Jazz Pharmaceuticals plc
Form 10-Q
May 08, 2014
Table of Contents

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

FORM 10-Q

(Mark One)
ý Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2014
or
¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from to
Commission File Number: 001-33500
JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 May 1, 2014, 59,391,915 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

Table of Contents

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2014

INDEX

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®, Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase®, Defitelio® (defibrotide), Prialt® (ziconotide) intrathecal infusion, FazaClo® (clozapine, USP), Versacloz™ (clozapine) oral suspension, Leukotac™ (inolimomab) and ProstaScint® (capromab pendetide). This report also includes trademarks, service marks, and trade names of other companies.

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$245,874	$636,504
Investments	5,502	—
Accounts receivable, net of allowances	154,986	124,805
Inventories	36,988	28,669
Prepaid expenses	14,335	7,183
Deferred tax assets, net	35,888	33,613
Other current assets	23,747	33,843
Total current assets	517,320	864,617
Property and equipment, net	30,048	14,246
Intangible assets, net	1,755,861	812,396
Goodwill	763,763	450,456
Deferred tax assets, net, non-current	94,250	74,597
Deferred financing costs	25,896	14,605
Other non-current assets	9,296	7,304
Total assets	$3,196,434	$2,238,221
LIABILITIES AND SHAREHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$72,538	$21,005
Accrued liabilities	147,737	119,718
Current portion of long-term debt	9,513	5,572
Income taxes payable	824	336
Contingent consideration	—	50,000
Deferred tax liability, net	6,259	6,259
Deferred revenue	1,138	1,138
Total current liabilities	238,009	204,028
Deferred revenue, non-current	5,433	5,718
Long-term debt, less current portion	1,189,096	544,404
Deferred tax liability, net, non-current	471,993	168,497
Other non-current liabilities	25,395	20,040
Commitments and contingencies (Note 8)		
Shareholders’ equity:		
Jazz Pharmaceuticals plc shareholders' equity		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	471	471
Additional paid-in capital	1,251,587	1,220,317
Accumulated other comprehensive income	70,892	56,153

Retained earnings (accumulated deficit)	(74,118)	18,532
Total Jazz Pharmaceuticals plc shareholders’ equity	1,248,893	1,295,534
Noncontrolling interests	17,615	—
Total shareholders' equity	1,266,508	1,295,534
Total liabilities and shareholders’ equity	$3,196,434	$2,238,221

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

Table of Contents

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

	Three Months Ended March 31,	
	2014	2013
Revenues:		
Product sales, net	$244,986	$194,652
Royalties and contract revenues	1,933	1,585
Total revenues	246,919	196,237
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technologies)	30,924	27,220
Selling, general and administrative	106,363	70,528
Research and development	18,109	6,747
Acquired in-process research and development	127,000	4,000
Intangible asset amortization	31,182	19,555
Total operating expenses	313,578	128,050
Income (loss) from operations	(66,659)	68,187
Interest expense, net	(10,076)	(7,399)
Foreign currency gain	123	271
Income (loss) before income tax provision	(76,612)	61,059
Income tax provision	17,027	17,634
Net income (loss)	(93,639)	43,425
Net loss attributable to noncontrolling interests, net of tax	(989)	—
Net income (loss) attributable to Jazz Pharmaceuticals plc	$(92,650)	$43,425
Net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc:		
Basic	$(1.58)	$0.74
Diluted	$(1.58)	$0.71
Weighted-average ordinary shares used in calculating net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc:		
Basic	58,526	58,358
Diluted	58,526	61,511

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 (LOSS)
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2014	2013
Net income (loss)	$(93,639)	$43,425
Other comprehensive income (loss):		
Foreign currency translation adjustments	15,016	(20,440)
Other comprehensive income (loss)	15,016	(20,440)
Total comprehensive income (loss)	(78,623)	22,985
Comprehensive loss attributable to noncontrolling interests, net of tax	(712)	—
Comprehensive income (loss) attributable to Jazz Pharmaceuticals plc	$(77,911)	$22,985

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

Table of Contents

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

	Three Months Ended March 31,	
	2014	2013
Operating activities		
Net income (loss)	$(93,639)	$43,425
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Amortization of intangible assets	31,182	19,555
Depreciation	1,309	575
Acquired in-process research and development	127,000	4,000
Loss on disposal of property and equipment	2	40
Share-based compensation	13,815	8,757
Excess tax benefit from share-based compensation	(5,777)	(889)
Acquisition accounting inventory fair value step-up adjustments	8,022	1,545
Change in fair value of contingent consideration	—	4,500
Deferred income taxes	(4,378)	(3,874)
Provision for losses on accounts receivable and inventory	813	142
Other non-cash transactions	1,868	1,975
Changes in assets and liabilities:		
Accounts receivable	(16,014)	(18,911)
Inventories	(3,071)	1,231
Prepaid expenses and other current assets	4,357	(6,272)
Other long-term assets	(1,545)	(999)
Accounts payable	8,579	16,158
Accrued liabilities	927	(2,660)
Income taxes payable	5,757	(1,397)
Deferred revenue	(273)	(207)
Contingent consideration	(14,900)	—
Other non-current liabilities	4,689	3,196
Net cash provided by operating activities	68,723	69,890
Investing activities		
Acquisitions, net of cash acquired	(828,676)	—
Acquisition of in-process research and development	(125,000)	(4,000)
Purchases of property and equipment	(3,527)	(1,143)
Acquisition of intangible assets	—	(1,300)
Net cash used in investing activities	(957,203)	(6,443)
Financing activities		
Net proceeds from issuance of debt	636,355	—
Proceeds from employee equity incentive and purchase plans and exercise of warrants	21,467	9,609
Acquisition of noncontrolling interests	(119,175)	—
Payment of contingent consideration	(35,100)	—
Payment of employee withholding taxes related to share-based awards	(9,363)	(1,427)
Excess tax benefit from share-based compensation	5,777	889
Repayment of long-term debt	(2,299)	(5,938)

Net cash provided by financing activities	497,662	3,133
Effect of exchange rates on cash and cash equivalents	188	(3,265)
Net increase (decrease) in cash and cash equivalents	(390,630)	63,315
Cash and cash equivalents, at beginning of period	636,504	387,196
Cash and cash equivalents, at end of period	$245,874	$450,511

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 differentiated 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 23, 2014, pursuant to a tender offer, we became the indirect majority shareholder of Gentium S.p.A., or Gentium, thereby acquiring control of Gentium on that date, which acquisition we refer to in this report as the Gentium Acquisition. In February 2014, we completed a subsequent offering period of the tender offer, resulting in total purchases pursuant to the tender offer of approximately 98% of the fully diluted voting securities of Gentium for an aggregate acquisition cost to us of $976.3 million, comprising cash payments of $993.4 million offset by proceeds from the exercise of Gentium share options of $17.1 million. Please see Note 2 for additional information regarding the Gentium 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.

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, 2013. The results of operations of the acquired Gentium business, along with the estimated fair values of the assets acquired and liabilities assumed in the transaction, have been included in our condensed consolidated financial statements since the closing of the Gentium Acquisition on January 23, 2014, which date we refer to in this report as the closing date of the Gentium Acquisition.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three months ended March 31, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014, for any other interim period or for any future period.

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

Reclassifications

Certain prior period amounts presented in these condensed consolidated financial statements and the accompanying footnotes have been reclassified to conform to current period presentation. Upfront license fees of $4.0 million, previously classified as research and development expense, have been reclassified to acquired in-process research and development, or IPR&D, in the condensed consolidated statements of operations and reclassified from operating activities to investing activities in the condensed consolidated statements of cash flows to conform to current period presentation. Inventories of $1.4 million previously classified as raw materials as of December 31, 2013 have been

reclassified to work in process to conform to current period presentation.

Table of Contents

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem® (sodium oxybate) oral solution. In the three months ended March 31, 2014, net product sales of Xyrem were $160.4 million, which represented 65.5% of total net product sales. Maintaining or increasing sales of Xyrem in its approved indications is subject to a number of risks and uncertainties, including the potential introduction of generic competition, changed or increased regulatory restrictions, and continued acceptance of Xyrem as safe and effective by physicians and patients. Three abbreviated new drug applications, or ANDAs, have been filed with the U.S. Food and Drug Administration, or FDA, by third parties seeking to market generic versions of Xyrem. We initiated lawsuits against all three third parties, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. Although no trial date has been scheduled in the lawsuit against the first ANDA filer, Roxane Laboratories, Inc., or Roxane, we anticipate that trial on some of the patents in that case could occur as early as late in the fourth quarter of 2014. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate products that compete with Xyrem, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are continuing our efforts on various regulatory matters, including updating 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. We have not reached agreement with the FDA on certain significant terms of our risk evaluation and mitigation strategies, or REMS, documents for Xyrem. 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, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We expect to receive the FDA's response to our initial dispute resolution submission in the second quarter of 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. 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, and/or negatively affect sales of Xyrem.

We also expect to 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. In January 2014, the FDA held an initial meeting with us and current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate), and we expect these interactions to continue among the parties. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared system REMS for Xyrem (sodium oxybate), licensing or sharing our REMS, or the FDA's response to a certification that a third party had been unable to obtain a license.

Sales of our second largest product, Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in markets outside of the United States, continue to grow. In the three months ended March 31, 2014, net product sales of Erwinaze/Erwinase were $46.9 million, which represented 19.2% of total net product sales for that period. 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 maintain and grow sales of Erwinaze is subject to a number of risks and uncertainties, including the limited population of patients with acute lymphoblastic leukemia, or ALL, and the incidence of hypersensitivity reactions to E. coli-derived asparaginase

within that population, our ability to obtain approval for the intravenous administration of Erwinaze in the United States, our ability to obtain data on the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase, as well as our need to apply for and receive marketing authorizations, through the EU's mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries. Another significant challenge to our ability to maintain the current sales level and continue to increase sales is our need to assure sufficient supply of Erwinaze on a timely basis. We have limited inventory of Erwinaze, and, during 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. In the past, we have experienced a disruption of supply of Erwinase in the European market due to manufacturing challenges, including shortages related to the failure of a batch to meet certain specifications in 2013, and we may experience similar or other manufacturing challenges in the future. If our continued efforts to avoid supply shortages are not successful, we could

Table of Contents

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.

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 demand or our requirements for clinical trial supplies; 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 healthcare cost containment and other austerity measures in the United States and worldwide, and in particular the need to maintain reimbursement for Xyrem in the United States and obtain appropriate pricing and reimbursement approvals for Defitelio® (defibrotide) in order to launch Defitelio in certain European countries representing a significant market opportunity for Defitelio; and 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. For example, in April 2014, we received a Form FDA 483 at the conclusion of a pharmacovigilance inspection recently conducted by the FDA. The Form FDA 483 included observations relating to certain aspects of our adverse drug experience reporting system for all of our products, including Xyrem. In light of the fact that we have previously received observations relating to adverse drug experience reporting, we do not know whether the FDA will take further action, including the issuance of a warning letter as a follow-up to its inspection, or require us to take further action, with respect to the matters covered in the Form FDA 483. Other risks and uncertainties related to our ability to execute on our strategy include: the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors, and in particular the successful launch of Defitelio in Europe throughout 2014 and 2015; the challenges inherent in the integration of the business of Gentium with our historic business, including the increase in geographic dispersion among our centers of operation and taking on the operation of a manufacturing plant; and the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval, especially as we continue to undertake increased activities, and make growing investment in, our product pipeline development projects; 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, which have increased significantly as a result of, among other things, the Gentium Acquisition.

Business Acquisitions

Our consolidated financial statements include the results of operations of an acquired business after the completion of the acquisition. We account for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that assets acquired, liabilities assumed and any noncontrolling interests in the acquired business be recognized at their estimated fair values as of the acquisition date, with limited exceptions, and that the fair value of acquired IPR&D be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the acquisition consideration over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings.

Acquired In-Process Research and Development

The initial costs of rights to IPR&D projects acquired in an asset acquisition are expensed as IPR&D unless the project has an alternative future use. The fair value of IPR&D projects acquired in a business combination are capitalized and accounted for as indefinite-lived intangible assets until the underlying project receives regulatory approval, at which point the intangible asset will be accounted for as a definite-lived intangible asset, or discontinuation, at which point the intangible asset will be written off. Development costs incurred after the acquisition are expensed as incurred.

Concentrations of Risk

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

Table of Contents

securities, corporate bonds or commercial paper issued by U.S. corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, and tax-exempt obligations of U.S. states, agencies and municipalities and places restrictions on credit ratings, maturities, and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents, investments and marketable securities and issuers of investments to the extent recorded on the balance sheet.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the United States, and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We monitor deteriorating economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of March 31, 2014, five customers accounted for 83% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, which accounted for 63% of gross accounts receivable, and Accredo Health Group, Inc., or Accredo, which accounted for 9% of gross accounts receivable. As of December 31, 2013, five customers accounted for 85% of gross accounts receivable, including Express Scripts, which accounted for 69% of gross accounts receivable, and Accredo, which accounted for 9% of gross accounts receivable.

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

Use of Estimates

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

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

Basic net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc is based on the weighted-average number of ordinary shares outstanding. Diluted net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc is based on the weighted-average number of ordinary shares outstanding and potentially dilutive ordinary shares outstanding. Basic and diluted net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc were computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2014	2013
Numerator:		
Net income (loss) attributable to Jazz Pharmaceuticals plc	$(92,650)	$43,425
Denominator:		
Weighted-average ordinary shares used in calculating net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc - basic	58,526	58,358
Dilutive effect of employee equity incentive and purchase plans	—	1,496
Dilutive effect of warrants	—	1,657
Weighted-average ordinary shares used in calculating net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc - diluted	58,526	61,511
Net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc:		
Basic	$(1.58)	$0.74

Diluted	$(1.58)	$0.71

Potentially dilutive ordinary shares from employee equity plans and warrants were not included in the diluted net loss per ordinary share attributable to Jazz Pharmaceuticals plc for the three months ended March 31, 2014 because the inclusion of such shares would have an anti-dilutive effect.

Table of Contents

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 (loss) per ordinary share attributable to Jazz Pharmaceuticals plc for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended March 31,	
	2014	2013
Options to purchase ordinary shares and RSUs	5,491	2,352
Warrants to purchase ordinary shares	1,257	—
Ordinary shares under ESPP	141	—

Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2014-08, “Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity”, or ASU 2014-08. Under ASU 2014-08, only disposals representing a strategic shift in operations should be presented as discontinued operations. Those strategic shifts should have a major effect on the organization’s operations and financial results. Additionally, ASU 2014-08 requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. ASU 2014-08 is effective for fiscal and interim periods beginning on or after December 15, 2014, with early adoption permitted. The impact of the adoption of this ASU on our results of operations, financial position, cash flows and disclosures will be based on our future disposal activity.

2. Business Combination and Asset Acquisition

Acquisition of Gentium

On December 19, 2013, we entered into a definitive agreement with Gentium, or the Gentium tender offer agreement, pursuant to which we made a cash tender offer of $57.00 per share for all outstanding Gentium ordinary shares and American Depositary Shares, or ADSs. As of the expiration of the initial offering period on January 22, 2014, 12,244,156 Gentium ordinary shares and ADSs were properly tendered and not withdrawn in the tender offer. These ordinary shares and ADSs represented approximately 79% of Gentium’s issued and outstanding ordinary shares and ADSs and 69% of the fully diluted number of ordinary shares and ADSs (in each case without duplication for ordinary shares underlying ADSs). All properly tendered ordinary shares and ADSs as of such date were accepted for payment, which was made in accordance with the terms of the tender offer.

Upon payment for the properly tendered ordinary shares and ADSs on January 23, 2014, the closing date of the Gentium Acquisition, we became the indirect majority shareholder of Gentium and acquired control of Gentium. Following the expiration of the initial offering period, and in accordance with the terms of the Gentium tender offer agreement, we commenced a subsequent offering period to acquire all remaining untendered ordinary shares and ADSs. The subsequent offering period expired on February 20, 2014. In total, pursuant to the tender offer agreement, we purchased approximately 98% of Gentium’s fully diluted ordinary shares and ADSs. The aggregate acquisition cost of the Gentium ordinary shares and ADSs we purchased pursuant to the tender offer was $976.3 million, comprising cash payments of $993.4 million offset by proceeds from the exercise of Gentium share options of $17.1 million. $857.1 million of the acquisition consideration is attributable to the 12,244,156 Gentium ordinary shares and ADSs purchased on the closing date of the Gentium Acquisition, as well as 1,345,023 ADSs committed to tender in accordance with the guaranteed delivery procedures contemplated by the tender offer and options to acquire 1,666,608 ordinary shares of Gentium subject to support agreements requiring that such options be exercised and the underlying ordinary shares be tendered in a subsequent offering period. These ADSs and ordinary shares represented in the aggregate approximately 86% of the fully diluted number of ordinary shares and ADSs of Gentium. The remaining

$119.2 million of the acquisition cost is attributable to the acquisition of an additional 12% of the fully diluted Gentium ordinary shares and ADSs during the subsequent offering period and is accounted for as an acquisition of noncontrolling interests.

We believe the acquisition will provide us with an opportunity to diversify our development and commercial portfolio and complement our clinical experience in hematology/oncology and our expertise in reaching targeted physicians who treat serious medical conditions. As a result of the Gentium Acquisition, we acquired defibrotide, which is marketed under the name

Table of Contents

Defitelio in Europe. In October 2013, the European Commission granted marketing authorization for Defitelio for the treatment of severe hepatic veno-occlusive disease, or VOD, in adults and children undergoing hematopoietic stem cell transplantation therapy. Under a license and supply agreement, Gentium has licensed the rights to commercialize defibrotide for the treatment and prevention of VOD in North America, Central America and South America, subject to receipt of marketing authorization, if any, in the applicable territory, to Sigma-Tau Pharmaceuticals, Inc.

The Gentium Acquisition was accounted for using the acquisition method of accounting under which assets and liabilities of Gentium were recorded at their respective estimated fair values as of the closing date of the Gentium Acquisition and added to the assets and liabilities of Jazz Pharmaceuticals plc, including an amount for goodwill representing the difference between the acquisition consideration and the estimated fair value of the identifiable net assets. The results of operations of Gentium and the estimated fair values of the assets acquired and liabilities assumed have been included in our consolidated financial statements since the closing date of the Gentium Acquisition.

During the three months ended March 31, 2014, we incurred $10.0 million in acquisition-related costs related to the Gentium Acquisition, which primarily consisted of banking, legal, accounting and valuation-related expenses. These expenses were recorded in selling, general and administrative expense in the accompanying condensed consolidated statements of operations. Our condensed consolidated statements of operations included revenues of $13.5 million and a net loss of $17.9 million from the acquired Gentium business, as measured from the closing date of the Gentium Acquisition.

The acquisition consideration (not including the acquisition cost of $119.2 million to acquire the 12% noncontrolling interests in the subsequent offering period) was comprised of (in thousands):

Cash consideration for shares acquired in initial tender offer period	$697,917
Liability for shares committed under guaranteed delivery procedures	76,666
Liability for options committed for exercise	82,503
Total acquisition consideration	$857,086

The fair values of assets acquired and liabilities assumed at the closing date of the Gentium Acquisition as well as the fair value at the acquisition date of the noncontrolling interests in Gentium, are summarized below (in thousands):

Cash and cash equivalents	$28,410
Short-term deposit	5,418
Accounts receivable (1)	13,855
Inventories	13,525
Prepaid and other current assets	1,383
Intangible assets	960,350
Goodwill	308,642
Deferred tax assets	22,999
Property, plant and equipment	10,201
Other long-term assets	431
Accounts payable	(11,778)
Accrued expenses	(51,477)
Income taxes payable	(502)
Other long-term liabilities	(654)
Debt (current and long-term)	(2,351)
Deferred tax liabilities	(304,788)
Noncontrolling interests	(136,578)
Total acquisition consideration	$857,086

(1) The estimated fair value of trade receivables acquired was $13.9 million and the gross contractual amount was $14.9 million, of which we expect that $1.0 million will be uncollectible.

Table of Contents

The intangible assets as of the closing date of the Gentium Acquisition included (in thousands):

Finite-lived intangible assets:	
Currently marketed product:	
Defibrotide VOD (Non-U.S.)	$719,500
Manufacturing contracts	14,500
Tradename	350
Total finite-lived intangible assets	734,350
IPR&D:	
Defibrotide VOD Prophylaxis	168,000
Defibrotide VOD (U.S.)	58,000
Total IPR&D	226,000
Total intangible assets	$960,350

The fair value of the currently marketed product was determined using the income approach. The income approach explicitly recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated costs for each product line. Indications of value were developed by discounting these benefits to their present worth at a discount rate that reflects the current return requirements of the market. The fair value of the currently marketed product was capitalized as of the closing date of the Gentium Acquisition and subsequently will be amortized over the estimated remaining life of the product of approximately 16 years.

Gentium produces active pharmaceutical ingredients, or APIs, including the defibrotide compound, urokinase, sodium heparin and sulglicotide. Other than defibrotide, these APIs are subsequently used to make the finished forms of various drugs and are distributed via supply contracts. The fair value of these supply contracts was determined using the income approach based on the expected cash flows from the projected net earnings of each API. The fair value of the API supply contracts was capitalized as of the closing date of the Gentium Acquisition and subsequently will be amortized over 4 years which approximates the remaining contractual term and reasonably expected renewal periods.

The fair value of IPR&D was determined using the income approach, including the application of probability factors related to the likelihood of success of the respective products reaching final development and commercialization. This approach also took into consideration information and certain program-related documents and forecasts prepared by management. The fair value of IPR&D was capitalized as of the closing date of the Gentium Acquisition and is subsequently accounted for as an indefinite-lived intangible asset until completion or abandonment of the associated research and development efforts. Accordingly, during the development period after the closing of the Gentium Acquisition, these assets will not be amortized into earnings; instead, these assets will be subject to periodic impairment testing. Upon successful completion of the development process for an acquired IPR&D project, determination as to the useful life of the asset will be made. The asset would then be considered a finite-lived intangible asset and amortization of the asset into earnings would begin over the remaining estimated useful life of the asset.

The excess of the total acquisition consideration over the fair value amounts assigned to the assets acquired and the liabilities assumed represents the goodwill amount resulting from the Gentium Acquisition. We believe that the factors that contributed to goodwill included the Gentium workforce, which will complement our clinical experience in hematology/oncology and our expertise in reaching targeted physicians who treat serious medical conditions, and the deferred tax consequences of intangible assets recorded for financial statement purposes. We do not expect any portion of this goodwill to be deductible for tax purposes.

The noncontrolling interests at the closing date of the Gentium Acquisition comprised 2,007,452 of Gentium’s issued and outstanding ordinary shares and ADSs and options to acquire 484,097 ordinary shares of Gentium that were not subject to support agreements. The fair value of the noncontrolling interests was estimated using Gentium’s closing market price quoted on the NASDAQ Global Market on January 22, 2014.

Pro Forma Financial Information (Unaudited)

The following unaudited supplemental pro forma information presents our combined historical results of operations with adjustments to reflect one-time charges and amortization of fair value adjustments in the appropriate pro forma periods as if the Gentium Acquisition had been completed on January 1, 2013. These adjustments include:

Table of Contents

- An increase in amortization expense of $2.9 million for the three months ended March 31, 2014 and $12.2 million for the three months ended March 31, 2013 related to the fair value of acquired identifiable intangible assets.
- The exclusion of acquisition-related expenses of $40.7 million for the three months ended March 31, 2014.
- An increase in interest expense of $1.4 million for the three months ended March 31, 2014 and $5.6 million for the three months ended March 31, 2013 incurred on additional borrowings made to fund the Gentium Acquisition as if the borrowings had occurred on January 1, 2013.
- The exclusion of other non-recurring expenses of $32.9 million for the three months ended March 31, 2014 and the inclusion of $12.8 million for the three months ended March 31, 2013 primarily related to Gentium transaction bonus costs, the fair value step-up to acquired inventory, share-based compensation incurred from the acceleration of stock option vesting upon closing of the Gentium Acquisition and integration-related expenses.

The unaudited pro forma results do not assume any operating efficiencies as a result of the consolidation of operations (in thousands, except per share data):

	Three Months Ended March 31,	
	2014	2013
Revenues	$250,222	$206,241
Net income (loss) attributable to Jazz Pharmaceuticals plc	$(77,677)	$14,135
Net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc - basic	$(1.33)	$0.24
Net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc - diluted	$(1.33)	$0.23

Acquisition of Rights to JZP-110 (formerly known as ADX-N05)

On January 13, 2014, we entered into a definitive agreement with Aerial BioPharma, LLC, or Aerial, under which we acquired certain assets related to JZP-110, a novel compound in clinical development for the treatment of excessive daytime sleepiness in patients with narcolepsy. Under the agreement, and in exchange for an upfront initial payment from us totaling $125.0 million, we acquired worldwide development, manufacturing and commercial rights to JZP-110, other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights. Aerial and SK are eligible to receive milestone payments, in an aggregate amount of up $272.0 million, based on development, regulatory and sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales. This acquisition was accounted for as a purchase of IPR&D assets with no alternative future use. Accordingly, the $125.0 million upfront payment was charged to acquired IPR&D expense in the three months ended March 31, 2014. The assignment of the JZP-110 rights from Aerial to Jazz triggered a liability for a milestone payment of $2.0 million to SK, which was also charged to acquired IPR&D expense in the three months ended March 31, 2014.

3. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2014	December 31, 2013
Raw materials	$3,709	$3,506
Work in process	10,575	10,301
Finished goods	22,704	14,862
Total inventories	$36,988	$28,669

As of March 31, 2014 and December 31, 2013, the fair value of inventories acquired included a step-up in the value of inventories of $2.5 million and $0.2 million, respectively.

Table of Contents

4. Fair Value Measurement

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

	March 31, 2014					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash	Investments
Cash	$245,874	$—	$—	$245,874	$245,874	$—
Time deposits	5,502	—	—	5,502	—	5,502
Totals	$251,376	$—	$—	$251,376	$245,874	$5,502

	December 31, 2013					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$495,990	$—	$—	$495,990	$495,990	$—
Time deposits	140,514	—	—	140,514	140,514	—
Totals	$636,504	$—	$—	$636,504	$636,504	$—

Cash equivalents and investments 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 operations.

Our investment balance represents a time deposit with original maturity of greater than 90 days which matured on April 30, 2014.

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

	March 31, 2014		December 31, 2013	
	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:				
Available-for-sale securities				
Time deposits	$5,502	$5,502	$140,514	$140,514
Liabilities:				
Contingent consideration	$—	$—	$50,000	$50,000

As of March 31, 2014 and December 31, 2013, our available-for-sale securities included time deposits which were measured at fair value using Level 2 inputs and their carrying values were approximately equal to their fair values. There were no transfers between the different levels of the fair value hierarchy in 2014 or in 2013.

As of March 31, 2014, the estimated fair value of the $902.1 million principal amount of our term loans was $901.0 million and the carrying amount was $896.3 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 term loans, see Note 7. The fair value of the borrowings under the revolving credit facility and other borrowings approximates book value based on the borrowing rates currently available for variable rate loans (Level 2).

15

Table of Contents

5. Certain Balance Sheet Items

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

	March 31, 2014	December 31, 2013
Construction-in-progress	$10,641	$4,388
Computer software	8,844	7,960
Machinery and equipment	7,255	417
Computer equipment	5,675	5,610
Leasehold improvements	5,519	4,587
Furniture and fixtures	2,196	1,897
Land and buildings	1,678	—
Subtotal	41,808	24,859
Less accumulated depreciation and amortization	(11,760)	(10,613)
Property and equipment, net	$30,048	$14,246

Accrued liabilities consisted of the following (in thousands):

	March 31, 2014	December 31, 2013
Rebates and other sales deductions	$44,284	$38,772
Employee compensation and benefits	41,932	31,829
Sales returns reserve	20,597	21,110
Professional fees	8,034	5,675
Royalties	6,770	6,082
Accrued interest	6,153	4,150
Other	19,967	12,100
Total accrued liabilities	$147,737	$119,718

6. Goodwill and Intangible Assets

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

Balance at December 31, 2013	$450,456
Goodwill arising from the Gentium Acquisition	308,642
Foreign exchange	4,665
Balance at March 31, 2014	$763,763

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

	March 31, 2014				December 31, 2013		
	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	13.3	$1,687,325	$ (209,703)	$1,477,622	$957,089	$ (179,225)	$777,864
Manufacturing contracts	3.3	14,723	(702)	14,021	—	—	—
Trademarks	0.8	2,955	(2,463)	492	2,600	(2,327)	273
Total finite-lived intangible assets		1,705,003	(212,868)	1,492,135	959,689	(181,552)	778,137
Acquired IPR&D assets		263,726	—	263,726	34,259	—	34,259

Total intangible assets	$1,968,729	$ (212,868)	$1,755,861	$993,948	$ (181,552)	$812,396

Table of Contents

The increase in the gross carrying amount of intangible assets as of March 31, 2014 compared to December 31, 2013 reflects the acquisition of the Gentium intangible assets, as described in Note 2, and the positive impact of foreign currency exchange which is primarily due to the strengthening of the Euro against the U.S. dollar.

Based on finite-lived intangible assets recorded as of March 31, 2014, 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
2014 (remainder)	$98,288
2015	126,170
2016	121,820
2017	121,728
2018	118,196
Thereafter	905,933
Total	$1,492,135

7. Long-Term Debt

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

	March 31, 2014	December 31, 2013
Term loan facility	$896,260	$549,976
Revolving credit facility	300,000	—
Other borrowings	2,349	—
Total debt	1,198,609	549,976
Less current portion	9,513	5,572
Total long-term debt	$1,189,096	$544,404

Amendment of Credit Facility and Term Loan Refinancing

In June 2012, Jazz Pharmaceuticals plc, as guarantor, and certain of its wholly owned subsidiaries, as borrowers, entered into a credit agreement providing for $475.0 million principal amount of term loans and a $100.0 million revolving credit facility. On June 13, 2013, we amended the credit agreement to provide for $557.2 million principal amount of new term loans and a $200.0 million revolving credit facility that replaced the $100.0 million revolving credit facility. We used a portion of the proceeds from these new term loans to refinance in full the $457.2 million aggregate principal amount of outstanding term loans under the credit agreement prior to the amendment. As a result of the June 2013 amendment, interest rate margins on the term loans and the revolving loans were reduced by 150 basis points.

On January 23, 2014, we entered into a second amendment to the credit agreement to provide for (i) a tranche of incremental term loans in the aggregate principal amount of $350.0 million, (ii) a tranche of term loans to refinance the $554.4 million aggregate principal amount of term loans previously outstanding under the amended credit agreement, or the prior term loans, in their entirety and (iii) a $425.0 million revolving credit facility that replaced the $200.0 million revolving credit facility. We used the proceeds from the incremental term loans and $300.0 million of loans under the revolving credit facility together with cash on hand, to purchase the Gentium ordinary shares and ADSs properly tendered and accepted for payment on the January 22, 2014 expiration of the initial tender offer period relating to the Gentium Acquisition. The January 2014 amendment also reduced the interest rate margins on the terms loans by 25 basis points.

The term loans under the credit agreement, as amended in January 2014, mature on June 12, 2018 and the revolving credit facility terminates, and any loans outstanding thereunder become due and payable, on June 12, 2017.

The term loans under the credit agreement, as amended in January 2014, bear interest, at our option, at a rate equal to either the LIBOR, plus an applicable margin of 2.50% per annum (subject to a 0.75% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 1.50% 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, 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%

Table of Contents

based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio.

The borrowers' obligations under the credit agreement, as amended in January 2014, and any hedging or cash management obligations entered into with a lender or an affiliate of a lender are guaranteed by us and certain of our subsidiaries and are secured by substantially all of our, the borrower's and the subsidiary guarantors' 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 term loans effected on or prior to July 23, 2014. We are required to make mandatory prepayments of the 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 term loans, which are due quarterly, began in March 2014 and are equal to 1.0% per annum of the original principal amount of $904.4 million with any remaining balance payable on the final maturity date.

The 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 credit agreement contains a financial covenant that requires Jazz Pharmaceuticals plc and its restricted subsidiaries to maintain a maximum secured leverage ratio. We were, as of March 31, 2014, and are currently in compliance with this financial covenant.

The refinancing of the 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. 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. The refinancing was accounted for as a modification as the change in debt terms was not substantial.

Deferred financing costs of $21.7 million and an original issue discount of $6.1 million were associated with modified and new debt and will be amortized to interest expense using the interest method over the life of the term loans. As of March 31, 2014, the interest rate on the term loans was 3.25% and the effective interest rate was 4.1%.

As the borrowing capacity relating to each creditor under the new revolving credit facility was greater than that under the original revolving credit facility, deferred financing costs totaling $5.4 million were associated with the new arrangement and are being amortized to interest expense on a straight-line basis over the life of the facility. As of March 31, 2014, we had borrowed $300.0 million under the revolving credit facility and the interest rate on these borrowings at that date was 2.69%.

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

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2014 (remainder)	$7,226
2015	9,479
2016	9,484

2017	309,490
2018	868,512
Thereafter	298
Total	$1,204,489

8. 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

Table of Contents

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 March 31, 2014 and December 31, 2013. 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 March 31, 2014 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2014 (remainder)	$7,786
2015	9,891
2016	6,995
2017	3,749
2018	910
Thereafter	130
Total	$29,461

As of March 31, 2014, we had $36.9 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 that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Roxane's initial 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 U.S. 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. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA had been stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane's initial Paragraph IV Certification, but that stay has expired. Additional patents covering Xyrem have issued since the original suit against Roxane was filed, and cases involving these patents have been consolidated with the original action.

In December 2013, the District Court permitted Roxane to amend its answer in the consolidated case to allege additional equitable defenses, and the parties have been given additional time for discovery on those new defenses. In addition, in March 2014, the District Court granted our motion to bifurcate and stay the portion of the lawsuit regarding certain patents covering the distribution system for Xyrem. Although no trial date for the case has been scheduled, based on the District Court's current scheduling order, we anticipate that trial on the patents that are not

subject to the court’s stay could occur as early as late in the fourth quarter of 2014. We do not have any estimate of a possible trial date for trial on the stayed patents. The actual timing of events in this litigation may be significantly earlier or later than contemplated by the scheduling order or than we currently anticipate, and we cannot predict the timing or outcome of events in this litigation.

On April 1, 2014, we received an additional Paragraph IV Certification from Roxane alleging that a tenth patent listed in the Orange Book for Xyrem in December 2013 is invalid or not infringed. We have not yet responded to this Paragraph IV

Table of Contents

Certification and cannot predict the timing or outcome of this matter or its impact on the other ongoing proceedings with Roxane.

On December 10, 2012, we received a Paragraph IV Certification notice 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 initial Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal's proposed generic product and that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification notice 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 seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. An additional patent covering Xyrem issued since the original suit was filed and the case involving this patent has been consolidated with the original case.

On April 7, 2014, we received an additional Paragraph IV Certification from Amneal alleging that a tenth patent listed in the Orange Book for Xyrem in December 2013 is invalid. We have not yet responded to this Paragraph IV Certification and cannot predict the timing or outcome of this matter or its impact on the other ongoing proceedings with Amneal.

On November 21, 2013, we received a Paragraph IV Certification notice from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Par's Paragraph IV Certification alleged that ten patents listed in the Orange Book for Xyrem are invalid, unenforceable, and/or will not be infringed by Par's proposed generic product. On December 27, 2013, we filed a lawsuit against Par in the District Court in response to Par's Paragraph IV Certification seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe our patents.

On April 23, 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request on May 5, 2014. The order consolidating the cases provides that Amneal's 30-month stay period will be extended to coincide with the date of Par's 30-month stay period, calculated to be May 20, 2016. As a result, FDA's approval of both ANDAs is stayed until the earlier of (i) May 20, 2016, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of events in the consolidated case.

FazaClo ANDA Matters: Azur Pharma Public Limited Company, or Azur Pharma, received Paragraph IV Certification notices from three generics manufacturers, Barr Laboratories, Inc., or Barr, Novel Laboratories, Inc., or Novel, and Mylan Pharmaceuticals, Inc., or Mylan, indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo® (clozapine, USP) LD orally disintegrating clozapine tablets. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification against Barr on August 21, 2008, against Novel on November 25, 2008 and against Mylan on July 23, 2010. Each case was filed in the U.S. District Court for the District of Delaware, or the Delaware Court. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD 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 and Mylan matters had been stayed pending reexamination of the patents in the lawsuits. In September 2013 and January 2014, reexamination certificates were issued for the two patents-in-suit, with the claims of the patents confirmed. The Delaware Court lifted the stay of litigation in the two cases in March 2014. No trial date has been set and we cannot predict the timing or outcome of this litigation.

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in the California Superior

Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to a $10.5 million and an additional $25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. In March 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. In July 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. That ruling was affirmed by the California Court of Appeal in January 2014, and the case was remanded to Superior Court. We cannot predict the timing or outcome of this litigation.

Table of Contents

Shareholder Litigation Matter: In January 2014, we became aware of a purported class action lawsuit filed in the U.S. District Court for the Southern District of New York in connection with the Gentium Acquisition. The lawsuit, captioned Xavion Jyles, Individually and on Behalf of All Others Similarly Situated v. Gentium S.P.A. et al., names Gentium, each of the Gentium's directors, us and our Italian subsidiary as defendants. The lawsuit alleges, among other things, that Gentium's directors breached their fiduciary duties to Gentium's shareholders in connection with the Gentium tender offer agreement that Gentium entered into with us and our Italian subsidiary valuing Gentium ordinary shares and ADSs at $57.00 per share, and that we and our Italian subsidiary violated Sections 14(e) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by allegedly overseeing Gentium's preparation of an allegedly false and misleading Section 14D-9 Solicitation/Recommendation Statement. The lawsuit seeks, among other relief, class action status, rescission, and unspecified costs, attorneys' fees and other expenses. We cannot predict the timing or outcome of this matter.

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

Other Contingencies

We have not previously submitted pricing data for our two radiopharmaceutical products, ProstaScint® (capromab pendetide) and Quadramet® (samarium sm 153 lexidronam injection), for Medicaid and 340B programs. We have been engaged in interactions with the Centers for Medicare and Medicaid Services, or CMS, and a trade group, the Council on Radionuclides and Radiopharmaceuticals, or CORAR, regarding the reporting of Medicaid pricing data and paying Medicaid rebates for radiopharmaceutical products. For ProstaScint, we plan to begin making any required reports when CMS provides guidance on this requirement and reporting methodology, which is currently expected in 2014. We sold Quadramet to a third party in December 2013, but have retained any liabilities related to sales of the product during prior periods. In addition to the discussions with CMS as part of CORAR, we have had separate discussions with CMS directly regarding Quadramet. We are currently unable to predict whether price reporting and rebates will be required for ProstaScint and Quadramet and if so, for what period they will be required. The initiation of any reporting of Medicaid pricing data for ProstaScint and Quadramet could result in retroactive 340B ceiling price liability for these two products as well as prospective 340B ceiling price obligations for ProstaScint. We are currently unable to reasonably estimate an amount or range of a contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results.

9. Shareholders' Equity

The following table presents a reconciliation of our beginning and ending balances in shareholders' equity for the three months ended March 31, 2014 (in thousands):

	Attributable to:		
	Jazz Pharmaceuticals plc	Noncontrolling interests	Total Shareholders' Equity
Shareholders' equity at January 1, 2014	$1,295,534	$—	$1,295,534
Noncontrolling interests from the Gentium Acquisition		136,578	136,578
Acquisition of noncontrolling interests	(924)	(118,251)	(119,175)
Issuance of ordinary shares in conjunction with employee equity incentive plans and warrant exercises	21,467	—	21,467
Employee withholding taxes related to share-based awards	(9,363)	—	(9,363)
Share-based compensation	14,313	—	14,313
Tax benefit from employee share options	5,777	—	5,777
Other comprehensive income	14,739	277	15,016
Net loss	(92,650)	(989)	(93,639)
Shareholders' equity at March 31, 2014	$1,248,893	$ 17,615	$1,266,508

The following table presents a reconciliation of our beginning and ending balances in shareholders' equity for the three months ended March 31, 2013 (in thousands):

Table of Contents

	Jazz Pharmaceuticals plc
Shareholders' equity at January 1, 2013	$ 1,121,292
Issuance of ordinary shares in conjunction with employee equity incentive plans and warrant exercises	9,609
Employee withholding taxes related to share-based awards	(1,427)
Share-based compensation	8,552
Tax benefit from employee share options	889
Other comprehensive income	(20,440)
Net income	43,425
Shareholders' equity at March 31, 2013	$ 1,161,900

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. During the three months ended March 31, 2014, we did not purchase any of our ordinary shares under the share repurchase program. As of March 31, 2014, the remaining amount authorized under the share repurchase program was $63.6 million.

Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income as of March 31, 2014 and December 31, 2013 were as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Income
Balance at December 31, 2013	$56,153	$56,153
Other comprehensive income	14,739	14,739
Balance at March 31, 2014	$70,892	$70,892

During the three months ended March 31, 2014, other comprehensive income reflects foreign currency translation adjustments which are primarily due to the strengthening of the Euro against the U.S. dollar.

10. Share-Based Compensation

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

	Three Months Ended March 31,	
	2014	2013
Selling, general and administrative	$11,175	$7,005
Research and development	2,459	1,043
Cost of product sales	181	709
Total share-based compensation expense, pre-tax	13,815	8,757

Tax benefit from share-based compensation expense	(4,286)	(2,853)
Total share-based compensation expense, net of tax	$9,529	$5,904

Table of Contents

Share Options

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

	Three Months Ended March 31,			
	2014		2013	
Shares underlying options granted (in thousands)	706		1,011	
Grant date fair value	$63.08		$27.75	
Black-Scholes option pricing model assumption information:				
Volatility	46	%	59	%
Expected term (years)	4.3		4.4	
Range of risk-free rates	1.1-1.2%		0.6-0.7%	
Expected dividend yield	—	%	—	%

Restricted Stock Units

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

	Three Months Ended March 31,	
	2014	2013
RSUs granted (in thousands)	341	447
Grant date fair value	$165.61	$58.93

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 March 31, 2014, compensation cost not yet recognized related to unvested share options and RSUs was $81.5 million and $80.4 million, respectively, which is expected to be recognized over a weighted-average period of 2.7 years and 2.9 years, respectively.

11. Related Party Transactions

In February 2014, certain holders of warrants to purchase 947,867 of our ordinary shares exercised the warrants in full for an aggregate cash purchase price payable to us of $3.8 million. The warrant holders are entities affiliated with one of our directors. In accordance with the terms of an existing investor rights agreement with the warrant holders, we registered the resale of the ordinary shares underlying the warrants and, pursuant to such agreement, we paid expenses of approximately $0.1 million in connection with the resale registration.

Table of Contents

12. Segment and Other Information

Our operating segment is reported in a manner consistent with the internal reporting provided to the chief operating decision maker, or CODM. Our CODM has been identified as our chief executive officer. We have determined that we operate in one business segment which is the development and commercialization of specialty pharmaceutical products. The following table presents a summary of total revenues (in thousands):

	Three Months Ended March 31,	
	2014	2013
Xyrem® (sodium oxybate) oral solution	$160,378	$117,526
Erwinaze® (asparaginase Erwinia chrysanthemi)/Erwinase®	46,920	41,816
Defitelio® (defibrotide)/defibrotide	12,209	—
Prialt® (ziconotide) intrathecal infusion	4,309	4,986
Psychiatry	9,866	17,650
Other	11,304	12,674
Product sales, net	244,986	194,652
Royalties and contract revenues	1,933	1,585
Total revenues	$246,919	$196,237

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

	Three Months Ended March 31,	
	2014	2013
United States	$214,956	$176,911
Europe	24,343	14,362
All other	7,620	4,964
Total revenues	$246,919	$196,237

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

	Three Months Ended March 31,			
	2014		2013	
Express Scripts	65	%	60	%
Accredo	15	%	17	%

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

	March 31, 2014	December 31, 2013
Ireland	$11,161	$5,799
Italy	10,283	—
United States	7,765	7,734
Other	839	713
Total long-lived assets (1)	$30,048	$14,246

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

Table of Contents

13. Income Taxes

Our income tax provision was $17.0 million for the three months ended March 31, 2014 compared to $17.6 million for the same period in 2013. After adjusting the loss before income tax provision by excluding an upfront license fee and milestone payment of $127.0 million for rights to JZP-110, the effective tax rate on the resulting income before income tax provision was 33.8% for the three months ended March 31, 2014, compared to 28.9% for the same period in 2013. The increase in the effective tax rate was primarily due to a higher level of profits subject to U.S. federal and state income taxes in the three months ended March 31, 2014, and higher losses in other jurisdictions where no tax benefit was available in the period. The effective tax rate for the three months ended March 31, 2014 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, uncertain tax positions, current year losses in some jurisdictions for which no tax benefit is available, and various expenses not deductible for tax purposes. 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 comprised 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 French tax authorities for fiscal years 2010, 2011 and 2012 and by the U.S. Internal Revenue Service for fiscal year 2010. We do not anticipate that the amount of our existing liability for unrecognized tax benefits will significantly change within the next 12 months.

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.

Overview

We are a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing differentiated 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 continue to make progress in the execution of our strategy. Our strong revenue growth continued in the first quarter of 2014, primarily from the sales of our lead marketed products, Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in markets outside of the United States. In the three months ended March 31, 2014, our total net product sales increased by 26% compared to the same period in 2013. Sales of Xyrem increased 36% in the three months ended March 31, 2014 compared to the same period in 2013. Sales of Erwinaze/Erwinase increased 12% in the three months ended March 31, 2014 compared to the same period in 2013. We expect total product sales will increase in 2014 over 2013 primarily due to growth in sales of Xyrem and Erwinaze and the addition of defibrotide, which is marketed under the name Defitelio® (defibrotide) in Europe, to our product portfolio.

We acquired Defitelio/defibrotide as a result of our acquisition, pursuant to a tender offer, of approximately 98% of the outstanding and fully diluted voting securities of Gentium S.p.A., or Gentium, which acquisition we refer to as the Gentium Acquisition. The Gentium Acquisition closed on January 23, 2014, and a subsequent offering period of the tender offer expired on February 20, 2014. The aggregate acquisition cost of the Gentium Acquisition was $976.3 million, comprising cash payments of $993.4 million offset by proceeds from the exercise of Gentium share options of $17.1 million.

In October 2013, the European Commission, or EC, granted marketing authorization for Defitelio under exceptional circumstances for the treatment of severe hepatic veno-occlusive disease, or VOD, in adults and children undergoing hematopoietic stem cell transplantation, or HSCT, therapy. We commenced the launch of Defitelio in Europe beginning in Germany and Austria in March 2014, in Italy (with reimbursement under Law 648/96) in April 2014 and in the United Kingdom in early May 2014. We expect to launch Defitelio in additional European countries on a rolling basis during 2014 and 2015 and are engaged in pricing and reimbursement submissions as applicable in preparation for planned launches in additional European countries. We intend eventually to promote Defitelio in all European markets where it has marketing authorization. In addition, we expect to continue to provide patients access to defibrotide in countries where it is not commercially available through continuation of an expanded access program in the United States and on a named patient basis elsewhere. We also launched Versacloz™ (clozapine) oral suspension in the United States in February 2014 for treatment-resistant schizophrenia and for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorders.

We have a portfolio of approved products that address medical needs in the following therapeutic areas, including:
Narcolepsy: Xyrem, the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in patients with narcolepsy;
Hematology/Oncology: Erwinaze, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to E. coli-derived asparaginase, and Defitelio, a product approved in Europe for the treatment of severe VOD in adults and children undergoing HSCT therapy;
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

Table of Contents

Psychiatry: A portfolio of products, including FazaClo® (clozapine, USP) HD and FazaClo LD, orally disintegrating clozapine tablets indicated for treatment-resistant schizophrenia, and Versacloz.

We also commercialize a portfolio of other products, mostly in markets outside of the United States. These products are primarily in the oncology, critical care and oncology supportive care therapeutic areas.

We continue to make progress and investment in our expanded product development pipeline, which currently includes clinical development of new product candidates, line extensions for existing products and the generation of additional clinical data for existing products. These projects are concentrated in our sleep and hematology and oncology therapeutic areas, where we believe we will be able to leverage our existing specialty commercial expertise and infrastructure, as well as our strong clinical, medical and commercial teams.

In the sleep area, we have planned clinical studies for our product and product candidates.

- JZP-110. JZP-110 is a late-stage investigational compound being developed for potential treatment of EDS in patients with narcolepsy. We also intend to pursue development of JZP-110 for EDS in patients with obstructive sleep apnea. We have requested a meeting and expect to meet with the FDA to discuss our development plans for JZP-110 in mid-2014. Thereafter, we intend to initiate our Phase 3 clinical program for JZP-110, subject to the availability of clinical trial materials. In January 2014, we acquired from Aerial BioPharma LLC, or Aerial, the worldwide development, manufacturing and commercial rights to JZP-110, other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights, with an upfront payment totaling $125.0 million.
- JZP-386. JZP-386 is a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem. We are conducting pre-clinical research and development work on JZP-386 for potential use in patients with narcolepsy. We submitted an investigational medicinal product dossier, or IMPD, for JZP-386 in Europe at the end of 2013 and received approval of the IMPD in January 2014. We intend to begin our first study of JZP-386 in humans later in 2014, subject to the availability of clinical trial materials.
- Xyrem. While in many patients narcolepsy can begin during childhood and adolescence, there is limited information on the treatment of pediatric narcolepsy patients with Xyrem. We have worked with the FDA and several leading specialists to design a clinical study to generate additional data on the treatment of pediatric narcolepsy patients with Xyrem. We plan to open clinical sites for this study in the second half of 2014.

In the hematology and oncology area, we have ongoing and planned clinical studies.

- JZP-416 (formerly known as Asparec). We are conducting a Phase 1 clinical trial in Europe of JZP-416, which is pegcrisantaspase, the PEGylated recombinant Erwinia chrysanthemi L-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 JZP-416 for the treatment of ALL. We have reviewed our development plans with the FDA and are working with investigators to initiate our first study of JZP-416 in children by the end of 2014.
- Erwinaze. We are preparing to initiate a clinical trial to further evaluate the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase. We expect to begin this planned trial in the second quarter of 2014. In 2013, we also completed a pharmacokinetic clinical trial of the intravenous administration of Erwinaze in North America. Based on data collected in the study, which met the primary end point, we submitted an amendment to the Erwinaze biologic license application, or BLA, to the FDA to allow intravenous administration of Erwinaze. The FDA determined that the data should be submitted as a supplemental BLA, or sBLA. We have resubmitted the data as an sBLA, which was accepted for filing by the FDA in April 2014. The Prescription Drug User Fee Act, or PDUFA, date for an FDA decision on the sBLA is December 28, 2014.
- Leukotac™ (inolimomab). We are conducting a Phase 3 clinical trial in Europe of Leukotac, an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute GvHD. We completed enrollment for this study in March 2014 and expect to receive preliminary data before mid-2015.

Under a license and supply agreement, Gentium has licensed to Sigma-Tau Pharmaceuticals, Inc. the rights to commercialize defibrotide for the treatment and prevention of VOD in North America, Central America and South America, subject to receipt of marketing authorization, if any, in the applicable territory. In 2011, Gentium voluntarily withdrew from consideration a new drug application, or NDA, submitted to the FDA in July 2011 seeking approval in the United States for defibrotide for the treatment of VOD in order to address issues raised by the FDA. We recently

met with the FDA to discuss issues related to the possible submission of an NDA for defibrotide for the treatment of severe VOD in patients undergoing HSCT therapy. Based on this meeting, we believe that it may be possible to submit an NDA without the need for data from an additional clinical trial. We are continuing to address the FDA's comments and questions and plan to have additional discussions with the FDA during 2014 prior to finalizing our strategy for seeking approval of defibrotide in the United States. We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in indications in addition to the treatment of severe VOD.

Table of Contents

For 2014 and beyond, we expect that our research and development expenses will increase substantially from historical levels as a result of upfront and milestone payments and our increased clinical trial and development activities.

In addition, through the Gentium Acquisition, we acquired a manufacturing facility that produces active pharmaceutical ingredients, including defibrotide, the drug substance in Defitelio, and in February 2014 we announced we commenced construction of a manufacturing and development facility in Ireland.

As of April 2, 2014, Gentium has delisted its American Depositary Shares, or ADSs, from The NASDAQ Stock Market, terminated the registration of its ordinary shares and ADSs under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and suspended its duty to file reports under the Exchange Act. Effective April 13, 2014, Gentium amended its deposit agreement with The Bank of New York Mellon, the ADS depositary, decreasing to 60 days the period that must elapse between the date of termination of the deposit agreement and the date on which the ADS depositary may sell the ordinary shares of Gentium it then holds and providing for the ADS depositary to accept any offer by one of our subsidiaries to purchase those shares at a price of no less than $57.00 per ordinary share, unless the ADS depositary has received what it considers to be a superior bona fide offer from another party. While the date or dates on which the ADS depositary will sell the remaining shares have not been determined, the sale will not occur before June 13, 2014. One of our subsidiaries has indicated to the ADS depositary that it intends to offer to purchase the remaining ordinary shares from the ADS depositary at a purchase price of $57.00 per share.

In June 2012, we entered into a credit agreement that provided for $475.0 million principal amount of term loans and a $100.0 million revolving credit facility. The proceeds from the term loans were used to partially finance our acquisition of EUSA Pharma Inc., or the EUSA Acquisition, in June 2012. In June 2013, we amended the credit agreement to provide for $557.2 million principal amount of term loans and a new revolving credit facility of $200.0 million that replaced the $100 million revolving credit facility. We used a portion of the proceeds from the new term loans to refinance in full the $457.2 million principal amount of term loans outstanding under the credit agreement prior to the amendment. In January 2014, in connection with the Gentium Acquisition, we further amended the credit agreement to provide for a tranche of incremental term loans in the aggregate principal amount of $350.0 million, a tranche of term loans that refinanced the approximately $554.4 million principal amount of term loans outstanding prior to this amendment, and a $425.0 million revolving credit facility that replaced the $200.0 million revolving credit facility. We used the proceeds from the incremental term loans and $300.0 million of loans under the revolving credit facility, together with cash on hand, to purchase Gentium ordinary shares and ADSs pursuant to the tender offer.

In 2013, we initiated purchases under a share repurchase program for up to $200 million of our ordinary shares. During the three months ended March 31, 2014, we did not purchase any of our ordinary shares under the share repurchase program. As of March 31, 2014, we had spent a total of $136.5 million, including commissions, to repurchase our ordinary shares under this program. For a more detailed discussion regarding our share repurchase program, see “Liquidity and Capital Resources” below.

Over the past two years, we have made targeted investments to strengthen our capabilities and enhance and diversify our commercial and development portfolio. We intend to continue to leverage our commercial, medical and scientific experience to seek to maximize the potential of our existing and potential products. Our investments have allowed us to build a scalable infrastructure to support future growth and to continue to create shareholder value.

We anticipate that we will continue to face a number of challenges and risks to our business and our ability to execute our strategy in 2014. 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 65.5% of our net product sales in the three months ended March 31, 2014 and 65.8% of our net product sales for the year ended December 31, 2013. 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 and develop product, service and safety improvements for patients. For example, in April 2014, we updated our Xyrem label in consultation with the FDA to include additional information for using Xyrem safely and effectively,

specifically a recommendation to reduce the dose of Xyrem when used concomitantly with divalproex sodium, which is based on data from a drug interaction study we conducted.

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 three abbreviated new drug applications, or ANDAs, submitted to the FDA by third parties seeking to market generic versions of Xyrem. We initiated lawsuits against all three third parties, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. Although no trial date has been scheduled in the lawsuit against the first ANDA filer, Roxane Laboratories, Inc., or Roxane, we anticipate that trial on some of the patents in that case could occur as early as late in the fourth quarter of 2014. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate products that compete with Xyrem, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Table of Contents

We are continuing our efforts on various regulatory matters, including updating 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. We have not reached agreement with the FDA on certain significant terms of our risk evaluation and mitigation strategies, or REMS, documents for Xyrem. 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, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We expect to receive the FDA's response to our initial dispute resolution submission in the second quarter of 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. 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, and/or negatively affect sales of Xyrem.

We also expect to 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. In January 2014, the FDA held an initial meeting with us and current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate), and we expect these interactions to continue among the parties. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared system REMS for Xyrem (sodium oxybate), licensing or sharing our REMS, or the FDA's response to a certification that a third party had been unable to obtain a license.

Sales of our second largest product, Erwinaze/Erwinase continue to grow. Sales of Erwinaze/Erwinase accounted for 19.2% of our net product sales in the three months ended March 31, 2014 and 20.1% of our net product sales for the year ended December 31, 2013. 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 maintain and 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 have limited inventory of Erwinaze, and, during 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. In the past, we have experienced a disruption of supply of Erwinase in the European market due to manufacturing challenges, including shortages related to the failure of a batch to meet certain specifications in 2013, and we may experience similar or other manufacturing challenges in the future. 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.

In April 2014, we received a Form FDA 483 at the conclusion of a pharmacovigilance inspection recently conducted by the FDA. The Form FDA 483 included observations relating to certain aspects of our adverse drug experience reporting system for all of our products, including Xyrem. Since May 2012, all of the approximately 3,500 adverse drug experiences, or ADEs, reported to Jazz for all products that were categorized as "serious and unexpected" had been

reported to the FDA. However, reports related to 92 of these ADEs had been submitted beyond the 15-day regulatory deadline. The Form FDA 483 included an observation related to these late filings. In addition, the Form FDA 483 included observations regarding our lack of written procedures for certain aspects of our evaluation of ADEs and certain deficiencies in our investigation of ADEs. We have responded to the Form FDA 483 with a description of the corrective actions and improvements we had implemented before or shortly following the inspection and additional improvements that we plan to implement to address the observations in the Form FDA 483. We intend to demonstrate our compliance to the FDA's satisfaction, but we do not know whether the FDA will take further action, or require us to take further action, with respect to the matters covered in the Form FDA 483.

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:

Table of Contents

- 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 demand or our requirements for clinical trial supplies;
- 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, and in particular the need to maintain reimbursement for Xyrem in the United States and obtain appropriate pricing and reimbursement approvals in order to launch Defitelio in certain European countries representing a significant market opportunity for Defitelio;
- 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 in particular the successful launch of Defitelio in Europe throughout 2014 and 2015;
- the challenges inherent in the integration of the business of Gentium with our historic business, including the increase in geographic dispersion among our centers of operation and taking on the operation of a manufacturing plant;
- the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval, especially as we continue to undertake increased activities and make growing investment in our product pipeline development projects;
- 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, which have increased significantly as a result of, among other things, the Gentium Acquisition.

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

Results of Operations

The following table presents revenues and expenses for the three months ended March 31, 2014 and 2013, respectively (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease)	
	2014 (1)	2013		
Product sales, net	$244,986	$194,652	26	%
Royalties and contract revenues	1,933	1,585	22	%
Cost of product sales (excluding amortization of acquired developed technologies)	30,924	27,220	14	%
Selling, general and administrative	106,363	70,528	51	%
Research and development	18,109	6,747	168	%
Acquired in-process research and development	127,000	4,000	3,075	%
Intangible asset amortization	31,182	19,555	59	%
Interest expense, net	10,076	7,399	36	%
Foreign currency gain	123	271	(55	)%
Income tax provision	17,027	17,634	(3	)%
Net loss attributable to noncontrolling interests, net of tax	989	—	N/A(2)	

(1) Our financial results include the financial results of the historic Gentium business since the closing of the Gentium Acquisition on January 23, 2014.

Table of Contents

(2) Comparison to prior period not meaningful.

Revenues

The following table presents product sales, royalties and contract revenues, and total revenues for the three months ended March 31, 2014 and 2013, respectively (amounts in thousands):

	Three Months Ended March 31,		Increase/ (Decrease)	
	2014	2013		
Xyrem® (sodium oxybate) oral solution	$160,378	$117,526	36	%
Erwinaze® (asparaginase Erwinia chrysanthemi)/Erwinase®	46,920	41,816	12	%
Defitelio® (defibrotide)/defibrotide	12,209	—	N/A(1)	
Prialt® (ziconotide) intrathecal infusion	4,309	4,986	(14	%)
Psychiatry	9,866	17,650	(44	)%
Other	11,304	12,674	(11	)%
Product sales, net	244,986	194,652	26	%
Royalties and contract revenues	1,933	1,585	22	%
Total revenues	$246,919	$196,237	26	%

(1) Comparison to prior period not meaningful since our financial results include the financial results of the historic Gentium business since the closing of the Gentium Acquisition on January 23, 2014.

Product Sales, Net

Xyrem product sales increased in the three months ended March 31, 2014 compared to the same period in 2013, primarily due to a higher average net selling price and, to a lesser extent, an increase in sales volume. Price increases were instituted in July 2013 and February 2014 based on market analysis. Xyrem product sales volume increased by 5% in the three months ended March 31, 2014 compared to the same period in 2013. The sales volume increase was driven by an increase in the average number of patients on Xyrem which includes both new patients and active patients who remained on Xyrem therapy. Erwinaze/Erwinase product sales increased in the three months ended March 31, 2014 compared to the same period in 2013, primarily due to increases in sales volume and to a lesser extent, a price increase in January 2014. The sales volume increase was 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. Defitelio/defibrotide product sales, from the closing of the Gentium Acquisition on January 23, 2014 to March 31, 2014, were $12.2 million. On a pro forma basis, Defitelio/defibrotide product sales increased by 75% in the three months ended March 31, 2014 compared to the same period in 2013, primarily due to territory-specific price increases in April 2013, partially offset by a decrease in sales volume reflecting strong demand in the three months ended March 31, 2013 ahead of anticipated price increases. Until commencement of the commercial launch of Defitelio in Europe in March 2014, we provided, and continue to provide, access to defibrotide to patients in countries where it is not commercially available through continuation of an expanded access program in the United States and on a named patient basis elsewhere. We expect to see growth in sales of Defitelio/defibrotide in 2014 over 2013 as the roll out of the commercial launch continues in Europe. Prialt product sales decreased in the three months ended March 31, 2014 compared to the same period in 2013, in part due to timing of shipments to the exclusive wholesale distributor and central pharmacy for Prialt. Psychiatry product sales decreased in the three months ended March 31, 2014 compared to the same period in 2013, 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. We expect total product sales will increase in 2014 over 2013, primarily due to growth in sales of Xyrem and Erwinaze/Erwinase and the inclusion of product sales resulting from the Gentium Acquisition, partially offset by decreases in sales of certain other products.

Royalties and Contract Revenues

Royalties and contract revenues increased in the three months ended March 31, 2014 compared to the same period in 2013 primarily due to increased royalties in relation to our out-licensed products. We expect royalties and contract

revenues in 2014 to be relatively consistent with 2013.

Table of Contents

Cost of Product Sales

Cost of product sales increased in the three months ended March 31, 2014 compared to the same period in 2013, primarily due to an increase in acquisition accounting inventory fair value step-up adjustments of $6.5 million, partially offset by lower cost of product sales primarily driven by product mix, with a greater proportion of higher margin products sold in the three months ended March 31, 2014. Gross margin as a percentage of net product sales was 87.4% in the three months ended March 31, 2014 compared to 86.0% for the same period in 2013. The increase in our gross margin percentage was primarily due to a change in product mix, in particular, the addition of Defitelio/defibrotide. We expect our gross margin percentage to increase slightly in 2014 compared to 2013, primarily driven by a change in product mix.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in the three months ended March 31, 2014 compared to the same period in 2013, primarily due to increases in transaction and integration expenses of $16.7 million; salary and benefit related expenses (including share-based compensation expense) of $13.3 million driven by increased headcount primarily due to our expanded business and the Gentium Acquisition; professional services expenses of $5.4 million; and increases in sales and promotional expenses of $4.0 million; partially offset by a $4.5 million change in fair value of the contingent consideration recognized in the 2013 period. We expect that selling, general and administrative expenses will be higher in 2014 than in 2013 due to increased headcount to support our larger, global organization, an increase in sales and marketing, including direct marketing spend on key products and the inclusion of expenses resulting from the Gentium Acquisition, including launch expenses for Defitelio.

Research and Development Expenses

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

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

	Three Months Ended March 31,	
	2014	2013
Clinical studies and outside services	9,506	1,507
Personnel expenses	7,716	4,470
Other	887	770
Total	$18,109	$6,747

Research and development expenses increased in the three months ended March 31, 2014 compared to the same period in 2013 by $11.4 million. Personnel expenses increased by $3.2 million due to a 89% increase in headcount primarily driven by the Gentium Acquisition. Clinical studies and outside services costs increased by $8.0 million due to an increase in costs incurred to develop sleep and hematology/oncology product candidates including, but not limited to, JZP-386 and JZP-416, as well as the addition of costs related to development programs for defibrotide. We also incurred increased costs related to the development of line extensions for existing products and the generation of additional clinical data.

For 2014 and beyond, we expect that our research and development expenses will increase substantially from historical levels, particularly as we initiate our various planned clinical trials and development work and potentially acquire rights to additional product candidates. A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of our product candidates, and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part II, Item 1A of this Quarterly report on Form 10-Q.

Table of Contents

Acquired in-process research and development

In January 2014, we acquired the worldwide development, manufacturing and commercial rights to JZP-110, other than in certain jurisdictions in Asia where SK retained rights, for an upfront payment of $125.0 million to Aerial. We also incurred a $2.0 million milestone expense to SK which was triggered on assignment of the JZP-110 rights from Aerial to us. In February 2013, we incurred $4.0 million in upfront license fees in connection with our licensing of JZP-386.

Intangible Asset Amortization

Intangible asset amortization increased by $11.6 million in the three months ended March 31, 2014 compared to the same period in 2013, primarily due to the Gentium Acquisition. We acquired finite-lived intangible assets of $734.4 million in connection with the Gentium Acquisition that are expected to be amortized over their weighted-average useful economic lives of approximately 16 years. Amortization expense will be significantly higher in 2014 than in 2013, due to the inclusion of amortization expense of approximately $46 million related to the intangible assets we acquired in the Gentium Acquisition.

Interest Expense, Net

Interest expense, net increased by $2.7 million in the three months ended March 31, 2014 compared to the same period in 2013, primarily due to a larger debt balance, partially offset by a decrease in interest rates associated with our long-term debt. In January 2014, in connection with the Gentium Acquisition, we incurred an additional $650.0 million in secured debt, comprising $350.0 million of incremental term loans and $300.0 million of loans under the revolving credit facility. As of March 31, 2014, $902.1 million principal amount was outstanding on our term loans and $300.0 million borrowings were outstanding under the revolving credit facility. As of March 31, 2014, the interest rate on the term loans was 3.25% and the interest rate on the revolving credit facility borrowings was 2.69%. Interest expense is expected to be higher in 2014 than in 2013 due to the increase in our debt balance.

Foreign Currency Gain

The foreign currency gain in the three months ended March 31, 2014 related to the translation of foreign currency monetary assets and liabilities, including intercompany balances.

Income Tax Provision

Our income tax provision was $17.0 million for the three months ended March 31, 2014 compared to $17.6 million for the same period in 2013. After adjusting the loss before income tax provision by excluding an upfront license fee and milestone payment of $127.0 million for rights to JZP-110, the effective tax rate on the resulting income before income tax provision was 33.8% for the three months ended March 31, 2014, compared to 28.9% for the same period in 2013. The increase in the effective tax rate was primarily due to a higher level of profits subject to U.S. federal and state income taxes in the three months ended March 31, 2014, and higher losses in other jurisdictions where no tax benefit was available in the period. The effective tax rate for the three months ended March 31, 2014 was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, uncertain tax positions, current year losses in some jurisdictions for which no tax benefit is available, and various expenses not deductible for tax purposes. 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.

Net Loss Attributable to Noncontrolling Interests, Net of Tax

Net loss attributable to noncontrolling interests, net of tax relates to the portion of the net loss of Gentium not attributable, directly or indirectly, to our ownership interest. The net loss attributable to noncontrolling interests, net of tax was $1.0 million for the three months ended March 31, 2014.

Non-GAAP Financial Measures

To supplement our financial results presented on a U.S generally accepted accounting principles, or GAAP, basis, we use certain non-GAAP, also referred to as adjusted or non-GAAP adjusted, financial measures as shown in the table 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 the company. 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

Table of Contents

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 attributable to Jazz Pharmaceuticals plc (and the related per share measures) exclude from GAAP net income (loss) attributable to Jazz Pharmaceuticals plc (and the related per share measures), 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 and milestone payments, depreciation expense and non-cash interest expense; adjust the income tax provision to the estimated amount of taxes payable in cash; and adjust for the amount attributable to noncontrolling interests.

Reconciliations of GAAP reported net income (loss) attributable to Jazz Pharmaceuticals plc to non-GAAP adjusted net income attributable to Jazz Pharmaceuticals plc and the related per share amounts are as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2014	2013
GAAP reported net income (loss) attributable to Jazz Pharmaceuticals plc	$(92,650)	$43,425
Intangible asset amortization	31,182	19,555
Share-based compensation expense	13,815	8,757
Acquisition accounting inventory fair value step-up adjustments	8,022	1,545
Transaction and integration costs	17,733	1,022
Restructuring charges	—	949
Change in fair value of contingent consideration	—	4,500
Upfront license fees and milestone payments	127,000	4,000
Depreciation	1,309	575
Non-cash interest expense	1,638	1,229
Income tax adjustments (1)	(5,944)	(1,132)
Adjustments for amount attributable to noncontrolling interests (2)	(1,258)	—
Non-GAAP adjusted net income attributable to Jazz Pharmaceuticals plc	$100,847	$84,425
GAAP reported net income (loss) attributable to Jazz Pharmaceuticals plc per diluted share	$(1.58)	$0.71
Non-GAAP adjusted net income attributable to Jazz Pharmaceuticals plc per diluted share	$1.61	$1.37
Shares used in computing GAAP reported net income (loss) attributable to Jazz Pharmaceuticals plc per diluted share amounts	58,526	61,511
	62,517	61,511

Shares used in computing non-GAAP adjusted net income attributable to Jazz Pharmaceuticals plc per diluted share amounts

(1) Tax adjustments to convert the income tax provision to the estimated amount of taxes payable in cash.
(2) The noncontrolling interests' share of the above adjustments, as applicable.

Liquidity and Capital Resources

As of March 31, 2014, we had cash and cash equivalents and short-term investments of $251.4 million, borrowing availability under the revolving credit facility of $125.0 million and long-term debt of $1.2 billion which included $902.1 million aggregate principal amount of term loans, $300 million of revolving loans and other borrowings of $2.4 million.

Table of Contents

We generated cash flows from operations of $68.7 million during the three months ended March 31, 2014 not including an upfront license fee and milestone payment totaling $127.0 million in respect of our acquisition of rights to JZP-110. We expect to continue to generate positive cash flows from operations during 2014.

In January 2014, we amended our credit agreement to provide for $350.0 million of incremental term loans, a tranche of term loans that refinanced the approximately $554.4 million aggregate principal amount of term loans previously outstanding, and a $425.0 million revolving credit facility that replaced our $200.0 million revolving credit facility. We used the proceeds from the incremental term loans and loans under the revolving credit facility, together with cash on hand, to purchase approximately 98% of the outstanding and fully diluted Gentium ordinary shares and ADSs for an acquisition cost of $976.3 million, comprising cash payments of $993.4 million offset by proceeds from the exercise of Gentium share options of $17.1 million.

In connection with the EUSA Acquisition in 2012, we agreed to make a contingent payment of $50.0 million in cash if Erwinaze achieved net sales in the United States of $124.5 million or more in 2013. This net sales milestone was achieved in the fourth quarter of 2013, and as a result we made the contingent payment in the first quarter of 2014.

We believe that our existing cash balances, cash we expect to generate from operations and funds remaining available under our revolving credit facility will be sufficient to fund our operations, to fund our share repurchase program, to fund our purchase of the remaining Gentium ordinary shares from the ADS depository and to meet our existing obligations for the foreseeable future, including our obligations under our current credit agreement. 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 versions of Xyrem or other sodium oxybate 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.

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, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue new operations or the expansion of our existing operations. For example, in February 2014, we announced that we had commenced construction of a manufacturing and development facility in Ireland, and we expect to invest approximately €45 to €50 million ($61 to $68 million) to build and open the facility. Accordingly, we may again seek to raise additional funds to license or acquire additional products, product candidates or companies, to expand our operations or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders, and the consent of the lenders under our current 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 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 current credit agreement, corporate and regulatory requirements and market conditions. Share repurchases may be suspended or discontinued at any time without prior notice. During the three months ended March 31, 2014, we did not purchase any of our ordinary shares under the share repurchase program. As of March 31, 2014, the remaining amount authorized under the share repurchase program was $63.6 million.

Table of Contents

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

	Three Months Ended March 31,	
	2014	2013
Net cash provided by operating activities	$68,723	$69,890
Net cash used in investing activities	(957,203)	(6,443)
Net cash provided by financing activities	497,662	3,133
Effect of foreign currency exchange rates on cash and cash equivalents	188	(3,265)
Net increase (decrease) in cash and cash equivalents	$(390,630)	$63,315

Net cash provided by operating activities of $68.7 million for the three months ended March 31, 2014 related to a net loss of $93.6 million, adjusted for an upfront license fee and milestone payment of $127.0 million in respect of our acquisition of rights to JZP-110 and non-cash items of $46.9 million primarily related to intangible asset amortization, share-based compensation expense and acquisition accounting inventory fair value step-up adjustments. This was partially offset by $11.5 million of net cash outflow related to changes in operating assets and liabilities which included $14.9 million in respect of the payment of the contingent consideration following the EUSA Acquisition. Net cash provided by operating activities of $69.9 million for the three months ended March 31, 2013 related to net income of $43.4 million, adjusted for non-cash items of $36.3 million primarily related to intangible asset amortization and share-based compensation and an upfront payment of $4.0 million in respect of the acquisition of JZP-386. This was partially offset by $9.9 million of net cash outflow related to changes in operating assets and liabilities.

Net cash used in investing activities for the three months ended March 31, 2014 primarily related to the funding of the Gentium Acquisition, the acquisition of rights to JZP-110 and, to a lesser extent, purchases of property and equipment. Net cash used in investing activities for the three months ended March 31, 2013 primarily related to the acquisition of JZP-386 and, to a lesser extent, purchases of property and equipment and intangible assets.

Net cash provided by financing activities for the three months ended March 31, 2014 primarily related to net proceeds of $636.4 million from our term loans and borrowings under our revolving credit facility, proceeds of $21.5 million from employee equity incentive and purchase plans and exercise of warrants, partially offset by $119.2 million for the acquisition of noncontrolling interests in Gentium and $35.1 million in respect of the payment of the contingent consideration following the EUSA Acquisition. Net cash provided by financing activities for the three months ended March 31, 2013 primarily related to proceeds from employee equity incentive and purchase plans and exercise of warrants of $9.6 million partially offset by a principal repayment of our long-term debt of $5.9 million.

Credit Agreement

As discussed above, we entered into our credit agreement in July 2012 in connection with the EUSA Acquisition, and we subsequently amended the credit agreement in July 2013 and January 2014. After giving effect to the January 2014 amendment, the credit agreement provides for $904.4 million principal amount of term loans and a $425.0 million revolving credit facility. The term loans under the credit agreement have a June 12, 2018 maturity date that was applicable to the refinanced term loans and the loans under the revolving credit facility have a June 12, 2017 maturity date that was applicable to the prior revolving credit facility.

As a result of the June 2013 amendment, the interest rate margins on the term loans and the revolving loans were reduced by 150 basis points, and as a result of the January 2014 amendment, the interest rate margins on the terms loans were reduced by a further 25 basis points. The term loans under the credit agreement bear interest, at our option, at a rate equal to either the LIBOR, plus an applicable margin of 2.50% per annum (subject to a 0.75% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 1.50% 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, 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 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.

As of March 31, 2014, the interest rates on the outstanding term loans was 3.25% and on our borrowings under the revolving credit facility was 2.69%.

Certain of our wholly-owned subsidiaries are borrowers under the credit agreement. The borrowers' obligations under the credit agreement, and any hedging or cash management obligations entered into with a lender or an affiliate of a lender, are guaranteed by us and certain of our subsidiaries and are secured by substantially all of our, the borrowers' and the guarantor subsidiaries' assets.

Table of Contents

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 term loans effected on or prior to July 23, 2014. We are required to make mandatory prepayments of the 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 current 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 term loans, which are due quarterly, began in March 2014 and are equal to 1.0% per annum of the original principal amount of $904.4 million with any remaining balance payable on the final maturity date.

Our credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to us and our restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement also contains a financial covenant that requires Jazz Pharmaceuticals plc and its restricted subsidiaries to maintain a maximum secured leverage ratio. We were, as of March 31, 2014, and are currently in compliance with this financial covenant.

Contractual Obligations

The table below presents a summary of our contractual obligations as of March 31, 2014 (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 and other loans - principal	$904,489	$9,513	$18,965	$875,744	$267
Term and other loans - interest (2)	122,761	29,726	58,527	34,488	20
Revolving credit facility - principal	300,000	—	—	300,000	—
Revolving credit facility - interest (3)	26,249	8,196	16,414	1,639	—
Revolving credit facility - commitment fee (4)	2,030	634	1,269	127	—
Purchase obligations (5)	38,708	36,948	400	410	950
Operating lease obligations (6)	29,461	10,329	15,925	3,207	—
Total	$1,423,698	$95,346	$111,500	$1,215,615	$1,237

(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. On January 13, 2014, we signed a definitive agreement with Aerial under which we acquired rights to JZP-110, a novel compound in clinical development for the treatment of EDS in patients with narcolepsy. Under the agreement, we acquired worldwide development, manufacturing and commercial rights to JZP-110 (other than in certain jurisdictions in Asia where SK retains rights). Under the agreement, Aerial received an upfront payment of $125.0 million in January 2014. Aerial and SK are eligible to receive milestone payments up to an aggregate of $272.0 million based on development, regulatory and sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales of JZP-110. Potential future milestone payments to other third parties under other agreements could be up to an aggregate of $286.0 million, of which up to $120.0 million will become due and payable to Perrigo Company plc (formerly Elan Pharmaceuticals, Inc.) in tiered contingent payments, with the first such payment becoming due if net sales of Prialt of at least $75.0 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) The interest rate was 3.25% at March 31, 2014, which we used to estimate interest owed on the term loans outstanding on March 31, 2014 until the final maturity date in June 2018.

(3) The interest rate was 2.69% at March 31, 2014, which we used to estimate interest owed on the amount borrowed under the revolving credit facility as of March 31, 2014 until the final maturity date in June 2017.

(4) Our 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. In the table above, we used a rate of 0.50% and assumed undrawn amounts of $125.0 million to estimate commitment fees owed.

Table of Contents

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

(6) Includes the minimum lease payments for our office buildings, manufacturing plant and automobile lease payments for our sales force.

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. 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, 2013. 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, 2013.

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,” “intend,” “continue,” “potential,” “possible,” “foreseeable,” “likely” and similar expressions in 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2014, 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, 2013.

Interest Rate Risk. We are exposed to risks associated with changes in interest rates in connection with our term loans and borrowings under our revolving credit facility. Our indebtedness under our term loans is subject to LIBOR or base rate floors of 0.75% and 1.75%, respectively. We have elected to have the terms loans and borrowings under the revolving credit facility bear interest based on LIBOR (as opposed to the prime lending rate). Currently LIBOR is below the floor of 0.75%, and therefore an increase in interest rates would only impact our net interest expense on our term loans to the extent LIBOR exceeds the floor. Based on indebtedness under our term loans of $902.1 million as of March 31, 2014, a 1.0% change in interest rates, above the LIBOR floor, would increase net interest expense on our term loans for the remainder of 2014 by approximately $6.9 million. Borrowings under our revolving credit facility are not subject to a LIBOR floor. Based on indebtedness under our revolving credit facility of $300.0 million as of March 31, 2014, a 1.0% change in interest rates would increase net interest expense on our revolving loan borrowings for the remainder of 2014 by approximately $2.3 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 March 31, 2014.

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

Changes in Internal Control over Financial Reporting. As discussed above, the Gentium Acquisition closed on January 23, 2014. The Gentium Acquisition was accounted for using the acquisition method of accounting. The results of operations of the acquired Gentium business have been included in our consolidated results of operations since January 23, 2014, and we are currently in the process of evaluating and integrating Gentium's historical internal controls over financial reporting with ours.

During the quarter ended March 31, 2014, other than continuing changes to our internal control process resulting from the Gentium Acquisition as discussed above, there have been no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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 U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem® (sodium oxybate) oral solution. Roxane's initial 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 U.S. 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. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA had been stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane's initial Paragraph IV Certification, but that stay has expired. Additional patents covering Xyrem have issued since the original suit against Roxane was filed, and cases involving these patents have been consolidated with the original action.

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

On April 1, 2014, we received an additional Paragraph IV Certification from Roxane alleging that a tenth patent listed in the Orange Book for Xyrem in December 2013 is invalid or not infringed. We have not yet responded to this Paragraph IV Certification and cannot predict the timing or outcome of this matter or its impact on the other ongoing proceedings with Roxane.

On December 10, 2012, we received a Paragraph IV Certification notice 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 initial Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal's proposed generic product and that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification notice 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 seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. An additional patent covering Xyrem issued since the original suit was filed and the case involving this patent has been consolidated with the original case.

On April 7, 2014, we received an additional Paragraph IV Certification from Amneal alleging that a tenth patent listed in the Orange Book for Xyrem in December 2013 is invalid. We have not yet responded to this Paragraph IV Certification and cannot predict the timing or outcome of this matter or its impact on the other ongoing proceedings with Amneal.

On November 21, 2013, we received a Paragraph IV Certification notice from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Par's Paragraph IV Certification alleged that ten patents listed in the Orange Book for Xyrem are invalid, unenforceable, and/or will not

be infringed by Par's proposed generic product. On December 27, 2013, we filed a lawsuit against Par in the District Court in response to Par's Paragraph IV Certification seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe our patents.

On April 23, 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request on May 5, 2014. The order consolidating the cases provides that Amneal's 30-month stay period will be extended to coincide with the date of Par's 30-month stay period, calculated to be May 20, 2016. As a result, FDA's approval of both ANDAs is stayed until the earlier of (i) May 20, 2016, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of events in the consolidated case.

FazaClo ANDA Matters: Azur Pharma Public Limited Company, or Azur Pharma, received Paragraph IV Certification notices from three generics manufacturers, Barr Laboratories, Inc., or Barr, Novel Laboratories, Inc., or Novel, and Mylan Pharmaceuticals, Inc., or Mylan, indicating that ANDAs had been filed with the FDA requesting approval to market generic

Table of Contents

versions of FazaClo® (clozapine, USP) LD orally disintegrating clozapine tablets. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification against Barr on August 21, 2008, against Novel on November 25, 2008 and against Mylan on July 23, 2010. Each case was filed in the U.S. District Court for the District of Delaware, or the Delaware Court. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD 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 and Mylan matters had been stayed pending reexamination of the patents in the lawsuits. In September 2013 and January 2014, reexamination certificates were issued for the two patents-in-suit, with the claims of the patents confirmed. The Delaware Court lifted the stay of litigation in the two cases in March 2014. No trial date has been set and we cannot predict the timing or outcome of this litigation.

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in the California Superior Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to a $10.5 million and an additional $25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. In March 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. In July 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. That ruling was affirmed by the California Court of Appeal in January 2014, and the case was remanded to Superior Court. We cannot predict the timing or outcome of this litigation.

Shareholder Litigation Matter: In January 2014, we became aware of a purported class action lawsuit filed in the U.S. District Court for the Southern District of New York in connection with our acquisition pursuant to a tender offer of a majority of the voting securities of Gentium S.p.A., or Gentium, which we refer to as the Gentium Acquisition. The lawsuit, captioned Xavion Jyles, Individually and on Behalf of All Others Similarly Situated v. Gentium S.P.A. et al., names Gentium, each of the Gentium's directors, us and our Italian subsidiary as defendants. The lawsuit alleges, among other things, that Gentium's directors breached their fiduciary duties to Gentium's shareholders in connection with the Gentium tender offer agreement that Gentium entered into with us and our Italian subsidiary valuing Gentium ordinary shares and American Depositary Shares, or ADSs, at $57.00 per share, and that we and our Italian subsidiary violated Sections 14(e) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by allegedly overseeing Gentium's preparation of an allegedly false and misleading Section 14D-9 Solicitation/Recommendation Statement. The lawsuit seeks, among other relief, class action status, rescission, and unspecified costs, attorneys' fees and other expenses. We cannot predict the timing or outcome of this matter.

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

Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our ordinary shares could decline

due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2013.

Table of Contents

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 65.5% of our net product sales for the three months ended March 31, 2014 and 65.8% of our net product sales for the year ended December 31, 2013. Our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2011 to 2012 and from 2012 to 2013, we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in February 2014, 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 or an alternative sodium oxybate product for treating cataplexy and/or excessive daytime sleepiness in narcolepsy;
- 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, and the pressure to develop a single shared system REMS with potential generic competitors, or regulatory actions by the FDA, including actions as a result of, or related to the matters raised in, the Form FDA 483 we received in April 2014, 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 versions of Xyrem or other sodium oxybate 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, three 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 or other sodium oxybate products for treatment of cataplexy and/or excessive daytime sleepiness in narcolepsy. If one or more companies receive FDA approval of an ANDA for generic versions of Xyrem or a new drug application, or NDA, for other sodium oxybate products, it is possible that such company or companies could introduce generic versions of Xyrem or other sodium oxybate products 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 competition to Xyrem at risk of potentially being held liable for damages for patent infringement.

In October 2010, December 2012 and November 2013 we received a Paragraph IV Certification from each of Roxane, Amneal and Par, respectively, that each had 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. We have sued Roxane, Amneal and Par 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.

Table of Contents

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. Although no trial date has been set in any of the ANDA suits, we anticipate that trial on some of the patents in the Roxane case could occur as early as late in the fourth quarter of 2014. However, the actual timing of events may be significantly earlier or later than contemplated by current scheduling orders, and we cannot predict the timing or outcome of events in this or the other ANDA litigations. 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. 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."

Other companies could also develop products that are similar, but not identical, to Xyrem, such as an alternative formulation or an alternative formulation combined with a different delivery technology, and seek approval in the United States by referencing Xyrem and relying, to some degree, on the FDA's approval of Xyrem and related determinations of safety and efficacy. For example, in April 2014, we learned about the completion of a "first in man" clinical trial by a company using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients. This company has stated its intent to submit an NDA, referencing Xyrem, to the FDA by the end of 2016. If this company is successful in developing a sodium oxybate formulation that could be effectively used with its delivery technology and is able to obtain FDA or other regulatory approval for its product to treat narcolepsy patients, we expect the launch of such a product would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

A generic manufacturer or manufacturer of an alternative sodium oxybate product 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 was allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. Consequently, a generic manufacturer or manufacturer of an alternative sodium oxybate product 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, in 2013, both our active pharmaceutical ingredient supplier and our finished product manufacturer had to request and justify increased quotas from the DEA. For 2014, both our active pharmaceutical ingredient supplier and finished product manufacturer have been allocated most, but not all, of their respective requested quotas and may need to request and justify increased quotas from the DEA in 2014. If we and our supplier and manufacturer cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

After any introduction of a generic competitor, a significant percentage of the prescriptions written for Xyrem may be filled with the generic version, resulting in a loss in sales of Xyrem. Generic competition often results in decreases in

the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. We expect that generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Table of Contents

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. 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. The FDAAA requires that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. We have not reached agreement with the FDA on certain significant terms of our REMS for Xyrem. 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, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We expect to receive the FDA's response to our initial dispute resolution submission in the second quarter of 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. 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, and/or negatively affect sales of Xyrem.

Section 505-1(i)(1) of the U.S. Federal Food, Drug and Cosmetic Act, or the FDCA, generally provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same elements as the referenced drug, such as a medication guide, a patient package insert and other "elements to assure safe use," or 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 separate but comparable 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 any aspects of the REMS 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. Accordingly, we expect to 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 we may take with respect to licensing or sharing our REMS, or the FDA's response to a certification that a third party has been unable to obtain a license.

In the FDA's December 2012 response denying a Citizen Petition that we filed in July 2012, the FDA stated that when an NDA holder has a deemed REMS, the FDA directs the ANDA applicant(s) 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 has further stated that it typically monitors the progress of industry working groups attempting to develop shared REMS systems, and that it has acted to help ensure that sponsors were cooperating and that there were no obstacles to developing a single shared system. In January 2014, the FDA held an initial meeting with us and current Xyrem ANDA applicants to facilitate the development of a single shared system REMS, and we expect these interactions to continue among the parties. We cannot predict the timing, outcome or impact on our business of 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),

including the impact of the ongoing process with respect to potential modifications to the Xyrem deemed REMS as discussed above, or the impact of any single shared system REMS on our ongoing litigation with each of the ANDA applicants. 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.”

If we do not develop a single shared system REMS 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 that are in our deemed REMS or, when 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

Table of Contents

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. Two of the ANDA applicants have asserted that our patents covering the distribution system for Xyrem should not have been listed in the Orange Book, and that the Xyrem REMS is blocking competition. We cannot predict the outcome of these claims in the ongoing litigation, or the impact of any similar claims that may be made in the future.

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.

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. Our Xyrem deemed REMS includes unique features that provide more extensive information about adverse events, including deaths, than is generally available for other products that are not subject to similar risk management programs. For example, 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 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 deaths that we discovered in April 2011 which had not been reported. We completed the actions and submitted the data required to address the observations in the 2011 warning letter and arising from a subsequent inspection. In August 2013, we received a close-out letter from the FDA.

In April 2014, we received a Form FDA 483 at the conclusion of a pharmacovigilance inspection recently conducted by the FDA. The Form FDA 483 included observations relating to certain aspects of our adverse drug experience reporting system for all of our products, including Xyrem. Since May 2012, all of the approximately 3,500 adverse drug experiences, or ADEs, reported to us for all products that were categorized as “serious and unexpected” had been reported to the FDA. However, reports related to 92 of these ADEs had been submitted beyond the 15-day regulatory deadline. The Form FDA 483 included an observation related to these late filings. In addition, the Form FDA 483 included observations regarding our lack of written procedures for certain aspects of our evaluation of ADEs and certain deficiencies in our investigation of ADEs. We have responded to the Form FDA 483 with a description of the corrective actions and improvements we had implemented before or shortly following the inspection and additional improvements that we plan to implement to address the observations in the Form FDA 483. In light of the fact that we have previously received observations relating to adverse drug experience reporting, we do not know whether the FDA will take further action, including the issuance of a warning letter as a follow-up to its inspection, or require us to take further action, with respect to the matters covered in the Form FDA 483. Such actions may be costly or time consuming and/or negatively affect the commercial success of Xyrem and our other products. In addition, we

Table of Contents

cannot assure you that we will be able to adequately address the matters raised by the FDA in the Form FDA 483 or otherwise, and the failure to do so could have a material adverse effect on our business, financial condition and results of operations.

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 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. 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 products. Our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

In addition to Xyrem, we are commercializing a portfolio of products, including our other key products Erwinaze® (asparaginase Erwinia chrysanthemi) (called Erwinase® in markets outside the United States), Defitelio® (defibrotide) and Prialt® (ziconotide) intrathecal infusion. We commenced the launch of Defitelio in Europe beginning in Germany and Austria in March 2014, in Italy (with reimbursement under Law 648/96) in April 2014 and in the United Kingdom in early May 2014. See the discussion regarding the launch of Defitelio in the risk factor in this Item 1A entitled "We may not be able to successfully commercialize Defitelio in Europe, or obtain marketing approval in other countries, including the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects."

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, and launched in the U.S. market in November 2011. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere.

Erwinaze 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, our ability to obtain approval for the intravenous administration of Erwinaze in the United States, our ability to obtain data on the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase, as well as our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise, in certain additional countries 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 ensure sufficient supply of Erwinaze on a timely basis. See the discussion regarding Erwinaze supply issues in the 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 other risks that may impact Erwinaze sales, including 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 favorable 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.

Table of Contents

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 distribute Prialt through an exclusive wholesale distributor and pharmacy. We face many challenges in maintaining and growing sales of Prialt, including acceptance of intrathecal administration by patients and physicians and challenges for physicians with timely reimbursement for use of Prialt. In addition, the FDA has required that the label for Prialt include a boxed warning regarding the risk of psychiatric symptoms and neurological impairment. We cannot predict whether the FDA will require additional warnings, or place any additional limitations on our ability to advertise and promote Prialt, which could negatively impact Prialt sales.

Failure to maintain or increase prescriptions and revenue from sales of our products, including Erwinaze, Defitelio 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 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. 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 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 may not be able to successfully commercialize Defitelio in Europe, or obtain marketing approval in other countries, including the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*

We acquired Defitelio/defibrotide as a result of the Gentium Acquisition. In October 2013, the European Commission, or EC, granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe hepatic veno-occlusive disease, or VOD, in adults and children undergoing hematopoietic stem cell transplantation, or HSCT, therapy. We commenced the launch of Defitelio in Europe beginning in Germany and Austria in March 2014, in Italy (with reimbursement under Law 648/96) in April 2014 and in the United Kingdom in early May 2014. We expect to launch in additional European countries on a rolling basis during 2014 and 2015, subject to receipt of pricing and reimbursement approvals as described below. Any delay in the planned timing of the launch of Defitelio in additional countries would negatively affect anticipated revenue from Defitelio in 2014 and could negatively affect our growth prospects.

We are in the process of making pricing and reimbursement submissions with respect to Defitelio, and discussing them with regulatory authorities, in those European countries where pricing and reimbursement approvals are required for launch. We cannot predict the timing of Defitelio’s launch in countries where we are awaiting pricing and reimbursement guidelines. If we experience delays and unforeseen difficulties in obtaining pricing and reimbursement approvals, planned launches in the affected countries would be delayed and our anticipated revenue from Defitelio in 2014 and our growth prospects could be negatively affected. We have developed estimates of anticipated pricing, which are based on our research and understanding of the product and target market. However, due to efforts to provide for containment of health care costs, one or more countries may not support our estimated level of governmental pricing and reimbursement for Defitelio, particularly in light of the budget crises faced by a number of countries in Europe, which would negatively impact anticipated revenue from Defitelio. While we have launched Defitelio in Italy under Law 648/96, which provides reimbursement for Defitelio by the Italian National Health System until final pricing and reimbursement approval is obtained, we cannot predict the timing for final approval or actual terms of commercial pricing and reimbursement we may receive in Italy. In addition, until 2008, Gentium sold forms of defibrotide in Italy to treat vascular disease with risk of thrombosis at a price that was substantially lower than the anticipated commercial price for Defitelio. Although our current pricing and reimbursement discussion relates to an unrelated indication, regulators in Italy may use the price of the past sales of defibrotide by Gentium as a reference price for Defitelio, which may make it more difficult for us to justify our requested higher commercial price,

which would also negatively impact anticipated revenue from Defitelio in Italy.

Furthermore, after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced countries. If any of these events occurs, our anticipated revenue from Defitelio would be negatively affected.

Due to the recent commercial launch of Defitelio in Europe and the limited amount of historical sales data, which has been limited to sales from named patient programs, our Defitelio sales will be difficult to predict from period to period, particularly since we may experience delays and unforeseen difficulties in obtaining pricing and reimbursement approvals in

Table of Contents

additional countries. As a result, you should not rely on Defitelio sales results in any period as being indicative of future performance. In addition, if sales of Defitelio do not reach the levels we expect, our anticipated revenue from Defitelio would be negatively affected which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Defitelio was authorized under "exceptional circumstances" because it was not possible to obtain complete information about the product due to the rarity of the disease and because ethical considerations prevented conducting a study directly comparing Defitelio with a placebo. A marketing authorization granted under exceptional circumstances is subject to approval conditions and an annual reassessment of the risk-benefit balance by the European Medicines Agency, or EMA. As such, if we fail to meet the approval condition for Defitelio, which requires that we set up a patient registry to investigate the long term safety, health outcomes and patterns of utilization of Defitelio during normal use, or if it is determined that the balance of risks and benefits of using Defitelio changes materially, the EMA could vary, suspend or withdraw the marketing authorization for Defitelio. This could negatively impact our anticipated revenue from Defitelio and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Under a license and supply agreement, Gentium has licensed to Sigma-Tau Pharmaceuticals, Inc. the rights to commercialize defibrotide for the treatment and prevention of VOD in North America, Central America and South America, subject to receipt of marketing authorization, if any, in the applicable territory. A prior NDA submission by Gentium seeking approval in the United States for defibrotide for the treatment of VOD was voluntarily withdrawn from consideration in 2011 in order to address issues raised by the FDA. We recently met with the FDA to discuss issues related to the possible submission of an NDA for defibrotide for the treatment of severe VOD in patients undergoing HSCT therapy. Based on this meeting, we believe that it may be possible to submit an NDA without the need for data from an additional clinical trial. We are continuing to address the FDA's comments and questions and plan to have additional discussions with the FDA during 2014 prior to finalizing our strategy for seeking approval of defibrotide in the United States. We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in indications in addition to the treatment of severe VOD. We cannot know when, if ever, defibrotide will be approved in the United States or in any other country or under what circumstances, and what, if any, additional clinical or other development activities will be required in order to potentially obtain such regulatory approval and the cost associated with such required activities, if any. If we fail to obtain approval for defibrotide in other countries or for new indications, our anticipated revenue from defibrotide and our growth prospects would be negatively affected.

The Marketing Authorization Application, or MAA, Gentium initially filed with the EMA in 2011 sought approval for defibrotide for the treatment and prevention of VOD in adults and children. The approval Gentium received from the EC in October 2013 was for the narrower indication of treatment of severe VOD in adults and children undergoing HSCT therapy. The scope of any future approvals we receive may negatively affect defibrotide's growth prospects.

While we have limited revenue from sales of defibrotide on a named patient basis, we cannot predict whether historical revenues from named patient programs will continue or whether we will be able to continue to distribute defibrotide on a named patient basis.*

Defibrotide is currently available in approximately 40 countries on a named patient basis and is being distributed to patients diagnosed with VOD in the United States through an expanded access program pursuant to a treatment investigational new drug application, or IND, protocol. In certain European countries, reimbursement for products that have not yet received marketing authorization is provided through national named patient or compassionate use programs. Such reimbursement may cease to be available if authorization for named patient or compassionate use programs expires or is terminated. While Gentium has generated and we continue to generate revenue from the distribution of defibrotide through named patient programs, we cannot predict whether historical revenues from these programs will continue, whether we will be able to continue to distribute defibrotide on a named patient basis in these countries, whether the rolling launch of Defitelio in Europe will proceed as planned, or whether commercial revenues will exceed revenues historically generated from sales on a named patient basis. Any failure to maintain revenues from sales of defibrotide on a named patient basis and/or to generate revenues from commercial sales of Defitelio

exceeding historical defibrotide sales on a named patient basis 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

Table of Contents

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.

Other than the manufacturing plant in Italy where we produce some active pharmaceutical ingredients, including the defibrotide drug substance, we do not currently have our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. 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 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 was nearly completely absorbed by demand for the product. In the past, we have experienced a disruption of supply of Erwinase in the European market due to manufacturing challenges, including shortages related to the failure of a batch to meet certain specifications in 2013, and we may experience similar or other manufacturing challenges in the future. 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, do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

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

Our current supplier of sodium oxybate, Siegfried USA LLC, or Siegfried, was approved by the FDA in late 2011 and became our sole supplier in 2012. We expect that Siegfried will continue to be our sole supplier of sodium oxybate for the foreseeable future, and we cannot assure you that Siegfried can or will continue to supply on a timely basis, or at all, sufficient quantities of 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. The FDA’s approval of the BLA for Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze by us and the PHE. Inability 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. 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

Table of Contents

shortage of supply of Erwinaze. While we continue to work with PHE 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. Any inability 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 believe that we are currently the sole worldwide producer of the defibrotide drug compound, and we conduct all of our manufacturing operations for the defibrotide drug compound in a single facility located in Villa Guardia, near Como, Italy. This facility could be damaged by fire, flood, earthquake, power loss, telecommunication and information system failure, terrorism or similar events. Any of these events could cause a delay or interruption in manufacturing and potentially a supply shortage of defibrotide, which could negatively impact our anticipated revenues. In addition, we have contracted with Patheon UK Limited, or Patheon, to process the defibrotide compound into its finished form at Patheon's manufacturing facility in Italy. Patheon is currently the sole processor of finished Defitelio. If Patheon does not or is not able to perform these services for any reason, it may take time and resources to implement and execute the necessary technology transfer to another processor, and such delay could negatively impact our product launch and anticipated revenues and potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need. We have initiated work with Fresenius Kabi Austria GmbH, or Fresenius Kabi, to conduct a technology transfer of our manufacturing process for the finished form of Defitelio to their manufacturing site in Austria. Subject to a successful technology transfer, including manufacture of process validation batches, and receipt of all necessary regulatory approvals, we intend to qualify Fresenius Kabi as a second source of Defitelio. The process of technology transfer is complicated, and Fresenius Kabi may not be able to successfully obtain regulatory approval to produce Defitelio commercially, which could negatively impact our anticipated revenues if Patheon for any reason does not or cannot provide us with sufficient quantities of finished product to meet our clinical and commercial needs.

We are in the process of changing our supplier for ziconotide, the active pharmaceutical ingredient in Prialt, and have commenced the transfer to the new supplier. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for finished product for a number of years, which we expect to be sufficient time to complete the transfer to the new supplier. In addition, our new manufacturer of finished product was approved by the FDA in December 2012 and started to supply us with Prialt finished product in January 2014. 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 finished product will be able to meet our demand in the future. 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 HD, FazaClo LD and Versacloz™ (clozapine) oral suspension, 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.

In order to commence our planned Phase 3 clinical program for JZP-110, we need to have sufficient quantities of clinical product manufactured. We have selected a supplier for JZP-110 and plan to work with the supplier to transfer the manufacturing methods to start production of JZP-110 as early as practicable. In addition, we rely on Concert Pharmaceuticals, Inc. to transfer its manufacturing methods to us and our contract manufacturers to produce sufficient quantity of JZP-386 required for our planned first study in humans. While we believe that we will be able to obtain sufficient supplies of JZP-110 and JZP-386 before the commencement of the applicable planned clinical trials, there can be no assurance that our suppliers will be able to produce sufficient clinical supplies of JZP-110 or JZP-386 in a timely manner or at all. Any delay in receiving sufficient supplies of JZP-110 or JZP-386 for our planned studies could negatively impact our development programs.

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 example, in 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, in 2013, both our active pharmaceutical ingredient supplier and our finished product manufacturer had to request and justify increased quotas from the DEA for 2013. For 2014, both our active pharmaceutical ingredient supplier and finished product manufacturer have been allocated most, but not all, of their respective requested quotas and may need to request and justify increased quotas from the DEA later in 2014. 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 ingredients for our products or backup manufacturers for our finished products.

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. For example, the FDA inspected the PHE facility where Erwinaze is manufactured in 2013 and will do so again in the future. 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 realize the anticipated financial and strategic benefits from the recent Gentium Acquisition or be able to successfully integrate the acquired business.

In January 2014, we closed the Gentium Acquisition in connection with which, pursuant to a tender offer, we acquired approximately 98% of the outstanding voting securities of Gentium for an aggregate acquisition cost of approximately $976.3 million, comprising cash payments of $993.4 million offset by proceeds from the exercise of Gentium share options of $17.1 million. The Gentium Acquisition creates numerous uncertainties and risks, and 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 transition activities and integration efforts, which include:

- the potential disruption of our historical core business;
- the risk that our relative lack of experience in the hematology/oncology market will not allow us to achieve anticipated sales of Defitelio;
- the strain on, and need to continue to expand, our existing operational, technical, financial and administrative infrastructure;
- the difficulties in assimilating employees and corporate cultures, including our lack of experience in maintaining positive interactions with unionized employees;
- the failure to retain key managers and other personnel, including the employees from the acquired Gentium business who might experience uncertainty about their future roles with us;
- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisition;
- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures;
- any unanticipated liabilities for activities of or related to Gentium or its operations, products or product candidates; and

- the challenges and risks associated with Gentium not being our wholly owned subsidiary, including needing to consider the rights of, and duties owed to, the minority shareholders of Gentium under Italian law when making future decisions that might impact Gentium, its business or operations.

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

Table of Contents

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.

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

We are headquartered in Dublin, Ireland and have multiple offices in the United States, the United Kingdom, Italy and other countries in Europe. Our headcount has grown from approximately 260 employees at the end of 2011 to approximately 815 in April 2014. This includes employees in fourteen 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, conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations 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 future changes to such requirements, in one or more countries where we are located or do business;
- country-specific tax, labor and employment laws and regulations;
- applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions and any changes to them;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations, as well as maintaining positive interactions with unionized employees in one of our international locations;
- 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. For example, although the EC granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe VOD in adults and children undergoing HSCT therapy in October 2013, before launching Defitelio in certain European countries, country-specific pricing and reimbursement approvals must be obtained. We commenced the launch of Defitelio in Europe beginning in Germany and Austria in March 2014, in Italy (with reimbursement under Law 648/96) in April 2014 and in the United Kingdom in early May 2014. We expect to launch Defitelio in additional European countries on a rolling basis during 2014 and 2015 and are engaged in pricing and reimbursement submissions as applicable in preparation for planned launches in additional European countries. If we experience delays or unforeseen difficulties in obtaining pricing and reimbursement for Defitelio in any of these countries, the planned timing of the launch of Defitelio in additional countries would be delayed and our anticipated revenue from Defitelio in 2014 would be negatively affected, which could negatively affect our growth prospects.

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. In addition, we expect to continue to grow our product sales in Europe, including through our planned launch of Defitelio. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe and the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, has led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively

impact our revenues and profitability.

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, including generic versions of our products, could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, from time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the 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. Similarly, negative publicity resulting from our recent receipt of a Form FDA 483 or other related regulatory actions could adversely affect sales of our products.

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. Price increases of our products and publicity regarding price increases of any products distributed by other pharmaceutical companies could negatively affect market acceptance of our products.

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

We have made significant investments into expanding our product development pipeline and expect to substantially increase our research and development organization to pursue targeted development activities in 2014 and beyond. Significant clinical, development and financial resources will be required to progress product candidates to obtain necessary regulatory approvals and to develop them into commercially viable products. We have a number of product candidates under development, including JZP-110 and JZP-386 in the sleep area and JZP-416 (formerly known as Asparec) and Leukotac™ (inolimomab) in the hematology and oncology area. 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. 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.

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. Specifically, in the hematology and oncology therapeutic area, we have ongoing projects involving Erwinaze and are evaluating potential development of defibrotide in indications in addition to the treatment of severe VOD in adults and children undergoing HSCT therapy. In the sleep therapeutic area, we have worked with the FDA and several leading specialists to design a clinical study to generate additional data on the treatment of pediatric narcolepsy patients with Xyrem and plan to open clinical sites for this study in the second half of 2014. Our 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.

Although Defitelio has been approved in Europe, a prior NDA submission by Gentium seeking approval in the United States for defibrotide for the treatment of VOD was voluntarily withdrawn from consideration in 2011 in order to address issues

Table of Contents

raised by the FDA. We recently met with the FDA to discuss issues related to the possible submission of an NDA for defibrotide for the treatment of severe VOD in patients undergoing HSCT therapy. Based on this meeting, we believe that it may be possible to submit an NDA without the need for data from an additional clinical trial. We are continuing to address the FDA's comments and questions and plan to have additional discussions with the FDA during 2014 prior to finalizing our strategy for seeking approval of defibrotide in the United States. We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in indications in addition to the treatment of severe VOD. We cannot know when, if ever, defibrotide will be approved in the United States and/or other countries or under what circumstances, and what, if any, additional clinical or other development activities will be required in order to potentially obtain regulatory approval in the United States and/or other countries and the cost associated with any such activities. These development efforts may not be successful, which could adversely affect our potential future revenue from defibrotide and our growth prospects.

We also intend to pursue clinical development of other product candidates that we may acquire or in-license in the future. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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.

We are required to demonstrate the safety and efficacy of products that we develop for each intended use through extensive preclinical studies and clinical trials. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. In addition, 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 and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials.

We are currently undertaking a Phase 1 clinical trial of JZP-416 in Europe. Under our license agreement with Alizé Pharma II, or Alizé, under which we obtained rights to develop and commercialize JZP-416, 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 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 JZP-416. We have reviewed our development plans with the FDA and are working with investigators to initiate our first study of JZP-416 in children by the end of 2014.

Table of Contents

In June 2013, the FDA granted Fast Track designation to the investigation of JZP-416 for ALL. Defibrotide has also been granted Fast Track designation by the FDA to treat severe VOD. The Fast Track program is designed to enable more frequent interactions with the FDA during drug development and to expedite new drug candidate review. Although we have obtained Fast Track designation from the FDA for JZP-416 and defibrotide, 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 either JZP-416 or defibrotide will receive any regulatory approvals.

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 the 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.

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.

Table of Contents

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

The commercial potential of our current products and any future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, have fewer side effects, are easier to administer or are less expensive than our products. 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 force and sales organization are not appropriately sized to adequately promote any current or potential future products, the commercial potential of our current products and any future products may be diminished.

In 2012 we added Erwinaze, as well as other smaller products in the oncology supportive care market, to our product portfolio. We are further expanding our hematology and oncology product offering with the launch of Defitelio in Europe on a rolling basis during 2014 and 2015. 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, Defitelio and other products.

We also face competition, and may in the future face additional competition, from manufacturers of generic drugs. 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. Other companies could also develop products that are similar, but not identical, to our marketed products, such as an alternative formulation of our product or an alternative formulation combined with a different delivery technology, and seek approval in the United States by referencing our products and relying, to some degree, on the FDA's finding that our products are safe and effective. See the risk factor in this Item 1A entitled "If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected."

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

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

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic

institutions, clinicians and scientists. We are highly dependent upon our executive management team and other critical personnel, all of whom work on many complex matters that are essential to our success. We do not carry “key person” insurance. The loss of services of one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities. Any employee may terminate his or her employment at any time without notice or with only short notice and without cause or good reason. The resulting loss of institutional knowledge may negatively impact our operations and future growth.

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

Table of Contents

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 or other sodium oxybate products for treatment of cataplexy and/or excessive daytime sleepiness in narcolepsy. If one or more companies receive FDA approval of an ANDA for generic versions of Xyrem or an NDA for other sodium oxybate products, it is possible that such company or companies could introduce generic versions of Xyrem or other sodium oxybate products 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 competition to Xyrem at risk of potentially being held liable for damages for patent infringement.

In October 2010, December 2012 and November 2013, we received a Paragraph IV Certification from each of Roxane, Amneal and Par, respectively, that each had 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 any one 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 Roxane, Amneal and Par seeking to prevent them 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.

In April 2014, we became aware of the completion of a “first in man” clinical trial by a company using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients. This company has stated its intent to submit an NDA referencing Xyrem to the FDA by the end of 2016. See the risk factor in this Item 1A entitled “If generic versions of Xyrem or other sodium oxybate 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 (one of the three generic manufacturers) and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and

Table of Contents

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 HD and FazaClo LD that we license from CIMA were under reexamination by the U.S. Patent and Trademark Office, or the USPTO, and both of the reexamination proceedings proceeded to appeal at the USPTO. The ANDA lawsuits with the other two generic manufacturers had been stayed pending the outcome of these reexamination proceedings. In September 2013 and January 2014, reexamination certificates were issued for the two patents, with the claims of the patents confirmed. The court lifted the stay of litigation in the remaining two ANDA lawsuits in March 2014. We cannot predict the timing or outcome of the patent litigation, or the impact on the entry of additional generic competitors for FazaClo HD or FazaClo LD.

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, including proceedings involving post-issuance patent review procedures before the Patent Trial and Appeal Board, or PTAB, within the USPTO. The final substantive provisions of the Leahy-Smith Act, including the first to file system, became effective on March 16, 2013. 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;
- 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

Table of Contents

secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. For example, Erwinaze has no patent protection, and we rely on trade secrets and other unpatented proprietary information to protect our commercial position, 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 provide assurance 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 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 JZP-416 pending in the United States and many other countries, it is not yet covered by any U.S. patents. JZP-416 was granted orphan drug designation in Europe and the United States subject to certain conditions. 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 JZP-416, including protection by one or more issued patents, JZP-416 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.

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. Under the Leahy-Smith Act, a third party may also have the option to challenge the validity of certain patents with the PTAB. These lawsuits and proceedings 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, or the PTAB will decide that certain patents are not valid, and that we do not have the right to stop the other party

Table of Contents

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, FazaClo HD and FazaClo LD. See Part II, Item 1 “Legal Proceedings” of this Quarterly Report on Form 10-Q. We cannot assure you that these, or other lawsuits or proceedings we may file or defend 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. We have not reached agreement with the FDA on certain significant terms of our REMS for Xyrem. 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, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA’s view, make the REMS more consistent with the FDA’s current practices for REMS documents.

The FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We expect to receive the FDA’s response to our initial dispute resolution submission in the second quarter of 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final

REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. 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, and/or negatively affect sales of Xyrem. In particular, depending on the extent to which certain provisions of our Xyrem deemed

Table of Contents

REMS which are currently protected by our method of use patents covering the distribution of Xyrem are changed, 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 distribution system set forth in our 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 one 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 in the EU member states until we receive approval from the FDA, the EC, or the competent authorities of the EU member states, respectively, generally of an NDA, a BLA or a marketing authorization application. The application must contain information demonstrating the quality, safety and efficacy of the medicinal product, including data from the preclinical and clinical trials, information pertaining to the preparation and manufacture of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and information concerning the stability of the medicinal product. Submission of an application for marketing authorization 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. Any delay or failure in obtaining approval of a drug candidate, or receiving approval for narrower conditions of use than sought, can have a negative impact on our financial performance.

If the FDA, the EC or the competent authorities of the EU member states determine that a REMS or the imposition of post-marketing obligations 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 to propose post-marketing obligations to be included in the marketing authorization for our products in the EU. We may also be required to include 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.

As another example, the marketing authorization in the EU for Defitelio requires us to comply with a number of post-marketing obligations, including obligations relating to the establishment of a patient registry. We may be unable to comply with the post-marketing obligations imposed as part of the marketing authorization for Defitelio. Failure to

comply with these requirements may lead to the suspension, variation or withdrawal of the marketing authorization for Defitelio in the EU.

Changes in healthcare law and implementing regulations, including those based on recently enacted legislation, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and these changes could have a material adverse effect on our business and financial condition.

In March 2010, the U.S. 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, benefits for patients within a coverage gap in the Medicare Part D prescription

Table of Contents

drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program and expanded the Public Health Service's 340B drug pricing discount program. Details of these changes are discussed under the risk factor "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."

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014. In 2012, the Centers for Medicare and Medicaid Services, or CMS, issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act but has not yet issued final regulations. CMS is expected to release the final regulations in 2014.

In 2012, the Supreme Court of the United States heard challenges to the constitutionality of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act; 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, some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. For each state that does not choose to expand its Medicaid program, there may 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.

Moreover, legislative changes to the Healthcare Reform Act 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.

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. Further, an increasing number of EU member states and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU member states, we may be required to conduct clinical trials that

compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

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 has also come to our attention that at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain drugs the insurer identified. In addition, in November 2013 CMS issued guidance to the issuers of qualified health plans sold through the Healthcare Reform Act's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. It is possible that the

Table of Contents

outcome of the pending litigation against other manufacturers, changes in insurer policies regarding co-pay coupons, and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these programs, which could result in fewer patients using affected products, which could include Xyrem, and therefore could have a material adverse effect on our sales, business and financial condition.

We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.*

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

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of our products are, and any of our product candidates that may be approved by the FDA, the EC, the competent authorities of the EU member states 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, 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, suspension or variation of product approval, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall, withdrawal 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.

In April 2014, we received a Form FDA 483 at the conclusion of a pharmacovigilance inspection recently conducted by the FDA. The Form FDA 483 included observations relating to certain aspects of our adverse drug experience reporting system for all of our products, including Xyrem. Since May 2012, all of the approximately 3,500 adverse drug experiences, or ADEs, reported to us for all products that were categorized as “serious and unexpected” had been reported to the FDA. However, reports related to 92 of these ADEs had been submitted beyond the 15-day regulatory deadline. The Form FDA 483 included an observation related to these late filings. In addition, the Form FDA 483 included observations regarding our lack of written procedures for certain aspects of our evaluation of ADEs and certain deficiencies in our investigation of ADEs. We have responded to the Form FDA 483 with a description of the corrective actions and improvements we had implemented before or shortly following the inspection and additional improvements that we plan to implement to address the observations in the Form FDA 483. In light of the fact that we have previously received observations relating to adverse drug experience reporting, we do not know whether the FDA will take further action, including the issuance of a warning letter as a follow-up to its inspection, or require us to take further action, with respect to the matters covered in the Form FDA 483. Such actions may be costly or time consuming and/or negatively affect the commercial success of Xyrem and our other products. In addition, we cannot assure you that we will be able to adequately address the matters raised by the FDA in the Form FDA 483 or otherwise, and the failure to do so could have a material adverse effect on our business, financial condition and results of operations.

If we receive regulatory approvals to sell our products, the FDA, the EC, the competent authorities of the EU member states 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 the EU 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. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

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 and/or PHE

Table of Contents

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.

The marketing authorization in the EU for Defitelio requires us to comply with a number of post-marketing obligations. These include obligations relating to the establishment of a patient registry. We may be unable to comply with the post-marketing obligations imposed as part of the marketing authorization for Defitelio. Failure to comply with these requirements may lead to the suspension, variation or withdrawal of the marketing authorization for Defitelio in the EU.

We have not obtained marketing authorizations and/or may not currently have updated the marketing authorization approval dossiers for Erwinaze and several other medicinal products in every international market in which those products are being sold. For example, in some EU member states where we do not have a marketing authorization, Erwinaze is being provided to patients on the basis of government-approved named patient programs or temporary use authorizations. In certain of these countries, reimbursement is provided for unauthorized products provided through national named patient or compassionate use programs. Such reimbursement may no longer be available if authorization for named patient or compassionate use programs expire or are terminated. 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 Erwinaze 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. In addition, we have provided, and expect to continue to provide, patients access to defibrotide in countries where it is not commercially available through continuation of an expanded access program in the United States and on a named patient basis elsewhere. See the discussion regarding sales of defibrotide through named patient programs in the risk factor in this Item 1A entitled "While we have limited revenue from sales of defibrotide on a named patient basis, we cannot predict whether historical revenues from named patient programs will continue or whether we will be able to continue to distribute defibrotide on a named patient basis."

For a patient to be prescribed Prialt, the patient must have a surgically implanted infusion pump. One of the two pumps the FDA has approved for use with Prialt is Medtronic Inc.'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 addition, certain of our products are currently marketed as medical devices in individual EU member states. If a competent authority in the EU were to determine that the products concerned are incorrectly classified as a medical device, we may be required to cease marketing or distribution of our products, or to recall or withdraw the products from the EU market. We may also be subject to other administrative and enforcement measures, including significant fines or 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 may not be considered final agency decisions, companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful. For example, in September 2012, we received a warning letter from the FDA related to a direct-to-consumer patient brochure for FazaClo. We were no longer using the allegedly violative promotional materials at the time we received the letter, but reviewed all of our other promotional materials for FazaClo in accordance with the letter. We agreed with the FDA on plans for correcting the promotional materials and disseminating the corrective messages to healthcare providers, patients and consumers and began implementation of the corrective actions in accordance with the agreed-upon plans in February 2013. We believe that we have taken necessary actions required to fully address the agency's concerns. However, there can be no assurance that the FDA will agree with our assessment. The FDA could take further action, could require us to take further action, with respect to our FazaClo promotional materials, or could otherwise conclude we have not

taken all appropriate corrective actions with respect to the warning letter. The FDA or other regulatory authorities may disagree with our response to the warning letter or challenge other of our promotional materials or activities in the future, through additional enforcement action, which may have a negative impact on our sales and/or may subject us to financial or other penalties.

The FDA, the competent authorities of the EU member states 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 U.S. 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, or OIG, of the U.S. Department of Health and Human Services, or HHS, 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

Table of Contents

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 and new legislation was passed in November 2013 which gives the FDA increased 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 OIG 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 Substances Act, or CSA. The states also impose similar requirements for handling controlled substances. The United States and the EU member states are parties to the Convention on Psychotropic Substances (1971), or the 1971 Convention. In October 2012, the World Health Organization sent a recommendation to the United Nations Commission on Narcotic Drugs, or the CND, to reschedule GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. In March 2013, the CND voted to reschedule GHB from Schedule IV to Schedule II under the 1971 Convention. While the DEA imposes its own scheduling requirements in the United States under the CSA, the United States is obligated as a signatory to the 1971 Convention to ensure that drug scheduling in the United States is consistent with its obligations under the international treaties. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, the international rescheduling of GHB means that Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements in the EU 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 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

Table of Contents

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.

In addition, the Physician Payment Sunshine provisions of the Healthcare Reform Act require extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. In February 2013, CMS issued a final rule implementing the Physician Payment Sunshine provisions which provided that manufacturers begin tracking payment data on August 1, 2013. Reporting of the payment data is occurring in two phases, with aggregated data to be submitted to CMS by March 31, 2014 and transactional data to be submitted before August 1, 2014. This data is expected to become public on or around October 1, 2014. It is widely anticipated that public reporting under the Sunshine Act will result in increased scrutiny of the financial relationships between industry, teaching hospitals and physicians, and such scrutiny may negatively impact our ability to engage with physicians on matters of importance to us.

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. Other states have considered similar proposals in recent years. Non-U.S. governments often have similar regulations which we also will be subject to in those countries where we market and sell products.

In the EU, the advertising and promotion of our products are subject to EU member states' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU member states may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the EU. The applicable laws at EU level and in the individual EU member states also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional

activities with health care professionals.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU member states. One example is the U.K. Bribery Act of 2010, or the UK Bribery Act. As further discussed below, the UK Bribery Act applies to any company incorporated in or "carrying on business" in the UK, irrespective of where in the world the alleged bribery activity occurs, which could have implications for our interactions with physicians both in and outside the UK. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent

Table of Contents

professional organization, and/or the competent authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Our business activities outside of the United States are subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or 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 company and to devise and maintain an adequate system of internal accounting controls. The UK Bribery Act prohibits giving, offering, or promising bribes to any person, including non-UK government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies which carry on a business or part of a business in the UK may be held liable for bribes given, offered or promised to any person, including non-UK government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the UK Bribery Act there is no exception for facilitation payments. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the 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 who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, 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. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

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 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 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 EU Data Protection 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 Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, that are not considered by the EC to provide an adequate level of data protection. There are also similar data transfer restrictions in Switzerland. However, there are a number of legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, including, among others, a voluntary U.S. - EU Safe Harbor Framework, a voluntary U.S. - Switzerland Safe Harbor Framework and the EU's set of standard form contractual clauses for the transfer of personal data outside of EEA. Our U.S. subsidiary, Jazz Pharmaceuticals, Inc., has certified compliance with the U.S. - EU Safe Harbor Framework 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. The EU Data Protection Regulation is expected to introduce new data

Table of Contents

protection requirements in the EU and substantial fines for breaches of the data protection rules. If the draft EU Data Protection Regulation is adopted in its current form it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

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, and 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. 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 EU, national, and 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 to whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner. 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. Two of the ANDA applicants have asserted that our patents covering the distribution system for Xyrem should not have been listed in the Orange Book, and that the Xyrem REMS is blocking competition. Such a challenge or any other 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.

We manufacture certain active pharmaceutical ingredients, including the defibrotide drug substance, at our manufacturing facilities in Italy. In addition, we have engaged a third party manufacturer to process defibrotide into the finished product at its Italian manufacturing plant. Our manufacturing facilities and those of our third party manufacturer are subject to continuing regulation by the Italian Health Authority and other Italian regulatory authorities with respect to the manufacturing of active pharmaceutical ingredients, including the defibrotide drug substance or its finished form. These facilities are also subject to inspection and regulation by the EMA with respect to the manufacturing of the defibrotide drug substance and its finished form. Also, part of the process to obtain approval for defibrotide is to pass a pre-approval inspection by the EMA, Italian Health Authority and the FDA to ensure that these facilities are in compliance with cGMP. Following initial approval, if any, these authorities will continue to inspect our manufacturing facilities and those of our third party manufacturer, in some cases, unannounced, to confirm ongoing compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our third party manufacturers will

need to ensure that all of our processes, methods and equipment are compliant with cGMP. These authorities may deny approval to manufacture our products, require us to stop manufacturing our products, deny approval to the sale of our products or suspend the sale of our products, if they determine that either our facilities or our third party manufacturer's facility in Italy does not meet the standards of compliance required under applicable regulations.

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

Table of Contents

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 which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. 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, the Council on Radionuclides and Radiopharmaceuticals, or CORAR, regarding the reporting of Medicaid pricing data and paying Medicaid rebates for radiopharmaceutical products. For ProstaScint, we plan to begin making any required reports when CMS provides guidance on this requirement and reporting methodology, which is currently expected in 2014. We sold Quadramet to a third party in December 2013, but have retained any liabilities related to sales of the product during prior periods. In addition to the discussions with CMS as part of CORAR, we have had separate discussions with CMS directly regarding Quadramet. We are currently unable to predict whether price reporting and rebates will be required for ProstaScint and Quadramet and if so, for what period they will be required. We are currently unable to reasonably estimate an amount or range of a potential contingent loss related to the payment of rebates for Quadramet or ProstaScint. Any material liability resulting from radiopharmaceutical price reporting and rebates would negatively impact our financial results.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, the Healthcare Reform Act increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11.0% to 13.0% for non-innovator products; 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 branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (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. Sales of orphan drugs are excluded from this fee as long as no non-orphan indications have been approved for such orphan drugs.

In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014. 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. 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 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. The initiation of any reporting of Medicaid pricing data for ProstaScint and Quadramet could result in retroactive 340B ceiling price liability for these two products as well as prospective 340B ceiling price obligations for ProstaScint. We are currently unable to reasonably estimate an amount or range of a contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results.

The Healthcare Reform Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts "orphan drugs" - those designated under section 526 of the FDCA - from the ceiling price requirements for these newly-eligible entities. The Health Resources and Services Administration, or HRSA, which administers the 340B program, 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

Table of Contents

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.

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 offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. HRSA is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. 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 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 ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. 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 information 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 OIG indicated that they intend to pursue more aggressively those 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.

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 and grantees, 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 non-federal average manufacturer price, or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an

Table of Contents

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.

Price approvals and 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. In many countries, price approvals must be obtained before products can be placed on the market or submitted for reimbursement. Third party payors, including government payors, decide which drugs can be reimbursed 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 and/or clinical 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 and maintain price approvals, 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’ reimbursement practices may affect the price levels for our products or the availability of reimbursement for our products, including Xyrem and Defitelio. Our business could be materially harmed if the Medicaid program, Medicare program or other third party payors in the United States or elsewhere were to deny reimbursement for our products or provide reimbursement only on unfavorable terms. This risk is particularly significant with respect to Xyrem in the United States and to Defitelio in Europe, in part due to payor sensitivity to the price of these products. Our business could also be harmed if the Medicaid program, Medicare program or other reimbursing bodies or payors limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances than we believe is appropriate.

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 fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) published in May 2013, and the third edition of International Classification of Sleep Disorders (ICSD-3) published in February 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 our products, including Xyrem

and Defitelio.

In many countries, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing approval. We are in the process of making pricing and reimbursement submissions with respect to Defitelio, and discussing them with regulatory authorities, in those European countries where pricing and reimbursement approvals are required for launch. We cannot predict the timing of Defitelio's launch in countries where we are awaiting pricing and reimbursement guidelines. If we experience delays and unforeseen difficulties in obtaining pricing and reimbursement approvals, planned launches in the affected countries would be delayed and our anticipated revenue from Defitelio in 2014 and our growth prospects could be negatively affected. See the discussion regarding the launch of Defitelio in the risk factor in this Item 1A entitled "We may not be able to successfully commercialize Defitelio in Europe, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects."

Table of Contents

We cannot predict actions third party payors may take, or whether they will limit the price approvals, coverage and level of reimbursement for our products or refuse to provide and maintain any approvals or coverage at all. For example, because some of our products compete in a market with both branded and generic products, obtaining and maintaining price approvals and reimbursement coverage by government and private payors may be more challenging than for new chemical entities for which no therapeutic alternatives exist. Additionally, in many countries, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness to prescribe our products. For example, the U.S. federal government follows a Medicare severity diagnosis-related group, or MS-DRG, payment system for certain institutional services provided under Medicare, which some states also use for Medicaid. The MS-DRG system entitles a healthcare facility to a fixed reimbursement based on discharge diagnoses rather than actual costs incurred in providing inpatient treatment, thereby increasing the incentive for the facility to limit or control expenditures for many healthcare products. For our products used in the inpatient setting, there may not be sufficient reimbursement under the MS-DRG to fully cover the cost of our products. 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.

Third party payors frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. We have agreed to provide such discounts and rebates to some third party payors in relation to our products. We expect increasing pressure to offer larger discounts or discounts to a greater number of third party payors to maintain acceptable reimbursement levels and access for patients at copay levels that are reasonable and customary. A number of third party payors also require prior authorization for, require reauthorization for continuation of, or even refuse to provide, reimbursement for our products, including Xyrem and Defitelio, and others may do so in the future. Patients who cannot meet the conditions of prior authorizations are often prevented from obtaining the prescribed medication, because they cannot afford to pay for the medication without reimbursement. If we are unsuccessful in maintaining reimbursement for our products at acceptable levels, or if reimbursement for our products by third party payors is subject to overly restrictive prior authorizations, our business will be harmed. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce our sales and harm our results of operations.

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. For example, much attention has been paid to legislation proposing federal rebates on Medicare Part D and Medicare Advantage utilization for drugs issued to certain groups of lower income beneficiaries and the desire to change the provisions that treat these dual-eligible patients differently from traditional Medicare patients. Any such changes could have a negative impact on revenues from sales of our products.

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 made draft National Average Drug Acquisition Cost, or NADAC, and draft National Average Drug Acquisition Cost, or NARP, data publicly available on at least a monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover products appropriately under our DoD pricing agreements, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the Federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate program, and the Medicare Part D prescription drug benefit also

could impact our revenues. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In various EU member states we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. We have periodically increased the price of Xyrem, most recently in February 2014, 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.

Table of Contents

There also continue to be legislative proposals to amend U.S. laws to allow the importation into the United States of prescription drugs, which can be sold at prices that are regulated by the governments of various non-U.S. countries. For example, in October 2013, the State of Maine enacted a bill to allow residents of the state to purchase prescription drugs from other countries, including Canada. The potential importation of prescription drugs could pose significant safety concerns for patients, increase the risk of counterfeit products becoming available in the market, and could also have a negative impact on prescription drug prices in the United States. For example, the potential importation of Xyrem without the safeguard of our Xyrem REMS program could harm patients and could also negatively impact Xyrem revenues.

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, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240. The Bipartisan Budget Act of 2013, Pub. L. No. 113-67, extended the 2% reduction to 2023, and the Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, extended the 2% reduction, on average, to 2024. If Congress does not take action in the future to modify these sequestrations, Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment provisions, as described below, could have a similar effect. 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. In many countries, including in EU member states, national laws provide for strict (no-fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party.

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 investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the EMA, or the competent authorities of the EU member states. 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, variation, or withdrawal of approval. Similarly, any such regulatory action by the FDA, the EMA or the competent authorities of

the EU member states could lead to product liability lawsuits as well. Similar investigations and risks can occur in other countries outside the United States.

We use hazardous materials in our manufacturing facility, and any claims relating to the improper handling, storage, release or disposal of these materials could be time-consuming and expensive.

Our manufacturing of active pharmaceutical ingredients in Italy involves the controlled storage, use and disposal of chemicals and solvents. We are subject to Italian laws, which implement EU directives and regulations governing the use, transportation, treatment, storage, handling and disposal of solid and hazardous materials, wastewater discharges and air emissions. We have obtained certification under the UNI EN ISO 14001 Standard for our environmental management system and have an Eco-management and Audit Scheme (EMAS) for our plant in Italy. Our environmental policy is designed to

Table of Contents

comply with current regulations on environmental protection, to provide for continuous improvement of our manufacturing performance, to protect our employees' health, to protect the safety of people working at our location in Italy and to respect the safety of people living close to our plant and in the surrounding community. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by these laws and regulations, we cannot completely eliminate the risk of contamination or injury from hazardous materials. If an accident occurs, an injured party could seek to hold us liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future environmental laws and regulations.

Risks Relating to Our Financial Condition

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

As of March 31, 2014, we had approximately $1.2 billion in secured debt outstanding, which was primarily incurred pursuant to a credit agreement that we entered into in June 2012 and subsequently amended in June 2013 and in January 2014, which is referred to in this report as our 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 our credit agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.

Our credit agreement currently provides for $904.4 million of term loans due in June 2018 and a $425.0 million revolving credit facility, with loans under such revolving credit facility due in June 2017, subject to early mandatory repayments under certain circumstances. The credit agreement contains various covenants that limit our ability and/or our restricted subsidiaries' ability to, among other things:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

Our credit agreement also includes 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. In addition, the covenants under the credit agreement 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. Our failure to comply with any of the covenants could result in a default under the credit agreement, which could

permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the

Table of Contents

revolving credit facility. In addition, if we are unable to repay those amounts, the lenders under the 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 has grown substantially since the beginning of 2012 through the combination of Azur Pharma and Jazz Pharmaceuticals, Inc. in a merger transaction closed on January 18, 2012, or the Azur Merger, our acquisition of EUSA Pharma Inc. in June 2012 and the Gentium Acquisition. To continue to grow our business over the longer-term, we will need to commit substantial additional resources to in-licensing and/or acquiring new products and product candidates, and to costly and time-consuming product development and clinical trials of our product candidates. We also intend to continue to invest in our commercial operations in an effort to grow sales of our current products. Our future capital requirements will depend on many factors, including many of those discussed above, such as:

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

Our strategy includes the expansion of 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 North America, 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

Table of Contents

any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are 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, the IRS could assert that we should 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. (the "ownership test"), 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 and in January 2014. We do not expect these regulations to affect the U.S. tax consequences of 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 can limit 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 $28.6 million for each of the years 2014 to 2016, $11.9 million for 2017, and a combined total of $3.3 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

Table of Contents

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.

Future changes to the tax laws under which we expect to be treated as a foreign corporation for U.S. federal tax purposes or in other tax laws relating to multinational corporations could adversely affect us.

As described above, under current law, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes. Changes to Section 7874 or the Treasury Regulations promulgated thereunder could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any changes could have prospective or retroactive application. In addition, recent legislative proposals have aimed to expand the scope of U.S. corporate tax residence. This legislation, if passed, could adversely affect us.

In addition, the U.S. Congress, the Organization for Economic Co-operation and Development and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is in the area of “base erosion and profit shifting,” where payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. As a result, the tax laws in the United States and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

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

As of March 31, 2014, we had recorded $2.5 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. Exchange rates between the U.S. dollar and each of the Euro and British Pound 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 functional currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. As we continue to expand our international operations, including with the Gentium Acquisition, we will conduct more transactions in currencies other than the U.S. dollar. To the extent that revenue and expense transactions are not denominated in the functional 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.

Table of Contents

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 Gentium 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, including sales by members of our management or board of directors, 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 May 1, 2014, we had 59,391,915 ordinary shares outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144.

In addition, we have in the past and may in the future grant rights to some of our shareholders that require us to register the resale of our ordinary shares on behalf of these shareholders and/or facilitate offerings of ordinary shares held by these shareholders, including in connection with potential future acquisitions of additional products, product candidates, or companies. For example, consistent with our obligations under existing registration rights agreements, we entered into underwriting agreements with certain underwriters and selling shareholders pursuant to which selling shareholders sold an aggregate of approximately 13 million ordinary shares in two separate registered public offerings in March 2012 and in March 2013. If 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 differ 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 and Irish law 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.

Table of Contents

In addition, several mandatory provisions of Irish law could prevent or delay an acquisition of us. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in its shares in certain circumstances.

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 credit agreement. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our credit agreement and other factors our board of directors deems relevant. 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.

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, EU 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

Table of Contents

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 5. Other Information.

As previously reported, Matthew Young was appointed as our Chief Financial Officer effective as of March 9, 2014. In connection with Mr. Young's appointment and promotion, on April 30, 2014, the Compensation Committee of our Board of Directors approved an increase in Mr. Young's 2014 base salary, effective as of March 9, 2014, to $415,000 per year.

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 Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the 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	Tender Offer Agreement, dated December 19, 2013, by and among Jazz Pharmaceuticals Public Limited Company, Jazz Pharmaceuticals Italy S.r.l. and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K/A (File No. 001-33500), as filed with the SEC on December 20, 2013).
2.6†	Asset Purchase Agreement, dated January 13, 2014, by and among Jazz Pharmaceuticals International III Limited, Aerial BioPharma, LLC and Jazz Pharmaceuticals plc (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 January 13, 2014).
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.
4.2	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).
10.1	Amended and Restated Commitment Letter, dated as of January 6, 2014, by and between Jazz Pharmaceuticals plc, Barclays Bank PLC, J.P. Morgan Securities LLC, JPMorgan Chase Bank, N.A., Merrill Lynch Pierce, Fenner & Smith Incorporated, Bank of America, N.A., Citigroup Global Markets Inc., Morgan Stanley Senior Funding, Inc., Royal Bank of Canada, DNB Bank ASA and DNB Capital Markets, Inc. (incorporated herein by reference to Exhibit 99.(B)(1) in Jazz Pharmaceuticals plc's tender offer statement on Schedule TO, as amended, as filed with the SEC on January 7, 2014).
10.2	Amendment No. 2, dated as of January 23, 2014, to the Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Financing I Limited and Jazz Pharmaceuticals Ireland Limited, as borrowers, Jazz Pharmaceuticals Public Limited Company, as guarantor, the Lenders thereto and Barclays Bank PLC, as Administrative Agent, Collateral Agent, L/C Issuer

	and Swing Line Lender (incorporated herein by reference to Exhibit 10.32 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).
10.3+	Offer Letter from Jazz Pharmaceuticals to Matthew Young.
10.4+	Jazz Pharmaceuticals plc 2014 Executive Officer Compensation Arrangements.
10.5+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2014) (incorporated herein by reference to Exhibit 10.24D in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).
10.6+	Jazz Pharmaceuticals plc Non-Employee Director Compensation Policy (approved May 1, 2014).
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.

Table of Contents

Exhibit Number	Description of Document
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

_____

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

* 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: May 8, 2014

Jazz Pharmaceuticals Public Limited Company
(Registrant)

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

/s/ Matthew P. Young
Matthew P. Young
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the 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	Tender Offer Agreement, dated December 19, 2013, by and among Jazz Pharmaceuticals Public Limited Company, Jazz Pharmaceuticals Italy S.r.l. and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K/A (File No. 001-33500), as filed with the SEC on December 20, 2013).
2.6†	Asset Purchase Agreement, dated January 13, 2014, by and among Jazz Pharmaceuticals International III Limited, Aerial BioPharma, LLC and Jazz Pharmaceuticals plc (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 January 13, 2014).
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.
4.2	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).
10.1	Amended and Restated Commitment Letter, dated as of January 6, 2014, by and between Jazz Pharmaceuticals plc, Barclays Bank PLC, J.P. Morgan Securities LLC, JPMorgan Chase Bank, N.A., Merrill Lynch Pierce, Fenner & Smith Incorporated, Bank of America, N.A., Citigroup Global Markets Inc., Morgan Stanley Senior Funding, Inc., Royal Bank of Canada, DNB Bank ASA and DNB Capital Markets, Inc. (incorporated herein by reference to Exhibit 99.(B)(1) in Jazz Pharmaceuticals plc's tender offer statement on Schedule TO, as amended, as filed with the SEC on January 7, 2014).
10.2	Amendment No. 2, dated as of January 23, 2014, to the Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Financing I Limited and Jazz Pharmaceuticals Ireland Limited, as borrowers, Jazz Pharmaceuticals Public Limited Company, as guarantor, the

	Lenders thereto and Barclays Bank PLC, as Administrative Agent, Collateral Agent, L/C Issuer and Swing Line Lender (incorporated herein by reference to Exhibit 10.32 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).
10.3+	Offer Letter from Jazz Pharmaceuticals to Matthew Young.
10.4+	Jazz Pharmaceuticals plc 2014 Executive Officer Compensation Arrangements.
10.5+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2014) (incorporated herein by reference to Exhibit 10.24D in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).
10.6+	Jazz Pharmaceuticals plc Non-Employee Director Compensation Policy (approved May 1, 2014).
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.

Table of Contents

Exhibit Number	Description of Document
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

_____

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

* 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.