	21,756	26,385
Royalties	3,139	3,271
Professional fees	1,944	2,163
Other	16,163	18,712
Total accrued liabilities	$106,390	$104,666

12

Table of Contents

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	4,223
Balance at September 30, 2013	$446,823

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

	September 30, 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	11.7	$946,595	$ (157,423)	$789,172	$930,834	$ (97,578)	$833,256
Trademarks	1.3	2,600	(2,259)	341	2,600	(2,054)	546
Total finite-lived intangible assets		949,195	(159,682)	789,513	933,434	(99,632)	833,802
Acquired IPR&D assets		34,211	—	34,211	36,150	—	36,150
Total intangible assets		$983,406	$ (159,682)	$823,724	$969,584	$ (99,632)	$869,952

Based on finite-lived intangible assets recorded as of September 30, 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)	$19,872
2014	79,284
2015	73,238
2016	68,908
2017	68,816
Thereafter	479,395
Total	$789,513

6. Long-Term Debt

Amendment of Credit Facility and Term Loan Refinancing

On June 13, 2013, Jazz Pharmaceuticals plc, as guarantor, and certain of its wholly-owned subsidiaries, as borrowers, entered into an amendment of our original credit agreement, dated as of June 12, 2012, with Barclays Bank PLC, as administrative agent, and certain other lenders.

The amended credit agreement provides for $557.2 million principal amount of new term loans and a new revolving credit facility of $200.0 million that replaced the revolving credit facility of $100.0 million provided for under the original credit agreement. We used a portion of the proceeds from the new term loans to refinance in full the outstanding term loans under the original credit agreement in an aggregate principal amount of $457.2 million, or the original term loans. The new term loans have the same June 12, 2018 maturity date that was applicable to the original term loans. Future loans under the new revolving credit facility, if any, will have the same June 12, 2017 maturity date that was applicable under the original credit agreement.

The new term loans bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 2.75% per annum (subject to a 0.75% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 1.75% per annum (subject to a 1.75% prime rate floor). Borrowings under the new revolving credit facility bear

interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 2.50% per annum, or the prime lending rate, plus an

Table of Contents

applicable margin equal to 1.50% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The new 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.

The borrowers' obligations under the amended credit agreement and any hedging or cash management obligations entered into with a lender or an affiliate of a lender are guaranteed by Jazz Pharmaceuticals plc and certain of its subsidiaries, referred to below as restricted subsidiaries, and are secured by substantially all of their assets.

We may make voluntary prepayments of principal at any time without payment of a premium, except that a 1% premium would apply to any repricing of the new term loans effected on or prior to December 13, 2013. We are required to make mandatory prepayments of the new term loans (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), (3) beginning with the fiscal year ending December 31, 2014, 50% of our excess cash flow as defined in the amended credit agreement (subject to decrease to 25% if our secured leverage ratio is equal to or less than 2.25 to 1.00 and greater than 1.25 to 1.00 or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.00), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the new term loans, which are due quarterly, began in September 2013 and are equal to 1.0% of the original principal amount with any remaining balance payable on the final maturity date. Scheduled maturities with respect to the new term loans are as follows (in thousands):

Year Ending December 31,	Scheduled New Term Loan Maturities
2013 (remainder)	$1,393
2014	5,572
2015	5,572
2016	5,572
2017	5,572
Thereafter	532,114
Total	$555,795

The amended credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to Jazz Pharmaceuticals plc and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The amended credit agreement contains a financial covenant that requires Jazz Pharmaceuticals plc and its restricted subsidiaries to maintain a maximum secured leverage ratio. We are currently in compliance with our financial covenants.

The refinancing of the original term loans involved multiple lenders who were considered members of a loan syndicate. In determining whether the refinancing was to be accounted for as a debt extinguishment or modification, we considered whether the creditors remained the same or changed and whether the change in debt terms was substantial. The debt terms were considered substantially different if the present value of the cash flows of the new term loans was at least 10% different from the present value of the remaining cash flows of the original term loans, or the 10% Test. We performed a separate 10% Test for each individual creditor participating in the loan syndication. The loans of creditors who did not participate in the amended credit agreement were accounted for as a debt extinguishment. When there was a change in principal balance for individual creditors, in applying the 10% Test, we used the cash flows related to the lowest common principal balance, or the Net Method. Under the Net Method, any principal in excess of a creditor's reinvested principal balance was treated as a new, separate debt issuance, and any decrease in principal was treated as a partial extinguishment of debt.

For debt considered to be extinguished, the unamortized deferred financing costs and unamortized original issue discount associated with the extinguished debt were expensed. For debt considered to be modified, the unamortized deferred financing costs and unamortized original issue discount associated with the modified debt continue to be

amortized, new creditor fees were capitalized and new third party fees were expensed. For new creditors, new creditor fees and new third party fees were capitalized. Deferred financing costs of $11.7 million and an original issue discount of $4.9 million were associated with modified and new debt and will be amortized to interest expense using the interest method over the life of the new term loans.

As the borrowing capacity relating to each creditor under the new revolving credit facility was greater than that under the original revolving credit facility, unamortized deferred financing costs, new creditor fees and new third party fees, totaling $4.7 million, were associated with the new arrangement and were deferred and are being amortized to interest expense on a straight-line basis over the life of the facility. We did not borrow under the original revolving credit facility and, as of September 30,

Table of Contents

2013, we had not borrowed under the new revolving credit facility.

The refinancing resulted in a $3.7 million charge in the nine months ended September 30, 2013, which was comprised of $2.7 million related to the expensing of unamortized deferred financing costs and unamortized original issue discount associated with extinguished debt and $1.0 million related to new third party fees associated with modified debt.

As of September 30, 2013, the interest rate on the new term loans was 3.5%. Interest expense associated with the new term loans is recorded using the interest method and includes non-cash interest related to the amortization of the debt discount and debt issuance costs. As of September 30, 2013, the effective interest rate on the new term loans was 4.3%. As of September 30, 2013, the current portion of the carrying amount of the new term loans was $5.6 million and the non-current portion was $545.6 million.

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

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 September 30, 2013 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2013 (remainder)	$2,391
2014	9,496
2015	8,832
2016	5,404
2017	2,606
Thereafter	163
Total	$28,892

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.

As of September 30, 2013, we had $68.1 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

Table of Contents

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 additional 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 current scheduling order, fact discovery concerning the '650 and '275 patents will remain open until November 2013, and expert discovery involving all ten of the patents involved in the consolidated case will close in May 2014. Although no trial date for the consolidated case has been scheduled, based on the current 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 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 September 30, 2013, we received a Paragraph IV Certification from Roxane alleging that a tenth patent listed in the Orange Book for Xyrem would not be infringed by Roxane's proposed generic product.

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. On August 2, 2013 we received a Paragraph IV Certification alleging that a tenth patent listed in the Orange Book for Xyrem would not be infringed by Amneal's proposed generic product. On September 12, 2013, we filed a lawsuit against Amneal alleging infringement of this patent as well as another issued patent which is not listed in the Orange Book. 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 continue to evaluate 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

Table of Contents

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 lawsuits. In May 2013, a decision was issued by the U.S. Patent and Trademark Office, or the USPTO, in one of the two reexamination proceedings, which held certain claims patentable, and there was no appeal of this decision. The second reexamination proceeding is still ongoing. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the timing or outcome of the second reexamination proceeding, 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.

Table of Contents

8. Shareholders' Equity

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

	Nine Months Ended September 30, 2013		Nine Months Ended September 30, 2012	
	Shares	Cash	Shares	Cash
Proceeds from employee equity incentive and purchase plans and warrant exercises	1,448	$23,577	2,943	$20,994
Share repurchases	(1,449)	(102,397)	—	—
Employee withholding taxes related to share-based awards (1)	—	(5,303)	—	(25,299)
Azur Merger	—	—	12,360	—
Directors' deferred compensation plan	—	—	45	—
Totals	(1)	$(84,123)	15,348	$(4,305)

(1) During the nine months ended September 30, 2013, we paid $5.3 million of income tax withholdings on behalf of employees related to the net share settlement of vested RSUs. During the nine months ended September 30, 2012, we 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.

Share Repurchase Program

In May 2013, our board of directors authorized a share repurchase program pursuant to which we may repurchase a number of ordinary shares having an aggregate repurchase price of up to $200 million, exclusive of any brokerage commissions. The authorization became effective immediately and has no set expiration date. Under this authorization, we may repurchase our ordinary shares through open market purchases, privately negotiated purchases or a combination of these transactions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the amended credit agreement, corporate and regulatory requirements and market conditions. Share repurchases may be suspended or discontinued at any time without prior notice. We initiated purchases under this program in May 2013. In the three months ended September 30, 2013, we spent a total of $48.8 million to repurchase 0.6 million of our ordinary shares at an average total purchase price, including commissions, of $80.91 per share. In the nine months ended September 30, 2013, we spent a total of $102.4 million to repurchase 1.4 million of our ordinary shares at an average total purchase price, including commissions, of $70.64 per share. All ordinary shares repurchased by the company were canceled. As of September 30, 2013, the remaining amount authorized under the share repurchase program was $97.6 million.

Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income as of September 30, 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 income	13,576	13,576
Balance at September 30, 2013	$44,622	$44,622

During the nine months ended September 30, 2013, other comprehensive income reflects foreign currency translation adjustments which are primarily due to the strengthening of the Euro against the U.S. dollar.

Additional Paid-in Capital

In April 2013, the Irish High Court approved a $1.6 billion reduction of the share premium account of Jazz Pharmaceuticals plc to offset its accumulated deficit, with the resulting reserve to be treated as distributable reserves of our

Table of Contents

parent company. This transaction impacted our parent company balance sheet only and had no impact on our U.S. GAAP consolidated balance sheet.

9. Share-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Selling, general and administrative	$9,354	$5,330	$25,898	$11,967
Research and development	1,931	681	4,453	1,718
Cost of product sales	591	344	1,788	999
Total share-based compensation expense, pre-tax	11,876	6,355	32,139	14,684
Tax benefit from share-based compensation expense	(3,502)	—	(9,850)	—
Total share-based compensation expense, net of tax	$8,374	$6,355	$22,289	$14,684

Share Options

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Shares underlying options granted (in thousands)	105	1,157	1,277	2,077
Grant date fair value	$37.17	$23.13	$28.49	$25.23
Black-Scholes option pricing model assumption information:				
Volatility	57%	64%	59%	64%
Expected term (years)	4.4	4.2	4.4	4.6
Range of risk-free rates	1.0-1.4%	0.5-0.6%	0.5-1.4%	0.5-1.1%
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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
RSUs granted (in thousands)	46	550	568	1,002
Grant date fair value	$80.35	$46.83	$60.73	$48.98

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 RSUs is recognized as expense ratably over the vesting period of four years.

As of September 30, 2013, compensation cost not yet recognized related to unvested share options and RSUs was $58.3 million and $46.3 million, respectively, which is expected to be recognized over a weighted-average period of 2.7 years and 3.0 years, respectively.

10. 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

19

Table of Contents

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

11. 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Xyrem® (sodium oxybate) oral solution	$153,664	$102,615	$404,932	$265,149
Erwinaze® (asparaginase Erwinia chrysanthemi)/Erwinase®	44,078	31,652	130,754	37,660
Prialt® (ziconotide) intrathecal infusion	11,046	5,413	20,726	20,491
Psychiatry	10,679	21,032	40,093	58,518
Other	10,919	13,418	35,097	16,767
Product sales, net	230,386	174,130	631,602	398,585
Royalties and contract revenues	1,774	1,385	5,047	3,691
Total revenues	$232,160	$175,515	$636,649	$402,276

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
United States	$209,299	$159,947	$577,484	$375,658
Europe	19,332	12,164	46,769	21,252
All other	3,529	3,404	12,396	5,366
Total revenues	$232,160	$175,515	$636,649	$402,276

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Express Scripts	66 %	58 %	63 %	66 %
Accredo	16 %	14 %	17 %	7 %

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

	September 30, 2013	December 31, 2012
Ireland	$4,057	$2,437
United States	7,394	4,451
Other	609	393
Total long-lived assets (1)	$12,060	$7,281

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

20

Table of Contents

12. Restructuring

Termination Benefits

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 incurred costs of severance for terminated employees as well as retention bonus costs for certain employees retained to assist with the transition process which was completed in June 2013. The one-time termination benefits were recorded over the remaining service period where employees were required to stay through their termination date to receive the benefits. We recorded costs related to these one-time termination benefits of $1.0 million in the nine months ended September 30, 2013 and $2.2 million in the nine months ended September 30, 2012, which are recorded within selling, general and administrative expenses in our condensed consolidated statements of income. To date, we have incurred one-time termination benefit costs under this plan of $3.8 million. We do not expect to incur any additional one-time termination benefit costs in connection with this plan.

Facility Closure Costs

In connection with our restructuring plan, we vacated our Langhorne, Pennsylvania facility in June 2013. We incurred facility closure costs of $0.4 million in the nine months ended September 30, 2013 for the remaining operating lease obligations related to this facility, net of estimated sublease rentals that could be reasonably obtained. Facility closure costs are recorded within selling, general and administrative expenses in our condensed consolidated statements of income. We do not expect to incur any additional facility closure costs in connection with this plan.

The following table summarizes the amounts related to restructuring for the nine months ended September 30, 2013 (in thousands):

	Termination Benefits	Facility Closure Costs	Total
Balance at December 31, 2012	$1,227	$—	$1,227
Costs incurred during the period	1,045	412	1,457
Cash payments	(2,272)	(104)	(2,376)
Balance at September 30, 2013	$—	$308	$308

The balance at September 30, 2013 was included within accrued liabilities in our condensed consolidated balance sheet.

13. 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 September 30, 2012	Nine Months Ended September 30, 2012
Product sales, net	$8,086	$19,277
Loss from discontinued operations (1)	$(386)	$(6,908)

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

Table of Contents

14. Income Taxes

Our income tax provision was $18.3 million and $59.6 million for the three and nine months ended September 30, 2013, respectively, compared to $12.9 million and $25.0 million for the same periods in 2012. Our effective tax rate from continuing operations was 19.6% and 27.0% for the three and nine months ended September 30, 2013, respectively, compared to 27.7% and 20.8% for the same periods in 2012. The decrease in the effective tax rate for the three months ended September 30, 2013 compared to the same period in 2012 was primarily due to estimated changes in the profit mix among the various tax jurisdictions in which we operate as well as higher taxes in 2012 related to acquisition restructuring. The increase in the effective tax rate for the nine months ended September 30, 2013 compared to the same period in 2012 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 rates for the 2013 periods were 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. Our income tax provision reflects our estimate of the effective tax rate expected to be applicable for the full year and we re-evaluate this estimate each quarter based on our forecasted tax expense for the full year. 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 all of our tax years remain open to federal, state, and foreign tax examination. Certain of our subsidiaries are currently under examination by the U.S. Internal Revenue Service and by the French tax authorities.

Table of Contents

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that could impact our business. In particular, we encourage you to review the risks and uncertainties described in 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 in the first nine months of 2013. In the three and nine months ended September 30, 2013, our total net product sales increased by 32% and 58%, respectively, compared to the same periods in 2012. Sales of our lead product, Xyrem® (sodium oxybate) oral solution, increased 50% and 53% in the three and nine months ended September 30, 2013, respectively, compared to the same periods in 2012. Sales of Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in markets outside the United States, increased by 39% in the three months ended September 30, 2013 compared to the same period in 2012, and by 34%, on a pro forma basis, in the nine months ended September 30, 2013 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.

In addition, in May 2013 we initiated purchases under a share repurchase program for up to $200 million of our ordinary shares. As of September 30, 2013, we had spent a total of $102.4 million to repurchase our ordinary shares under this program. For a more detailed discussion regarding our share repurchase program, see "Liquidity and Capital Resources" below.

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, a treatment for patients with 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 HD orally disintegrating clozapine tablets indicated for treatment-resistant schizophrenia. 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 plan to launch Versacloz in the first quarter of 2014.

Table of Contents

We also commercialize 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).

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 700 employees in thirteen countries in October 2013. 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.

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. The first is a clinical trial evaluating the intravenous administration of Erwinaze in North America, which has completed enrollment. Based on data collected in the study, which met the primary end point, we have recently submitted an amendment to the Erwinaze biological license application to the FDA to allow intravenous administration of Erwinaze. The second is 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. We have identified a principal investigator for this study, are working with the investigator to finalize the study protocol and will begin the process of identifying and recruiting global study sites.
- Development programs for two clinical product candidates. We are conducting a Phase 1 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. In June 2013, the FDA granted Fast Track designation to the investigation of Asparec for ALL. The Fast Track program is designed to enable more frequent interactions with the FDA during drug development and to expedite the FDA's review of a new drug candidate. We are working with investigators and will be reviewing our plans with the FDA for our first study of Asparec in children. We are also conducting our Phase 3 clinical trial in Europe of Leukotac (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease.
- Pre-clinical research and development work on JZP-386, a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem. We licensed JZP-386 from Concert Pharmaceuticals, Inc. in February 2013, for potential use in patients with narcolepsy. We plan to make a regulatory filing by the end of 2013 that, if approved, would allow the first study of JZP-386 in humans.

Our research and development expenses will be higher in 2013 compared to 2012 due to an increase in development activities and due to the inclusion of a full year of expense from the acquired EUSA Pharma business.

During the remainder of 2013, we intend to continue to focus on executing our business strategy. 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 67% and 64% of our net product sales in the three and nine months ended September 30, 2013, respectively, 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 efforts on various regulatory matters, including working with the FDA on updated documents that we have submitted to the FDA on our Xyrem Risk Management Program, and potential modifications to this program. The updated documents are intended to conform to current formatting requirements for a REMS required by law, as well as to make other updates to the program and its documentation. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy. We expect that final REMS documents for Xyrem will include modifications to, and/or 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

Table of Contents

expensive for us to distribute Xyrem, make it easier for future generic competitors to enter the market and/or negatively affect sales of Xyrem. We cannot predict whether, or on what terms, we will reach agreement with FDA on final REMS documents for Xyrem, whether we will initiate dispute resolution or other proceedings with FDA prior to finalizing the REMS documents, or, if any such proceedings are initiated, the outcome or timing thereof. In addition, the FDA is seeking to schedule an initial meeting with us and ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). Also, we may face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any discussions with the FDA and/or any ANDA applicant with respect to the potential creation of a single shared system REMS for Xyrem, 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.

Our financial results are increasingly influenced by sales of our second largest product, Erwinaze, which have continued to grow. Sales of Erwinaze/Erwinase accounted for 19% and 21% of our net product sales in the three and nine months ended September 30, 2013, respectively. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available through ongoing research and development activities. However, our ability to successfully and sustainably grow sales of Erwinaze 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, a key challenge to our ability to maintain the current sales level and continue to increase sales is our need to assure sufficient supply of Erwinaze on a timely basis. We maintain very limited inventory of Erwinaze and, in 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. While we have been able to resolve potential supply shortages and meet product demand to date, if our continued efforts to avoid supply shortages are not successful, we could experience Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. In addition, while we continue to work with the manufacturer of Erwinaze to evaluate potential steps to increase the supply of Erwinaze over the longer term to address expected growing worldwide demand, our ability to increase sales of Erwinaze may be limited by our ability to obtain an increased supply of the product.

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 and Erwinaze, 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;
- 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;
- the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval;
- our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business; and
- possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

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.

Table of Contents

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 for the 2012 periods. The following table presents revenues and expenses from continuing operations for the three and nine months ended September 30, 2013 and 2012, respectively (amounts in thousands):

	Three Months Ended September 30,		Increase/ (Decrease)		Nine Months Ended September 30,		Increase/ (Decrease)	
	2013	2012 (1)			2013	2012 (1)		
Product sales, net	$230,386	$174,130	32	%	$631,602	$398,585	58	%
Royalties and contract revenues	1,774	1,385	28	%	5,047	3,691	37	%
Cost of product sales (excluding amortization of acquired developed technologies)	24,252	32,629	(26	)%	76,503	52,662	45	%
Selling, general and administrative	74,970	60,924	23	%	223,004	162,505	37	%
Research and development	12,814	6,920	85	%	32,811	13,200	149	%
Intangible asset amortization	19,564	19,742	(1	)%	58,518	43,444	35	%
Interest expense, net	6,202	7,750	(20	)%	20,743	9,199	125	%
Foreign currency loss	614	1,099	(44	)%	728	1,357	(46	)%
Loss on extinguishment and modification of debt	—	—	N/A(2)		3,749	—	N/A(2)	
Income tax provision	18,335	12,856	43	%	59,574	24,966	139	%

(1) Our financial results include the financial results of the historic Azur Pharma and EUSA Pharma businesses since the completion of the Azur Merger on January 18, 2012 and the EUSA Acquisition on June 12, 2012.

(2) Comparison to prior period is not meaningful.

Revenues

The following table presents product sales, royalties and contract revenues, and total revenues for the three and nine months ended September 30, 2013 and 2012, respectively (amounts in thousands):

	Three Months Ended September 30,		Increase/ (Decrease)		Nine Months Ended September 30,		Increase/ (Decrease)	
	2013	2012			2013	2012		
Xyrem	$153,664	$102,615	50	%	$404,932	$265,149	53	%
Erwinaze/Erwinase	44,078	31,652	39	%	130,754	37,660	247	%
Prialt	11,046	5,413	104	%	20,726	20,491	1	%
Psychiatry	10,679	21,032	(49	)%	40,093	58,518	(31	)%
Other	10,919	13,418	(19	)%	35,097	16,767	109	%
Product sales, net	230,386	174,130	32	%	631,602	398,585	58	%
Royalties and contract revenues	1,774	1,385	28	%	5,047	3,691	37	%
Total revenues	$232,160	$175,515	32	%	$636,649	$402,276	58	%

Product Sales, Net

Xyrem product sales increased in the three and nine months ended September 30, 2013 compared to the same periods in 2012, primarily due to a higher average net selling price in the 2013 periods and, to a lesser extent, increases in sales volume. Price increases were instituted in 2012, February 2013 and July 2013 based on market analysis. Xyrem product sales volumes increased by 13% in both the three and nine months ended September 30, 2013 compared to the same periods in 2012. The sales volume increases were 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. In addition, we have seen higher growth in sales volume from new or previously infrequent physician prescribers who treat narcolepsy. We acquired

Table of Contents

Erwinaze/Erwinase in the EUSA Acquisition in June 2012. Erwinaze/Erwinase product sales increased by 39% in the three months ended September 30, 2013 compared to the same period in 2012, primarily due to an increase in sales volume. Erwinaze/Erwinase product sales increased in the nine months ended September 30, 2013 compared to the same period in 2012, primarily due to the inclusion of product sales for the full reporting period in 2013. On a pro forma basis, Erwinaze/Erwinase product sales increased by 34% in the nine months ended September 30, 2013 compared to the same period in 2012, primarily due to an increase in sales volume. The sales volume increases in both periods were driven primarily by a growth in new treatment sites prescribing Erwinaze as well as existing treatment sites identifying additional ALL patients with hypersensitivity to E. coli-derived asparaginase. Prialt product sales increased in the three months ended September 30, 2013 compared to the same period in 2012, primarily due to a $5.7 million sale to our European distributor in the three months ended September 30, 2013. During 2012, the sale to our European distributor occurred during the three months ended March 31, 2012. Psychiatry product sales decreased in the three and nine months ended September 30, 2013 compared to the same periods in 2012, primarily due to the launch of a generic version of Luvox CR in March 2013 and, to a lesser extent, the continued impact of the sale of the authorized generic product for FazaClo LD. Total product sales will be higher in 2013 than in 2012 primarily due to growth in sales of Xyrem and Erwinaze, partially offset by decreases in sales of some of our other products.

Royalties and Contract Revenues

Royalties and contract revenues increased in the nine months ended September 30, 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 decreased in the three months ended September 30, 2013 compared to the same period in 2012 due to a decrease in acquisition accounting inventory fair value step-up adjustments of $9.8 million. Cost of product sales increased in the nine months ended September 30, 2013 compared to the same period in 2012, primarily due to increased sales, partially offset by a decrease in acquisition accounting inventory fair value step-up adjustments of $11.5 million. Gross margin as a percentage of net product sales was 89.5% and 87.9% in the three and nine months ended September 30, 2013, respectively, compared to 81.3% and 86.8% for the same periods in 2012, respectively. The increase in our gross margin percentages was primarily due to a decrease in acquisition accounting inventory fair value step-up adjustments of $9.8 million and $11.5 million in the three and nine months ended September 30, 2013, respectively, compared to the same periods 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three and nine months ended September 30, 2013 compared to the same periods in 2012, primarily due to increases in salary and benefit related expenses (including share-based compensation expense) of $6.9 million and $37.1 million, respectively, driven primarily by the expansion of our business; increases in the change in fair value of the contingent consideration payable of $4.1 million and $11.8 million, respectively; increases in sales and promotional expenses of $1.8 million and $9.5 million, respectively; and increases in facility and maintenance expenses of $1.5 million and $6.0 million, respectively; partially offset by decreases in transaction, integration and restructuring expenses of $3.0 million and $16.6 million, respectively. 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.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Personnel expenses	$5,989	$3,083	$15,328	$6,567
Clinical studies and outside services	5,908	3,394	15,142	5,741
Other	917	443	2,341	892
Total	$12,814	$6,920	$32,811	$13,200

Research and development expenses increased in the three and nine months ended September 30, 2013 compared to the same periods in 2012 by $5.9 million and $19.6 million, respectively, primarily due to increased clinical studies and outside services costs of $2.5 million and $9.4 million, respectively, and increased personnel expenses of $2.9 million and $8.8 million, respectively. Clinical studies and outside services expenses in the three and nine months ended September 30, 2013 included upfront license fees of $1.0 million and $5.0 million, respectively, with no similar expense in the same periods in 2012. Clinical studies and outside services costs increased in the three and nine months ended September 30, 2013 compared to the same periods in 2012, primarily due to an increase in costs incurred to develop new product candidates that we acquired in the EUSA Acquisition.

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. Amortization expense for the three months ended September 30, 2013 was consistent with that in the same period in 2012. The increase in amortization expense in the nine months ended September 30, 2013 compared to the same period in 2012 was primarily due to amortization relating to the intangible assets acquired in the EUSA Acquisition. Amortization expense will be higher in 2013 than in 2012 due to the inclusion of a full year of amortization expense related to the intangible assets we acquired in the EUSA Acquisition.

Interest Expense, Net

Interest expense, net was lower in the three months ended September 30, 2013 compared to the same period in 2012 due to a decrease in interest rates associated with our long-term debt, partially offset by an increase in the principal balance outstanding. Interest expense, net was higher in the nine months ended September 30, 2013 compared to the same period in 2012 due to the inclusion of interest expense in 2013 on the original term loans we obtained under the original credit agreement in June 2012. We amended the credit agreement and refinanced the original term loans in June 2013. As of September 30, 2013, $555.8 million principal amount was outstanding on our new term loans under the amended credit agreement and the interest rate on the new term loans was 3.5%. Interest expense will be higher in 2013 than in 2012 due to a higher average debt balance.

Foreign Currency Loss

Foreign currency loss in the three and nine months ended September 30, 2013 related to the translation of foreign currency net monetary assets, including intercompany balances.

Loss on Extinguishment and Modification of Debt

We recorded a loss of $3.7 million in the nine months ended September 30, 2013 in connection with the refinancing of the original term loans, which was comprised of $2.7 million related to the expensing of unamortized deferred financing costs and unamortized original issue discount associated with extinguished debt and $1.0 million related to new third party fees associated with modified debt.

Table of Contents

Income Tax Provision

Our income tax provision was $18.3 million and $59.6 million for the three and nine months ended September 30, 2013, respectively, compared to $12.9 million and $25.0 million for the same periods in 2012. Our effective tax rate from continuing operations was 19.6% and 27.0% for the three and nine months ended September 30, 2013 compared to 27.7% and 20.8% for the same periods in 2012. The decrease in the effective tax rate for the three months ended September 30, 2013 compared to the same period in 2012 was primarily due to estimated changes in the profit mix among the various tax jurisdictions in which we operate as well as higher taxes in 2012 related to acquisition restructuring. The increase in the effective tax rate for the nine months ended September 30, 2013 compared to the same period in 2012 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 rates for the 2013 periods were 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. Our income tax provision reflects our estimate of the effective tax rate expected to be applicable for the full year and we re-evaluate this estimate each quarter based on our forecasted tax expense for the full year. 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 September 30, 2012	Nine Months Ended September 30, 2012
Product sales, net	$8,086	$19,277
Loss from discontinued operations (1)	$(386)	$(6,908)

(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, also referred to as adjusted or non-GAAP adjusted, financial measures as shown in the table and footnotes below. We believe that each of these non-GAAP financial measures is 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 financial measures. In addition, we believe that the presentation of these non-GAAP financial measures is useful to investors because it enhances the ability of investors to compare our results from period to period and allows for greater transparency with respect to key financial metrics we use in making operating decisions, and also because our investors and analysts regularly use them to model and track our financial performance. Investors should note that these non-GAAP financial measures are not prepared under any comprehensive set of accounting rules or principles and do not reflect all of the amounts associated with our results of operations as determined in accordance with GAAP. Investors should also note that these non-GAAP financial measures have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. In addition, from time to time in the future there may be other items that we may exclude for the purposes

of our non-GAAP financial measures; likewise, we may in the future cease to exclude items that we have historically excluded for the purpose of our non-GAAP financial measures. Because of the non-standardized definitions, the non-GAAP financial measures used 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 GAAP income from continuing operations, as applicable, 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 expense, loss on extinguishment and modification of debt and other non-cash expense, and adjust the income tax provision to the estimated amount of taxes payable in cash.

Table of Contents

Reconciliations of GAAP reported income from continuing operations to non-GAAP adjusted net income and related per share amounts are as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
GAAP reported income from continuing operations	$75,409	$33,595	$161,019	$94,943
Intangible asset amortization	19,564	19,742	58,518	43,444
Share-based compensation expense	11,876	6,355	32,139	14,684
Acquisition accounting inventory fair value step-up	512	10,336	3,143	14,676
Transaction and integration costs	113	1,503	1,846	17,692
Restructuring charges	—	1,633	1,457	2,180
Change in fair value of contingent consideration	5,000	900	12,900	1,100
Upfront license fees	988	—	4,988	—
Depreciation	895	—	2,065	—
Loss on extinguishment and modification of debt	—	—	3,749	—
Other non-cash expense	1,083	1,261	3,505	1,569
Income tax adjustments (1)	(6,043)	3,263	(3,198)	6,160
Non-GAAP adjusted net income (2)	$109,397	$78,588	$282,131	$196,448
GAAP reported income from continuing operations per diluted share	$1.23	$0.56	$2.62	$1.59
Non-GAAP adjusted net income per diluted share (2)	$1.78	$1.29	$4.59	$3.28
Shares used in computing GAAP reported income from continuing operations and non-GAAP adjusted net income per diluted share amounts	61,519	60,883	61,532	59,846

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

(2) Non-GAAP adjusted net income and non-GAAP adjusted net income per diluted share in the table above exclude the impact of discontinued operations.

Liquidity and Capital Resources

As of September 30, 2013, we had cash and cash equivalents of $588.5 million and borrowing availability under the revolving credit facility of $200.0 million. We generated cash flows from operations of $204.4 million during the nine months ended September 30, 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, to fund our share repurchase program and to meet our existing obligations for the foreseeable future, including our obligations under the amended 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.

On June 13, 2013, Jazz Pharmaceuticals plc, as guarantor, and certain of its wholly-owned subsidiaries, as borrowers, entered into an amendment of our original credit agreement, dated as of June 12, 2012, with Barclays Bank PLC, as

Table of Contents

administrative agent, and certain other lenders.

The amended credit agreement provides for $557.2 million principal amount of new term loans and a revolving credit facility of $200.0 million that replaced the revolving credit facility of $100.0 million provided for under the original credit agreement. We used a portion of the proceeds from the new term loans to refinance in full the outstanding term loans under the original credit agreement in an aggregate principal amount of $457.2 million. We expect that the remaining proceeds from the new term loans and the proceeds from future loans under the revolving credit facility, if any, will be used for general corporate purposes, including business development activities. The new term loans have the same June 12, 2018 maturity date that was applicable to the original term loans. Future loans under the new revolving credit facility, if any, will have the same June 12, 2017 maturity date that was applicable under the original credit agreement.

The new term loans bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 2.75% per annum (subject to a 0.75% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 1.75% per annum (subject to a 1.75% prime rate floor). Borrowings under the new revolving credit facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 2.50% per annum, or the prime lending rate, plus an applicable margin equal to 1.50% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The new 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 may make voluntary prepayments of principal at any time without payment of a premium, except that a 1% premium would apply to any repricing of the new term loans effected on or prior to December 13, 2013. We are required to make mandatory prepayments of the new term loans (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), (3) beginning with the fiscal year ending December 31, 2014, 50% of our excess cash flow as defined in the amended credit agreement (subject to decrease to 25% if our secured leverage ratio is equal to or less than 2.25 to 1.00 and greater than 1.25 to 1.00 or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.00), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the new term loans, which are due quarterly, began in September 2013 and are equal to 1.0% of the original principal amount with any remaining balance payable on the final maturity date.

We had not borrowed under the original revolving credit facility and, as of September 30, 2013, we had not borrowed under the new revolving credit facility. As of September 30, 2013, the interest rate on the new term loans was 3.5%.

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. The credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to us, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement contains a financial covenant that requires us to maintain a maximum secured leverage ratio. 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 expansion of 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 again 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.

In May 2013, our board of directors authorized a share repurchase program pursuant to which we may repurchase a number of ordinary shares having an aggregate repurchase price of up to $200 million, exclusive of any brokerage commissions. The authorization became effective immediately and has no set expiration date. Under this authorization, we

Table of Contents

may repurchase our ordinary shares through open market purchases, privately negotiated purchases or a combination of these transactions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the amended credit agreement, corporate and regulatory requirements and market conditions. Share repurchases may be suspended or discontinued at any time without prior notice. We initiated purchases under this program in May 2013. In the nine months ended September 30, 2013, we spent a total of $102.4 million to repurchase 1.4 million of our ordinary shares at an average total purchase price, including commissions, of $70.64 per share. All ordinary shares repurchased by the company were canceled. As of September 30, 2013, the remaining amount authorized under the share repurchase program was $97.6 million.

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

	Nine Months Ended September 30,	
	2013	2012
Net cash provided by operating activities	$204,409	$145,407
Net cash used in investing activities	(8,174)	(482,483)
Net cash provided by financing activities	4,867	444,940
Effect of foreign currency exchange rates on cash and cash equivalents	164	(147)
Net increase in cash and cash equivalents	$201,266	$107,717

Net cash provided by operating activities of $204.4 million for the nine months ended September 30, 2013 related to net income of $161.0 million, adjusted for non-cash items of $100.7 million primarily related to intangible asset amortization, share-based compensation expense and the change in fair value of contingent consideration. This was partially offset by $57.3 million of net cash outflow related to changes in operating assets and liabilities which included an increase in accounts receivable of $37.6 million primarily related to a pre-negotiated change in payment terms under a long-term contract with one large customer in connection with the elimination of a prompt pay discount as well as the impact of income tax payments. The revised payment terms will continue to result in higher accounts receivable balances in future periods that will reduce net cash from operating activities in those periods. However, we do not anticipate that the change in payment terms will result in potential collectability difficulties nor do we expect that the change will materially impact our liquidity. Net cash provided by operating activities of $145.4 million for the nine months ended September 30, 2012 related to net income of $88.0 million, adjusted for non-cash items of $77.5 million primarily related to intangible asset amortization, acquisition accounting inventory fair value step-up adjustments and share-based compensation expense. This was partially offset by $20.1 million of net cash outflow related to changes in operating assets and liabilities.

Net cash used in investing activities for the nine months ended September 30, 2013 related to purchases of property and equipment and acquisition of intangible assets. Net cash used in investing activities for the nine months ended September 30, 2012 primarily related to funding the EUSA Acquisition, partially offset by net proceeds from the sales and maturities of investments of $75.8 million.

Net cash provided by financing activities for the nine months ended September 30, 2013 primarily related to net proceeds of $553.4 million from our new term loans and proceeds of $23.6 million from employee equity incentive and purchase plans and exercise of warrants, partially offset by repayments totaling $464.5 million for the full principal amount outstanding under the original term loans and $102.4 million used to repurchase our ordinary shares under our share repurchase program. Net cash provided by financing activities for the nine months ended September 30, 2012 primarily related to net proceeds of $450.9 million from the original term loans and proceeds of $21.0 million from employee equity incentive and purchase plans and exercise of warrants, partially offset by 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.

Table of Contents

Contractual Obligations

The table below presents a summary of our contractual obligations as of September 30, 2013 (in thousands):

	Payments Due By Period				
Contractual Obligations (1)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Term loans—principal (2)	$555,795	$5,572	$11,144	$539,079	$—
Term loans—interest (2)	90,656	19,649	38,757	32,250	—
Purchase obligations (3)	71,205	68,055	1,590	400	1,160
Operating lease obligations (4)	28,892	9,441	15,706	3,704	41
Revolving credit facility (5)	2,814	760	1,523	531	—
Contingent consideration obligation (6)	50,000	50,000	—	—	—
Total	$799,362	$153,477	$68,720	$575,964	$1,201

(1) 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 $290 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.

(2) In June 2013, we entered into an amendment of our original credit agreement that provides for new term loans in an aggregate principal amount of $557.2 million, which mature in June 2018, and a $200.0 million revolving credit facility, which matures in June 2017. In June 2013, we borrowed $557.2 million under the new term loans. The interest rate was 3.5% at September 30, 2013, which we used to estimate interest owed on the new term loans until the final maturity date. In September 2013, we made our first principal repayment of $1.4 million.

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

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

(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 0.375% and assumed undrawn amounts of $200.0 million to estimate commitment fees owed. No amount was borrowed under the revolving credit facility as of September 30, 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 September 30, 2013 was $47.7 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 twelve months.

Critical Accounting Estimates

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect

the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in determining the amounts to be deducted from gross revenues, in particular estimates of government rebates, which include Medicaid and TRICARE rebates, and estimated product returns. Significant estimates and assumptions are also required to determine whether to capitalize intangible assets, the amortization periods for identifiable intangible assets, the potential impairment of goodwill and other intangible assets, income taxes, 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.

Table of Contents

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," "believ "estimate," "project," "predict," "propose," "intend," "continue," "potential," "possible," "foreseeable," "likely" and similar ex 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 nine months ended September 30, 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.

Interest Rate Risk. In June 2013, we entered into an amended credit agreement that provides for $557.2 million principal amount of new term loans and a revolving credit facility of $200.0 million. We used a portion of the new term loans to refinance in full the outstanding term loans under our original credit agreement in an aggregate principal amount of $457.2 million. We are exposed to risks associated with changes in interest rates in connection with our new term loans. Our indebtedness outstanding under our new term loans is subject to a LIBOR floor of 0.75%. Currently LIBOR rates are below the floor of 0.75%, and therefore an increase in interest rates would only impact our net interest expense to the extent it exceeds the floor. Based on variable rate debt levels of $555.8 million as of September 30, 2013, a 1.0% change in interest rates, above the LIBOR floor, would increase net interest expense for the remainder of 2013 by approximately $1.4 million.

Item 4. Controls and Procedures

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

Table of Contents

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. There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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 additional 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 current scheduling order, fact discovery concerning the '650 and '275 patents will remain open until November 2013, and expert discovery involving all ten of the patents involved in the consolidated case will close in May 2014. Although no trial date for the consolidated case has been scheduled, based on the current 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 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 September 30, 2013, we received a Paragraph IV Certification from Roxane alleging that a tenth patent listed in the Orange Book for Xyrem would not be infringed by Roxane's proposed generic product.

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. On August 2, 2013 we received a Paragraph IV Certification alleging that a tenth patent listed in the Orange Book for Xyrem would not be infringed by Amneal's proposed generic product. On September 12, 2013, we filed a lawsuit against Amneal alleging infringement of this patent as well as another issued patent which is not listed in the Orange Book. 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

Table of Contents

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 continue to evaluate 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® (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 lawsuits. In May 2013, a decision was issued by the U.S. Patent and Trademark Office, or the USPTO, in one of the two reexamination proceedings, which held certain claims patentable, and there was no appeal of this decision. The second reexamination proceeding is still ongoing. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the timing or outcome of the second reexamination proceeding, 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,

Table of Contents

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.

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 67% of our net product sales for the three months ended September 30, 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 July 2013, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

In addition to other risks described herein, our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, the most important of which are discussed 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, 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, before applicable ongoing patent litigation is concluded, to launch generic competition to Xyrem 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

Table of Contents

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 deadlines for the consolidated case. Although no trial date for the consolidated case has been scheduled, based on the current 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 continue to evaluate 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, 2013 and 2014, our supplier has

been allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. Consequently, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In addition, our supplier was initially allocated only a portion of the quota it requested for 2013 to make the active pharmaceutical ingredient of Xyrem. Similarly, our finished product manufacturer for Xyrem was initially allocated only a portion of the quota it requested to make finished product. As a result, both our active pharmaceutical ingredient supplier and our finished product manufacturer had to request and justify increased quotas from the DEA for 2013 earlier this year. While we believe that both our active pharmaceutical ingredient supplier and our finished product manufacturer have now obtained sufficient quotas from the DEA to meet our needs for 2013, we cannot assure you that sufficient quotas will be received in the future to meet our needs. 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.

Table of Contents

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.

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 documentation. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy. We expect that final REMS documents for Xyrem will include modifications to, and/or 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. We cannot predict whether, or on what terms, we will reach agreement with FDA on final REMS documents for Xyrem, whether we will initiate dispute resolution or other proceedings with FDA prior to finalizing the REMS documents, or, if any such proceedings are initiated, the outcome or timing thereof.

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 ETASU, 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 ETASU 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 ETASU 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 ETASU that will be approved as a final REMS. More broadly, the FDA has stated that it expects the negotiation of a single shared REMS between an NDA holder and ANDA applicants to proceed concurrently with the FDA's review of ANDA applications. The FDA is seeking to schedule an initial meeting with us and ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). We cannot predict the outcome or impact on our business of any discussions with the FDA and/or any ANDA applicant with respect to the potential creation of a single shared system REMS for Xyrem (sodium oxybate).

Table of Contents

We may face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, 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.

If we do not develop a shared system or license or share our REMS with a generic competitor within a time frame or on terms 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 deemed REMS or, when the Xyrem REMS documents are approved, with a separate REMS that includes different, but comparable, ETASU.

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 ETASU 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 the REMS of a sponsor holding a deemed REMS, the FDA will direct the ANDA applicant to submit a proposed risk management plan with ETASU that are comparable to the ETASU 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 certain aspects of our adverse event reporting system for Xyrem and drug safety procedures. We completed the actions and submitted the data that we believed were required to address the observations in the May 2012 Form FDA 483 and the matters raised in the 2011 warning letter, and earlier this year we submitted a request to the FDA to close out the warning letter. In August 2013, we received a close-out letter from the FDA. The FDA issues a close-out letter once the FDA has completed an

Table of Contents

evaluation of corrective actions undertaken in response to a warning letter and concluded, based on the FDA's evaluation, that the company subject to the warning letter has taken corrective action to address the violations contained in the warning letter. We believe that the close-out letter also reflects the completion of the FDA's review of the corrective actions required to address the observations in the May 2012 Form FDA 483.

Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the FDA's or any other regulatory authority's satisfaction could result in such regulatory authorities taking actions in the future, which 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 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® (asparaginase Erwinia chrysanthemi) (called Erwinase® in markets outside the United States) and Prialt® (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 Public Health England, a U.K. national executive agency, 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

Table of Contents

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 May 2013, we completed the roll-out of the NAVIGATOR Reimbursement and Access Program™, a centralized program that provides a single point of access to Prialt, and transitioned to a centralized distribution system for Prialt through an exclusive distributor and pharmacy. In connection with the implementation of the new distribution system, we have experienced, and may continue to experience in the near future, some fluctuation in 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 availability of supply to meet the demand for the product, 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 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, including shortages related to the failure of a batch to meet certain specifications earlier this year, and meet product demand to date, if our continued efforts to avoid supply shortages are not successful, we could experience Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. Other difficulties or delays in production, such as those described elsewhere in this risk factor, could also result in supply interruptions in the future. If, for any reason, our suppliers and manufacturers, including any new suppliers without a track record of meeting our supply needs, 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

Table of Contents

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 LLC, 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 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 part of the BLA approval and monitored by the FDA, could adversely affect its ability to supply Erwinaze 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 Erwinaze 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 Erwinaze, we may face challenges having product produced to meet such specifications, and PHE may charge us more to supply Erwinaze meeting such specifications, which may result in additional costs to us and may decrease any profit we would otherwise achieve with Erwinaze.

We cannot assure you that PHE will be able to continue to supply our ongoing commercial needs of Erwinaze in a timely manner, or at all, especially if our demand for product continues to increase. We have limited inventory of Erwinaze. 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 Erwinaze 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 Erwinaze. Any failure of PHE to supply sufficient quantities of Erwinaze 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 efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2013, our supplier was initially allocated only a portion of the quota it requested to make the active pharmaceutical ingredient of Xyrem. Similarly, our finished product manufacturer for Xyrem was initially allocated only a portion of the quota it requested to make finished product. As a result, earlier this year, both our active pharmaceutical ingredient supplier and our finished product manufacturer had to request and justify increased quotas from the DEA for 2013. While we believe that both our active pharmaceutical ingredient supplier and our finished product manufacturer have now obtained sufficient quotas from the DEA to meet our needs for 2013, we cannot assure you sufficient quotas will be received in the future to meet our needs. 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.

Table of Contents

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, Xyrem's active pharmaceutical ingredient, are manufactured. Manufacturing facilities of our suppliers have been and are subject to periodic 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

Table of Contents

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 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 2012 and 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 700 in October 2013. This includes employees in thirteen countries in North America and 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:

Table of Contents

- 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 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. In addition, we have periodically increased the price of Xyrem and may do so again in the future. We also have made and may in the future make similar price increases on our other products. Any adverse publicity associated with price increases of our products or any products distributed by other pharmaceutical companies could negatively affect market acceptance of our products.

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.

Table of Contents

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 continue to grow our research and development organization to pursue targeted development activities for the remainder of 2013 and in 2014. We have several development pipeline projects, including the development of two clinical product candidates: Asparec (mPEG-r-crisantaspase), which is in a Phase 1 clinical trial in Europe; and Leukotac (inolimomab), which is in a Phase 3 clinical trial also in Europe. We obtained a worldwide exclusive license for JZP-386, a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem, from Concert Pharmaceuticals, Inc. in February 2013. Preclinical research and development work has been initiated on this compound for potential use in patients with narcolepsy. We plan to make a regulatory filing by the end of 2013 that, if approved, would allow the first study of JZP-386 in humans. 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, 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.

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, also known as Ethics Committees in Europe, 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 and other regulatory agencies' Good Clinical Practice Guidelines;
- 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 satisfactorily perform 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 the applicable timeframes provided under the license agreement. Our ability to meet some of these milestones is uncertain, and depends upon a number of factors, including our ability to obtain clinical material, to recruit study centers with appropriate expertise and patient populations and to develop a clinical program

Table of Contents

meeting the development requirements of both the FDA and European regulatory authorities in a timely fashion. If our development activities are delayed and we fail to meet our licensing obligations to Alizé, we may lose our rights to develop and commercialize Asparec. 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. In June 2013, the FDA granted Fast Track designation to the investigation of Asparec for ALL. The Fast Track program is designed to enable more frequent interactions with the FDA during drug development and to expedite the review of a new drug candidate. We are working with investigators and will be reviewing our plans with the FDA for our first study of Asparec in children. Although we have obtained Fast Track designation from the FDA for Asparec, receipt of Fast Track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, and Fast Track designation may be withdrawn by the FDA at any time. In addition, Fast Track designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that Asparec will receive any regulatory approvals.

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 have completed enrollment in a clinical trial evaluating the intravenous administration of Erwinaze in North America. Based on data collected in the study, which met the primary end point, we have recently submitted an amendment to the Erwinaze biological license application to the FDA to allow intravenous administration of Erwinaze. We are also planning a clinical trial to further evaluate the use of Erwinaze in adolescents and young adults with ALL who are hypersensitive to E. coli-derived asparaginase. We have identified a principal investigator for this study, are working with the investigator to finalize the study protocol and will begin the process of identifying and recruiting global study sites. 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 a high priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as FDA's and non-U.S. regulatory 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.

Table of Contents

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.

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Related to Our Intellectual Property

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

Our commercial success depends in part on obtaining 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 companies decide, before applicable ongoing patent litigation is concluded, to launch generic versions of Xyrem 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

Table of Contents

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 an affiliate of Teva a license of our rights to have manufactured, market and sell a generic version of FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. 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. 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, to some extent, FazaClo HD and is expected to continue to do so.

The two formulation patents covering FazaClo LD and FazaClo HD that we license from CIMA are under reexamination by the U.S. Patent and Trademark Office, or the USPTO, and both of the reexamination proceedings have proceeded to appeal at the USPTO. The ANDA lawsuits with the other two generic manufacturers have been stayed pending the outcome of these reexamination proceedings. In May 2013, a decision was issued in one of the two reexamination proceedings, which held certain claims to be patentable, and there was no appeal of this decision. The second reexamination proceeding is still ongoing. We cannot predict the timing or outcome of the second reexamination proceeding, or when the stays will be lifted. Any decision on the part of the USPTO or by the Court of Appeals for the Federal Circuit on appeal 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 are being filed and 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 not clear 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.

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;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;

Table of Contents

- 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, since Erwinaze has no patent protection, one method of protection is to rely on trade secrets and other unpatented proprietary information in order to obtain a competitive advantage, which we may be unable to do. Another method of protection is regulatory exclusivity. 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, or EU, 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 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, it is not yet covered by any issued patents. Asparec was granted orphan drug designation in Europe and the United States 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 not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

Table of Contents

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, for a variety of reasons, including the existence of relevant prior research performed and the existence of conflicting 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 patented subject matter. 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.

In the pharmaceutical and life sciences industry, like other industries, 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 are 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, including patents that cover the use of a single central pharmacy to distribute Xyrem. 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 documentation. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that,

Table of Contents

as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy. See the 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."

We expect that final REMS documents for Xyrem will include modifications to, and/or 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. For example, 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

Table of Contents

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.

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 or later, and their details will be shaped significantly by implementing regulations. 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, many states have chosen not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and there may 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. Where patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Healthcare Reform Act, including the employer mandate. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

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

Table of Contents

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 respective central pharmacies for Xyrem and for Prialt, 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 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 pump or delivery of Prialt via the pump 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. 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, and the FDA has determined that no action is necessary at this time based on available information. However, the FDA is continuing to evaluate this issue. We cannot assure you that additional information we may learn will not modify the current FDA assessment or that the FDA will not take further actions related to this or other potential safety signals, either of which could have an 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 products to 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

Table of Contents

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.

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 acquired businesses 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 with other products by pharmacies, 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 the impact of any new legislation on our business.

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

Table of Contents

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 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 of federal funds, 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 reimbursement 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 restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada 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 in 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

Table of Contents

these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and the Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, private individuals may report to the SEC information concerning a company's securities and FCPA violations and may be eligible for a whistleblower award. 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 information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business, including recently enacted laws in all jurisdictions where we operate. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. In addition, we obtain patient health information from most healthcare providers who prescribe our products and research institutions we collaborate with, and they are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal or civil penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Moreover, 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 directive and national laws differently, which adds to the complexity of processing personal data in the EU, 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. The EU member states and Switzerland permit U.S. companies to comply with the EU Data Protection Directive using several means, including a voluntary safe-harbor arrangement and a set of standard form contractual clauses for the transfer of personal data outside of Europe. Our U.S. subsidiary, Jazz Pharmaceuticals, Inc., has certified compliance with the EU safe harbor through the U.S. Department of Commerce. 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 Medicare Services, or CMS, 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 begin tracking on August 1, 2013 and 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

Table of Contents

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® (capromab pendetide) and Quadramet® (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 plan to begin making any required reports when CMS provides guidance on reporting methodology, currently expected in 2014. 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 Drug 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 Drug 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

Table of Contents

requirements for these newly-eligible entities. The Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation to implement the orphan drug exception in July 2013. The final regulation interprets the orphan drug exception narrowly. It exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. The newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. The final regulation, which became effective October 1, 2013, is subject to a pending lawsuit that seeks to block its implementation. The narrow scope of the orphan drug exception in HRSA's final regulation will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations.

Federal law also requires that a company that participates in the Medicaid Drug 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 as well as regulations 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 a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for 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 Drug 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 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, or 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

Table of Contents

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, each of our covered drugs is listed on 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 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. In addition, third party payors draw on diagnostic criteria to establish reimbursement guidelines. Meaningful changes to the diagnostic criteria for narcolepsy are included in the recently published fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and are expected to be included in the third edition of International Classification of Sleep Disorders (ICSD-3), which is expected to be published in 2014. As a result, third party payors may make changes to the coverage and reimbursement for our products, which may have a negative impact on revenues from Xyrem. 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. CMS has begun making pharmacy National Average Drug Acquisition Cost and, until suspended in July 2013, 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

Table of Contents

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 July 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 reduce reimbursement payments related to our products, which could potentially 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® (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, 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.

Table of Contents

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 September 30, 2013, we had approximately $555.8 million in secured debt outstanding, all of which was incurred under our credit agreement originally entered into in connection with the EUSA Acquisition in June 2012 and subsequently amended in June 2013, which is referred to in this report as the amended credit agreement. 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 the amended credit agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.*

In June 2013, we entered into the amended credit agreement which provides for a tranche of term loans in the aggregate principal amount of approximately $557.2 million due in June 2018 and a $200.0 million revolving credit facility, with any loans under such revolving credit facility due in June 2017. The amended 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
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

The amended 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 amended credit agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the revolving credit facility, 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 the amended 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/

Table of Contents

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 the amended 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 again 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 growth prospects. 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 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

Table of Contents

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 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.

Table of Contents

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

As of September 30, 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.

In addition, the market price of our ordinary shares may decline if the effects of the Azur Merger, the EUSA Acquisition and/or potential future acquisitions on the financial results of our company are 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 October 29, 2013, we had 57,789,719 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

Table of Contents

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.

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

Other than funds we have allocated for the purposes of supporting our share repurchase program announced in May 2013, 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 amended 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 amended credit agreement and other factors our board of directors deems relevant. Accordingly, holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future.

Table of Contents

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.

Table of Contents

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

Issuer Purchases of Equity Securities

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our "affiliated purchasers" as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934, as amended, during each fiscal month during the three-month period ended September 30, 2013:

	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (3)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (4)
July 1 - July 31, 2013	144,775	$70.95	144,775	$136,170,894
August 1 - August 31, 2013	245,985	$80.82	245,985	$116,296,140
September 1 - September 30, 2013	212,595	$87.81	212,595	$97,632,865
Total	603,355	$80.91	603,355	

(1) This table does not include ordinary shares that we withheld in order to satisfy minimum tax withholding requirements in connection with the vesting or exercise of restricted stock units.

(2) Average price paid per share includes brokerage commissions.

(3) The ordinary shares reported in the table above were purchased pursuant to our publicly announced share repurchase program. On May 7, 2013, we announced that our board of directors authorized the use of up to $200 million to repurchase our ordinary shares. This authorization has no expiration date.

(4) The dollar amount shown represents, as of the end of each period, the approximate dollar value of ordinary shares that may yet be purchased under our publicly announced share repurchase program, exclusive of any brokerage commissions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the amended credit agreement, corporate and regulatory requirements and market conditions, and may be discontinued at any time without prior notice.

Table of Contents

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

	(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).
4.3	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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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+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved July 31, 2013).
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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
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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+ Indicates management contract or compensatory plan.

* 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.

Table of Contents

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: November 5, 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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