

Jazz Pharmaceuticals plc
Form 10-Q
May 08, 2012
Table of Contents

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

FORM 10-Q

(Mark One)

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended March 31, 2012

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)

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

Ireland
(State or other jurisdiction of
incorporation or organization)

98-1032470
(I.R.S. Employer
Identification No.)

45 Fitzwilliam Square

Dublin 2, Ireland

011-353-1-634-4183

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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

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

None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

Large accelerated filer Accelerated filer

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

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

As of April 30, 2012, 56,732,899 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, 2012

INDEX

	Page
<u>PART I FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets March 31, 2012 and December 31, 2011</u>	3
<u>Condensed Consolidated Statements of Income Three Months Ended March 31, 2012 and 2011</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income Three Months Ended March 31, 2012 and 2011</u>	5
<u>Condensed Consolidated Statements of Cash Flows Three Months Ended March 31, 2012 and 2011</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	27
Item 4. <u>Controls and Procedures</u>	27
<u>PART II OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	28
Item 1A. <u>Risk Factors</u>	29
Item 5. <u>Other Information</u>	50
Item 6. <u>Exhibits</u>	52

We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, FazaClo® (clozapine, USP), Luvox CR® (fluvoxamine maleate) Extended-Release Capsules, Luvox® (fluvoxamine maleate), Prial® (ziconotide intrathecal infusion), Elestrin® (estradiol gel 0.06%), Urelle® (urinary antiseptic), Gesticare® (prenatal vitamin), Natelle® (prenatal vitamin), Gastrocrom® (cromolyn sodium oral concentrate), Niravam® (alprazolam), Parcopa® (carbidopa/levodopa), and AVC Cream (sulfanilamide). 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, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 170,654	\$ 82,076
Marketable securities	73,564	75,822
Accounts receivable, net of allowances of \$1,487 and \$366 at March 31, 2012 and December 31, 2011, respectively	56,143	34,374
Inventories	16,992	3,909
Prepaid expenses	5,714	1,690
Other current assets	4,073	1,260
Total current assets	327,140	199,131
Property and equipment, net	2,026	1,557
Intangible assets, net	326,072	14,585
Goodwill	239,737	38,213
Other long-term assets	385	87
Total assets	\$ 895,360	\$ 253,573
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 13,689	\$ 5,129
Accrued liabilities	74,566	34,783
Purchased product rights liability	15,191	4,500
Liability under government settlement	-	7,320
Deferred revenue	1,138	1,138
Total current liabilities	104,584	52,870
Deferred revenue, non-current	7,630	7,915
Other non-current liabilities	1,314	-
Commitments and contingencies (Note 7)		
Shareholders' equity:		
Ordinary shares	6	4
Non-voting euro deferred shares	55	-
Capital redemption reserve	471	-
Additional paid-in capital	1,103,498	542,697
Accumulated other comprehensive income (loss)	3	(31)
Accumulated deficit	(322,201)	(349,882)

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

Total shareholders' equity	781,832	192,788
Total liabilities and shareholders' equity	\$ 895,360	\$ 253,573

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

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

	Three Months Ended March 31,	
	2012	2011
Revenues:		
Product sales, net	\$ 107,336	\$ 49,903
Royalties and contract revenues	1,078	978
Total revenues	108,414	50,881
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technology)	10,758	2,809
Selling, general and administrative	46,999	19,911
Research and development	3,959	3,695
Intangible asset amortization	13,513	1,862
Total operating expenses	75,229	28,277
Income from operations	33,185	22,604
Interest income and other, net	71	-
Interest expense	(58)	(777)
Income before provision for income tax expense	33,198	21,827
Provision for income tax expense	5,517	-
Net income	\$ 27,681	\$ 21,827
Net income per ordinary share:		
Basic	\$ 0.51	\$ 0.54
Diluted	\$ 0.48	\$ 0.48
Weighted-average ordinary shares used in computing net income per share:		
Basic	53,923	40,362
Diluted	58,084	45,697

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

Table of Contents

JAZZ PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2012	2011
Net income	\$ 27,681	\$ 21,827
Unrealized gain on available-for-sale securities, net of income taxes	34	-
Comprehensive income	\$ 27,715	\$ 21,827

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,	
	2012	2011
Operating activities		
Net income	\$ 27,681	\$ 21,827
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	186	104
Amortization of intangible assets	13,513	1,862
Share-based compensation expense	3,281	3,148
Excess tax benefit from share-based compensation	(1,914)	-
Other non-cash transactions	2,411	206
Changes in assets and liabilities:		
Accounts receivable	(8,794)	698
Inventories	(58)	50
Prepaid expenses and other current assets	(2,217)	(842)
Other assets and liabilities	(299)	(5)
Accounts payable	4,649	599
Accrued liabilities	(6,539)	(298)
Deferred revenue	(285)	3
Liability under government settlement	(7,320)	(2,904)
Net cash provided by operating activities	24,295	24,448
Investing activities		
Cash acquired from merger with Azur Pharma	81,751	-
Purchases of marketable securities	(30,628)	-
Proceeds from sale of marketable securities	15,082	-
Proceeds from maturities of marketable securities	17,838	-
Purchases of property and equipment	(285)	(66)
Purchase of product rights	(1,250)	(1,125)
Net cash provided by (used in) investing activities	82,508	(1,191)
Financing activities		
Proceeds from exercise of stock options and warrants	5,160	4,526
Payment of employee withholding taxes upon exercise of share-based awards	(25,299)	-
Excess tax benefit from share-based compensation	1,914	-
Repayment of long-term debt	-	(4,166)
Net repayments under revolving credit facilities	-	(3,350)
Net cash used in financing activities	(18,225)	(2,990)
Net increase in cash and cash equivalents	88,578	20,267
Cash and cash equivalents, at beginning of period	82,076	44,794
Cash and cash equivalents, at end of period	\$ 170,654	\$ 65,061

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

See Note 2 for supplemental disclosures of non-cash investing activities related to the merger with Azur Pharma.

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

Jazz Pharmaceuticals Public Limited Company, or Jazz Pharmaceuticals plc, a public limited company formed under the laws of Ireland, is a specialty biopharmaceutical company focused on the identification, development and commercialization of pharmaceutical products to meet important unmet medical needs in focused therapeutic areas.

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, or the Azur Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company in the Azur Merger for accounting purposes. As part of the Azur Merger, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Prior to the Azur Merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc. Upon the consummation of the Azur Merger, the historical financial statements of Jazz Pharmaceuticals, Inc. became our historical financial statements. Accordingly, the historical financial statements of Jazz Pharmaceuticals, Inc. are included in the comparative prior periods. For additional information regarding the Azur Merger see Note 2.

Unless otherwise indicated or the context otherwise requires, references to Jazz Pharmaceuticals, the registrant, we, us, and our refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, including its predecessor, Jazz Pharmaceuticals, Inc. All references to Azur Pharma or the acquired company are references to Jazz Pharmaceuticals plc (f/k/a Azur Pharma Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Azur Merger on January 18, 2012. The disclosures in this report relating to the pre-merger business of Jazz Pharmaceuticals plc, unless noted as being the business of Azur Pharma prior to the Azur Merger, pertain to the business of Jazz Pharmaceuticals, Inc. prior to the Azur Merger.

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared following the requirements of the 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, Inc. included in the Annual Report on Form 10-K for the year ended December 31, 2011 that we filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. Because the Azur Merger was consummated after December 31, 2011, we also filed a separate Annual Report on Form 10-K covering the last full fiscal year of Azur Pharma that includes the annual consolidated financial statements and accompanying notes of Azur Pharma (Commission File Number 333-177528). The results of operations of the acquired Azur Pharma business and the estimated fair market values of the assets acquired and liabilities assumed have been included in our condensed consolidated financial statements since the date of merger.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements of Jazz Pharmaceuticals, Inc. 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, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012 or for any other interim period or for any future period.

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

Significant Risks and Uncertainties

We are subject to risks common to companies in the pharmaceutical industry with development and commercial operations including, but not limited to, risks and uncertainties related to commercial success and acceptance of our products by patients, physicians and payors, competition from branded and generic products, regulatory approvals, regulatory requirements, including those of the United States Food and Drug

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

Administration, or FDA, and the United States Drug Enforcement Administration, dependence on key customers and sole source suppliers and protection of intellectual property rights. In addition, most of our revenues are derived from sales of one product, Xyrem. During 2010, an abbreviated new drug application, or ANDA, was filed with the FDA by a third party seeking to market a generic form of Xyrem. We have sued that third party for infringement of our patents, and the litigation is ongoing. We cannot predict the timing or outcome of this litigation. If an ANDA for Xyrem is approved and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected.

Table of Contents**Business Acquisitions**

Our condensed consolidated financial statements include the 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 most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, and that the fair value of acquired in-process research and development, or IPR&D, be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the purchase price 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.

Concentrations of Risk

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

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company, primarily in the United States, and to international distributors. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced significant credit losses on our accounts receivable. As of March 31, 2012 five customers accounted for 88% of gross accounts receivable and one customer, Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, accounted for 57% of gross accounts receivable. Express Scripts accounted for 79% of gross accounts receivable as of December 31, 2011.

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

Use of Estimates

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

Net Income per Ordinary Share

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

	Three Months Ended March 31,	
	2012	2011
Numerator:		
Net income	\$ 27,681	\$ 21,827
Denominator:		
Weighted-average ordinary shares outstanding - basic	53,923	40,362
Dilutive effect of employee equity incentive and purchase plans	1,825	2,867
Dilutive effect of warrants	2,336	2,468

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

Weighted-average ordinary shares outstanding - diluted	58,084	45,697
Net income per ordinary share:		
Basic	\$ 0.51	\$ 0.54
Diluted	\$ 0.48	\$ 0.48

Table of Contents

Potentially dilutive ordinary shares from employee share 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, and the assumed issuance of ordinary shares under our employee stock purchase plan. The following table represents the weighted-average ordinary shares that were excluded from the computation of diluted net income per share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended	
	March 31,	
	2012	2011
Options to purchase ordinary shares	498	660

All references to common stock in the comparative prior year period in the discussion above were replaced with references to ordinary shares to reflect the capital structure of Azur Pharma, the legal acquirer in the merger. Our earnings per share in the comparative prior year period were not impacted by the Azur Merger since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and automatically converted into and become the right to receive one ordinary share upon the consummation of the merger. This one-for-one conversion ratio is referred to in this report as the merger exchange ratio .

2. Business Combination

On January 18, 2012, pursuant to an Agreement and Plan of Merger and Reorganization dated as of September 19, 2011, as amended, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Prior to the Azur Merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc.

At the effective time of the Azur Merger, each share of the common stock of Jazz Pharmaceuticals, Inc. issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and automatically converted into and became the right to receive one ordinary share of Jazz Pharmaceuticals plc. Further, the stock options and stock awards outstanding under Jazz Pharmaceuticals, Inc.'s equity incentive plans were converted into stock options and stock awards to purchase or receive an equal number of ordinary shares of Jazz Pharmaceuticals plc with substantially the same terms and conditions, including the same per share exercise price, where applicable. In addition, outstanding warrants to purchase Jazz Pharmaceuticals, Inc. common stock were converted into substantially the same warrants to purchase an equal number of ordinary shares of Jazz Pharmaceuticals plc at the same per share exercise price. Our ordinary shares trade on the same exchange, The NASDAQ Global Select Market, and under the same trading symbol, JAZZ, as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger. We are deemed to be the successor to Jazz Pharmaceuticals, Inc. pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The Azur Merger was accounted for using the acquisition method of accounting with Jazz Pharmaceuticals, Inc. treated as the accounting acquirer. Under the acquisition method of accounting, assets and liabilities of Azur Pharma were recorded at their respective fair values and added to those of Jazz Pharmaceuticals, Inc. including an amount for goodwill representing the difference between the acquisition consideration and the fair value of the identifiable net assets.

The total acquisition consideration of \$576.5 million was determined based on the market value of our ordinary shares that were held by the historic Azur Pharma shareholders immediately following the closing of the Azur Merger. The closing price of the Jazz Pharmaceuticals, Inc. common stock on January 17, 2012 (\$46.64) was used to determine the fair value of consideration because the closing of the transaction on January 18, 2012 occurred prior to the opening of regular trading on January 18, 2012. Immediately following the consummation of the Azur Merger, 12,360,000, or 22%, of our ordinary shares were held by the persons and entities who acquired ordinary shares of Azur Pharma prior to the Azur Merger, and the remaining 43,838,000, or 78%, of the ordinary shares were held by the former stockholders of Jazz Pharmaceuticals, Inc.

We believe the Azur Merger has resulted in a company with a strengthened management team, a broader commercial organization and an efficient platform for further growth, with resources to build our product portfolio and a future pipeline.

During the three months ended March 31, 2012, we incurred \$2.4 million in transaction costs related to the Azur Merger, 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 income. During the three months ended March 31, 2012, the contribution of the acquired Azur Pharma business to our total revenues was \$24.3 million. The portion of total expenses and net income associated with the

acquired Azur Pharma business were not separately identifiable due to the integration with our operations.

Table of Contents

The results of operations of the acquired Azur Pharma business and the estimated fair market values of the assets acquired and liabilities assumed have been included in our condensed consolidated financial statements since the date of merger.

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the closing date of the Azur Merger based upon their respective fair values as summarized below (in thousands):

Cash and cash equivalents	\$ 81,751
Accounts receivable	12,975
Inventories	15,344
Property and equipment	370
Intangible assets	325,000
Goodwill	201,524
Other assets	4,862
Accounts payable and accrued liabilities	(52,148)
Purchased product rights liability	(11,899)
Above market lease obligation	(1,315)
Total purchase price	\$ 576,464

Asset categories acquired in the Azur Merger included working capital, long-term assets and liabilities, fixed assets and identifiable intangible assets, including IPR&D. The allocation of the purchase price for the acquisition has been prepared on a preliminary basis and changes to that allocation may occur as additional information becomes available.

The intangible assets as of the date of the acquisition (i.e. the closing date of the Azur Merger) included (in thousands):

Acquired developed technologies	\$ 323,000
In-process research and development	2,000
Total intangible assets	\$ 325,000

Intangible assets related to acquired developed technologies reflect the estimated fair value of the rights we acquired to those products in the Azur Merger. The fair value was determined using an income approach, which 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 direct costs for each product line. Indications of value are developed by discounting these benefits to their present worth at a discount rate that reflects the current return requirements of the market. Acquired developed technologies are finite-lived intangible assets and are being amortized over their estimated lives ranging from two to fifteen years.

The excess of purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill attributable to the acquired Azur Merger business has been recorded as a non-current asset and is not amortized, but is subject to an annual review for impairment. We believe the factors that contributed to goodwill include synergies that are specific to our consolidated business and not available to market participants, the acquisition of a talented workforce that expands our expertise in business development and commercializing pharmaceuticals products as well as other intangible assets that do not qualify for separate recognition. We do not expect any portion of this goodwill to be deductible for tax purposes.

Table of Contents**Pro forma financial information (unaudited)**

The following unaudited pro forma information presents the combined results of operations for the three months ended March 31, 2012 and 2011 as if the merger with Azur Pharma had been completed on January 1, 2011.

Pro forma net income for the three months ended March 31, 2012 was adjusted to exclude \$14.4 million of transaction related expense incurred in 2012 and approximately \$11.1 million of non-recurring expenses primarily related to the fair value step up to acquired inventory and integration related expenses.

Pro forma net income for the three months ended March 31, 2011 was adjusted to include \$8.7 million of amortization expense related to acquired identifiable intangible assets and \$4.9 million of other non-recurring expenses primarily related to the fair value step up to acquired inventory and integration related expenses. Net income was also adjusted to exclude fair value adjustments related to a share-based liability granted to certain former Azur Pharma investors of \$0.9 million, which was extinguished upon merger.

The unaudited pro forma results do not reflect operating efficiencies or potential cost savings which may result from the consolidation of operations (in thousands, except per share data):

	Three Months Ended	
	March 31,	
	2012	2011
Revenues	\$ 109,295	\$ 72,347
Net income	36,122	11,220
Basic earnings per share	0.64	0.21
Diluted earnings per share	0.60	0.19

3. Inventories

The components of inventories were as follows (in thousands):

	March 31,	December 31,
	2012	2011
Raw materials	\$ 3,116	\$ 1,937
Work in process	1,319	524
Finished goods	12,557	1,448
Total inventories	\$ 16,992	\$ 3,909

As of March 31, 2012, inventories included \$7.0 million related to purchase accounting inventory fair value step-up.

Table of Contents**4. Fair Value**

Available-for-sale securities consisted of the following (in thousands):

	March 31, 2012			December 31, 2011			Estimated Fair Value	Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses		
Money market funds	\$ 56,010	\$ -	\$ -	\$ 56,010	\$ 48,518	\$ -	\$ -	\$ 48,518
U.S. treasury securities	30,007	-	-	30,007	-	-	-	-
Certificates of deposit	7,300	-	(4)	7,296	7,300	-	(6)	7,294
Corporate debt securities	40,595	17	(12)	40,600	50,371	7	(34)	50,344
Obligations of U.S. government agencies	5,662	2	-	5,664	18,433	3	(1)	18,435
Total available-for-sale securities	\$ 139,574	\$ 19	\$ (16)	\$ 139,577	\$ 124,622	\$ 10	\$ (41)	\$ 124,591

	March 31, 2012	December 31, 2011
Available-for-sale securities	\$ 139,577	\$ 124,591
Cash	104,641	33,307
Totals	\$ 244,218	\$ 157,898

Reported as	March 31, 2012	December 31, 2011
Amounts classified as cash and cash equivalents	\$ 170,654	\$ 82,076
Amounts classified as marketable securities	73,564	75,822
Totals	\$ 244,218	\$ 157,898

All available-for-sale securities held as of March 31, 2012 had contractual maturities of less than one year. No available-for-sale securities held as of March 31, 2012 had been in a continuous loss position for more than 12 months. The aggregate fair value of available-for-sale securities which had unrealized losses was \$39.0 million and \$43.6 million as of March 31, 2012 and December 31, 2011, respectively.

During the three months ended March 31, 2012, realized gains or losses recognized on the sale of investments were not significant. Gross unrealized losses on investments as of March 31, 2012 related to available-for-sale securities were insignificant and we believe the impairment was temporary. In determining that the decline in fair value of these securities was temporary, we considered the length of time each security was in an unrealized loss position and the extent to which fair value was less than cost.

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

	March 31, 2012			December 31, 2011		
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

	(Level 1)			(Level 1)		
Money market funds	\$ 56,010	\$ -	\$ 56,010	\$ 48,518	\$ -	\$ 48,518
U.S. treasury securities	30,007	-	30,007	-	-	-
Certificates of deposit	-	7,296	7,296	-	7,294	7,294
Corporate debt securities	-	40,600	40,600	-	50,344	50,344
Obligations of U.S. government agencies	-	5,664	5,664	-	18,435	18,435
Total available-for-sale securities	\$ 86,017	\$ 53,560	\$ 139,577	\$ 48,518	\$ 76,073	\$ 124,591

Table of Contents

Available-for-sale securities include corporate debt securities, obligations of U.S. government agencies and certificates of deposit which were measured at fair value using Level 2 inputs. We review trading activity and pricing for these investments as of the measurement date. Level 2 inputs, obtained from various third party data providers, represent quoted prices for similar assets in active markets, or these inputs were derived from observable market data, or if not directly observable, were derived from or corroborated by other observable market data. Level 1 inputs are quoted prices in active markets for identical assets or liabilities.

There were no transfers between Level 1 and Level 2 of the fair value hierarchy in 2012.

5. Certain balance sheet items

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

	March 31, 2012	December 31, 2011
Computer software	\$ 4,164	\$ 4,010
Computer equipment	2,662	2,046
Furniture and fixtures	926	556
Leasehold improvements	818	763
Construction-in-progress	148	689
Machinery and equipment	77	76
Subtotal	8,795	8,140
Less accumulated depreciation and amortization	(6,769)	(6,583)
Property and equipment, net	\$ 2,026	\$ 1,557

Accrued liabilities consisted of the following (in thousands):

	March 31, 2012	December 31, 2011
Sales returns reserve	\$ 23,296	\$ 4,302
Government rebates reserve	20,838	10,631
Accrued personnel expense	9,429	11,643
Accrued professional fees and services	4,244	1,612
Accrued taxes payable	3,125	-
Accrued gross to net items	2,804	1,747
Accrued transaction and integration costs	1,733	2,409
Accrued inventory and cost of product sales	918	846
Other	8,179	1,593
Total accrued liabilities	\$ 74,566	\$ 34,783

6. Goodwill and Intangible Assets

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

March 31, 2012	December 31, 2011
---------------------------	------------------------------

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

Goodwill	\$ 239,737	\$ 38,213
----------	------------	-----------

We recorded goodwill of \$201.5 million in January 2012 in connection with the Azur Merger. There were no changes to the initial carrying amount of our goodwill during the three months ended March 31, 2012.

Table of Contents

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

	Remaining Weighted- Average Useful Life (In years)	March 31, 2012			December 31, 2011		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
		Acquired developed technologies	12	\$ 372,400	\$ (49,079)	\$ 323,321	\$ 49,400
Trademarks	3	2,600	(1,849)	751	2,600	(1,781)	819
Total finite-lived intangible assets		375,000	(50,928)	324,072	52,000	(37,415)	14,585
Acquired IPR&D assets		2,000	-	2,000	-	-	-
Total intangible assets		\$ 377,000	\$ (50,928)	\$ 326,072	\$ 52,000	\$ (37,415)	\$ 14,585

Based on finite-lived intangible assets recorded as of March 31, 2012, 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
2012 (remainder)	\$ 33,790
2013	37,871
2014	32,872
2015	26,093
2016	20,022
Thereafter	173,424
Total	\$ 324,072

7. Commitments and Contingencies**Indemnification**

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

We have agreed to indemnify our executive officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we have not recognized any liabilities relating to these obligations as of March 31, 2012 and December 31, 2011. 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 located in Dublin, Ireland, Palo Alto, California and Philadelphia, Pennsylvania. We are also obligated to make payments under noncancelable operating leases for automobiles used by our sales force.

Table of Contents

Future minimum lease payments under our noncancelable operating leases at March 31, 2012 were as follows (in thousands):

Year ending December 31,	Lease Payments
2012 (remainder)	\$ 2,658
2013	4,176
2014	3,227
2015	2,702
2016	2,626
Thereafter	5,131
Total	\$ 20,520

In May 2012, we amended and extended the operating lease for our Philadelphia office building and as a result, we are obligated to make additional payments of at least \$1.3 million through February 2016 which are not included in the above table. In May 2012, we entered into a new operating lease agreement for our Dublin office and as a result, we are obligated to make additional payments of \$4.5 million through 2022 which are not included in the table above. We have an option to terminate the new Dublin office lease on May 8, 2017, with no less than six months prior written notice and the payment of a termination fee in the amount of approximately \$0.2 million.

As of March 31, 2012, we had \$9.8 million of noncancelable purchase commitments under agreements with contract manufacturers, all of which were due within one year.

Legal Proceedings

On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it filed an abbreviated new drug application, or ANDA, with the FDA requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleged that all five patents listed for Xyrem in the FDA's approved drug products with therapeutic equivalence evaluation documents, or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States District Court for the District of New Jersey. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) April 18, 2013, which is 30 months from our October 18, 2010 receipt of Roxane's Paragraph IV certification notice, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. An additional method of use patent covering the distribution system for Xyrem issued in December 2010 and is listed in the Orange Book, and we amended our lawsuit against Roxane on February 4, 2011 to include the additional patent in the litigation in response to Roxane's Paragraph IV Certification against this patent. An additional method of use patent covering the distribution system for Xyrem issued in February 2011 and is listed in the Orange Book, and we amended our lawsuit on May 2, 2011 to include this additional patent in response to Roxane's Paragraph IV Certification against it. The District Court held a Markman hearing, a pretrial hearing in which the trial judge construes the claims of a patent, on April 26, 2012, and the discovery phase of the proceeding is ongoing. No trial date has been scheduled. We cannot predict the outcome of this matter.

In August 2009, we received a Paragraph IV Certification from Actavis Elizabeth, LLC, or Actavis, advising that Actavis had filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. Actavis' Paragraph IV Certification alleged that the United States patent covering Luvox CR, which is owned by Elan Pharma International Limited, or Elan, which has subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes, and licensed to us, is invalid on the basis that the inventions claimed therein were obvious. On October 6, 2009, we and Elan, as plaintiffs, filed a lawsuit against Actavis in the United States District Court for the District of Delaware claiming infringement of the Alkermes patent. On September 10, 2011, we received a Paragraph IV Certification from Torrent Pharma Limited, or Torrent, advising us that it had filed an ANDA with the FDA requesting approval to market a generic version of Luvox CR. On October 21, 2011, we and Alkermes, as plaintiffs, filed a lawsuit against Torrent in the United States District Court for the District of Delaware asserting infringement of the Alkermes patent. On April 5, 2012 and April 10, 2012, we and Alkermes entered into settlement agreements with Actavis and Torrent, respectively. Under the agreements, we, Alkermes and each of Actavis and Torrent agreed to dismiss all of the claims brought in the litigation without prejudice, each of Actavis and Torrent agreed not to contest the validity or enforceability of the Alkermes patent in the United States, and we, Alkermes and each of Actavis and Torrent agreed to release each other from all claims arising in the litigation or relating to the product each of Actavis and Torrent intends to market under its ANDA. In addition, we granted a sublicense to each of Actavis and

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

Torrent of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicenses are non-transferable, non-sublicensable and royalty-free and are exclusive even as to us and Alkermes (except with respect to Luvox CR) for a period of time. The sublicenses will commence on April 15, 2014 or earlier upon the occurrence of certain events.

Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD. Azur Pharma and CIMA Labs Inc., a subsidiary of Teva, or CIMA, 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 in the U.S. District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma

Table of Contents

and Teva, which had acquired Barr Laboratories, Inc., entered into an agreement settling the patent litigation and granted a sublicense of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD. The sublicenses will commence in July 2012 and May 2015 for FazaClo LD and FazaClo HD, respectively, or earlier upon the occurrence of certain events. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in California Superior Court in the County of Los Angeles. The complaint, among other things, alleges that Azur Pharma and its subsidiary breached certain contractual obligations relating to contingent payments in respect of FazaClo. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations owing to Dr. Cutler in relation to FazaClo. The complaint further alleges that certain contingent payments are due because sales thresholds have been achieved, entitling Dr. Cutler to either \$10.5 million or \$25.0 million, plus unspecified punitive damages and attorneys' fees. Azur Pharma denied the allegations in the complaint, moved to quash the summons for lack of jurisdiction by the California state court, and requested that the court send the dispute to arbitration under the contract under which Azur Pharma was sued. On March 14, 2012, the Superior Court denied the motion to quash but granted our petition to compel arbitration in New York and stayed the litigation. We intend to vigorously defend ourselves in connection with this litigation; however, this, like all litigation, carries certain risks and there can be no assurance of the outcome.

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

8. Shareholders' Equity

Following the Azur Merger, our capital structure is comprised of ordinary shares and euro deferred shares. The outstanding 4,000,000 non-voting euro deferred shares of €0.01 each are held by nominees and were issued to satisfy the statutory minimum of Euro-denominated share capital required for a public limited company incorporated in Ireland. The non-voting euro deferred shares have no right to receive dividends, no rights to attend and vote at our general meetings, are redeemable only at our option and have no substantive right to participate in a distribution of assets upon a winding up of our company. All references to common stock in the comparative prior year period in the discussion below were replaced with references to ordinary shares to reflect the capital structure of Azur Pharma, the legal acquirer in the Azur Merger. Our earnings per share in comparative periods were not impacted by the Azur Merger as a result of the one-for-one merger exchange ratio.

The total purchase price consideration of \$576.5 million related to the Azur Merger was recorded by increasing total par value of our ordinary shares and euro deferred shares by \$1,236 and \$54,862, respectively, creating a capital redemption reserve of \$0.5 million as required by Irish company law, to preserve permanent capital in the company; and increasing our additional paid-in capital by \$575.9 million.

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

	Three Months Ended March 31, 2012		Three Months Ended March 31, 2011	
	Shares issued	Cash Proceeds	Shares issued	Cash Proceeds
Merger with Azur Pharma	12,360	\$ -	-	\$ -
Employee withholding taxes related to share option exercises (1)	-	(25,299)	-	-
Option and warrant exercises	1,722	5,160	713	4,526
Directors deferred compensation plan	29	-	-	-
Totals	14,111	\$ (20,139)	713	\$ 4,526

- (1) During the three months ended March 31, 2012, we paid \$25.3 million of income tax withholdings on behalf of certain employees related to the net share settlement of exercised share options in connection with the Azur Merger.

Table of Contents**9. Share-Based Compensation**

Share-based compensation expense related to share options, restricted stock units, shares of ordinary shares credited to the directors phantom share accounts and grants under our employee stock purchase plan was classified as follows (in thousands):

	Three Months Ended March 31,	
	2012	2011
Selling, general and administrative	\$ 2,405	\$ 2,412
Research and development	515	656
Cost of product sales	361	80
Total share-based compensation expense	\$ 3,281	\$ 3,148

Share Options

The table below shows (i) the number of shares (in thousands) underlying options to purchase our ordinary shares granted to employees, (ii) the weighted-average grant date fair value per share of those share options, and (iii) certain information about the weighted-average assumptions used in the Black-Scholes option pricing model which was used to estimate the grant date fair value per share:

	Three Months Ended March 31,	
	2012	2011
Shares	825	1,170
Weighted-average grant date fair value	\$ 27.89	\$ 17.58
Black-Scholes option pricing model assumption information:		
Weighted-average volatility	63%	74%
Weighted-average expected term (years)	5.2	5.6
Range of risk-free rates	1.0%	2.4-2.7%
Expected dividend yield	0.0%	0.0%

Restricted Stock Units

In March 2012, we granted 404,878 restricted stock units, or RSUs, to employees with a weighted average grant date fair value of \$51.83. The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares. The fair value of the RSUs is recognized as expense ratable over the vesting period of four years.

10. Related Party Transactions

In connection with the Azur Merger, we assumed a lease for office space in Dublin, Ireland which expires in October 2029. The lease agreement is with Seamus Mulligan, the former Chief Executive Officer of Azur Pharma, who is currently our Chief Business Officer, International Business Development and a member of our board of directors. Rentals paid on this lease amounted to \$71,000 in the three months ended March 31, 2012. There were no amounts unpaid at March 31, 2012.

In May 2011, Azur Pharma entered into an agreement with Circ Pharma Limited/Circ Pharma Research and Development Limited, or Circ, companies controlled by Seamus Mulligan, whereby it obtained an option to license certain rights and assets in relation to Tramadol (a chronotherapeutic formulation) and to conduct certain development activities. Azur Pharma paid Circ \$250,000 for this option in 2011. On January 9, 2012, Azur Pharma amended the agreement, which provided us an extension to consider and evaluate the program contemplated by the option for a period of six months from the closing of the Azur Merger.

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

In March 2012, we entered into an underwriting agreement with two underwriters and certain selling shareholders, pursuant to which the selling shareholders agreed to sell to the underwriters 7.9 million of our ordinary shares, resulting in aggregate gross proceeds to the selling shareholders of approximately \$390.7 million. The selling shareholders included entities affiliated with certain members of our board of directors, four of our directors and four of our executive officers. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering, and we are obligated to pay expenses of approximately \$0.4 million in connection with this offering.

Table of Contents**11. Segment Reporting**

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,	
	2012	2011
Xyrem	\$ 73,437	\$ 42,778
Psychiatry:		
Luvox CR	9,558	7,125
FazaClo LD	5,579	-
FazaClo HD	2,561	-
Prialt	9,522	-
Women's health and other	6,679	-
Product sales, net	107,336	49,903
Royalties and contract revenues	1,078	978
Total revenues	\$ 108,414	\$ 50,881

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

	Three Months Ended March 31,	
	2012	2011
United States	\$ 102,154	\$ 49,899
Europe	5,914	977
All other	346	5
Total revenues	\$ 108,414	\$ 50,881

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

	Three Months Ended March 31,	
	2012	2011
Express Scripts	67%	84%

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

	March 31, 2012	December 31, 2011
Ireland	\$ 201,678	\$ -
International	366,542	54,442

Total long-lived assets	\$ 568,220	\$ 54,442
-------------------------	------------	-----------

12. Income Tax

During the three months ended March 31, 2012, our effective income tax rate was 16.6%. This rate was higher than the Irish statutory rate of 12.5% due to profits taxable at a rate higher than the Irish statutory rate offset by a valuation allowance release in connection with the utilization of current year net operating losses. We recorded a provision for income tax expense of \$5.5 million for the three months ended March 31, 2012 resulting from the application of a projected effective tax rate against the profit for the quarter.

Table of Contents

13. Subsequent Event

On April 26, 2012, Jazz Pharmaceuticals, Jewel Merger Sub Inc., or Merger Sub, a Delaware corporation and an indirect wholly-owned subsidiary of Jazz Pharmaceuticals, EUSA Pharma Inc., or EUSA Pharma, and Essex Woodlands Health Ventures, Inc., a Delaware corporation, Mayflower L.P., a Jersey limited partnership, and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma, entered into an Agreement and Plan of Merger, or the EUSA Merger Agreement. The EUSA Merger Agreement provides that, upon the terms and subject to the conditions set forth in the EUSA Merger Agreement, Merger Sub will merge with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly owned subsidiary of Jazz Pharmaceuticals, which merger we refer to herein as the EUSA Acquisition. Under the terms of the EUSA Merger Agreement, the consideration to be paid by us to EUSA Pharma's security holders in the EUSA Acquisition consists of \$650 million in cash, subject to increase or decrease based on EUSA Pharma's (a) working capital as of consummation of the EUSA Acquisition relative to an agreed upon target and (b) cash as of consummation of the EUSA Acquisition, plus a potential contingent payment of \$50 million in cash based upon EUSA Pharma's lead product, Erwinaze (asparaginase Erwinia chrysanthemi), achieving U.S. net sales of \$124.5 million in 2013. EUSA Pharma obtained the consent of its stockholders required under applicable law shortly after the execution of the EUSA Merger Agreement. The EUSA Acquisition is not subject to approval by our shareholders. The consummation of the EUSA Acquisition is subject to customary closing conditions, including, among other conditions, antitrust approvals in the U.S. and certain other jurisdictions and the absence of a material adverse effect on EUSA Pharma. The EUSA Acquisition is not subject to a financing contingency. The EUSA Acquisition is expected to close in June 2012. We recorded transaction costs of approximately \$1.2 million during the three months ended March 31, 2012 related to the proposed EUSA Acquisition.

The EUSA Merger Agreement contains customary representations and warranties regarding EUSA Pharma and us, covenants regarding the conduct of EUSA Pharma's business prior to consummation of the EUSA Acquisition, indemnification provisions, termination rights and other customary provisions. \$50 million of the consideration to be paid upon consummation of the EUSA Acquisition would be deposited in an escrow account for 12 months as partial security for our indemnification rights under the EUSA Merger Agreement; in addition, \$25 million of the contingent payment, if payable, would be subject to reduction for indemnification claims, if any, that are not fully satisfied by the funds in the escrow account.

In connection with the EUSA Merger Agreement, we also entered into a commitment letter with Barclays Bank PLC, or Barclays, pursuant to which Barclays has committed, subject to certain customary conditions, to provide (i) \$500 million under a six year term loan facility, and (ii) \$100 million under a five year revolving loan facility. Under the commitment letter, Barclays is authorized to act as administrative and collateral agent and as lead arranger, bookrunner and syndication agent. The commitment to provide the loan facilities is subject to certain conditions, including the negotiation of definitive documentation and other customary closing conditions consistent with the EUSA Merger Agreement. We expect to finance the EUSA Acquisition with a combination of cash on hand and proceeds from the new term loan. The funding under the term loan facility and the revolving loan facility is not a condition to our obligations under the terms of the EUSA Merger Agreement. Upon execution of the commitment letter and related documents, we became obligated to reimburse Barclays for its expenses incurred in connection with the loan facilities. Upon the closing of the EUSA Acquisition, we will also become obligated to pay customary fees to Barclays, but we are not obligated with respect to such fees prior to the closing. We have also agreed to indemnify the lenders if certain losses are incurred by the lenders in connection with the loan facilities.

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 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 characterize 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 and statements, including statements related to the potential acquisition of EUSA Pharma see 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.

The Merger with Azur Pharma

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction, or the Azur Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company in the Azur Merger for accounting purposes. The operating results of the accounting acquiree, Azur Pharma, are included only after the effective time of the Azur Merger on January 18, 2012 through the end of the period covered by this report, and the historical financial statements of Jazz Pharmaceuticals, Inc., and not Azur Pharma, are included in the comparative prior periods. As part of the Azur Merger, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Prior to the Azur Merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc.

Throughout this report, unless otherwise indicated or the context otherwise requires, references to Jazz Pharmaceuticals, we, us, and our refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, including its predecessor, Jazz Pharmaceuticals, Inc. All references to Azur Pharma are references to Jazz Pharmaceuticals plc (f/k/a Azur Pharma Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Azur Merger on January 18, 2012.

Business and Financial Overview

We are a specialty biopharmaceutical company focused on the identification, development and commercialization of pharmaceutical products to meet important unmet medical needs in focused therapeutic areas. Our marketed products include Xyrem (sodium oxybate oral solution), which is the only product approved by the United States Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy; our psychiatry products, FazaClo (clozapine, USP) LD and FazaClo HD, orally disintegrating clozapine tablets indicated for treatment resistant schizophrenia, and Luvox CR (fluvoxamine maleate) marketed for the treatment of obsessive compulsive disorder; Prialt (ziconotide intrathecal injection), the only non-opioid intrathecal analgesic indicated for refractory severe chronic pain; and a portfolio of women's health and other products led by Elestrin (estradiol gel 0.06%), indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause. We plan to continue to leverage the commercial, medical and scientific experience of the combined enterprise resulting from the Azur Merger in expanding our product portfolio through a combination of internal development, acquisition and in-licensing.

While we have a more diversified product portfolio as a result of the Azur Merger, we continue to be dependent on sales of Xyrem, which accounted for 68% of our net product sales in the quarter ended March 31, 2012. As a result, we continue to place a high priority on growing sales of Xyrem in its approved indications and enforcing our intellectual property rights. Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, as set forth in Part II Item 1A of this Quarterly Report on Form 10-Q. In particular, during 2010, an abbreviated new drug application, or ANDA, was filed with the FDA by a third party seeking to market a generic form of Xyrem. We have sued that third party for infringement of our patents, and the litigation is ongoing. We cannot predict the timing or outcome of the litigation. If an ANDA for Xyrem is approved and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected.

On April 26, 2012, we, an indirect wholly-owned subsidiary of ours, or Merger Sub, EUSA Pharma Inc., or EUSA Pharma, and the representatives of the equity holders of EUSA Pharma entered into an Agreement and Plan of Merger, or the EUSA Merger Agreement. The EUSA Merger Agreement provides that, upon the terms and subject to the conditions set forth in the EUSA Merger Agreement, Merger Sub will merge with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly owned subsidiary of ours, which we refer to in this report as the EUSA Acquisition. Under the terms of the EUSA Merger Agreement, the consideration to be paid by us to EUSA Pharma's security holders in the EUSA Acquisition consists of \$650 million in cash, subject to increase or decrease based on EUSA Pharma's (a) working capital as of consummation of the EUSA Acquisition relative to an agreed upon target and (b) cash as of consummation of the EUSA Acquisition, plus a potential contingent payment of \$50 million in cash based upon EUSA Pharma's lead product, Erwinaze

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

(asparaginase *Erwinia chrysanthemi*), achieving U.S. net sales of \$124.5 million in 2013. Subject to customary closing conditions, the EUSA Acquisition is expected to close in June 2012. We recorded transaction costs of approximately \$1.2 million during the three months ended March 31, 2012 related to the proposed EUSA Acquisition.

Table of Contents

In connection with the EUSA Merger Agreement, we also entered into a commitment letter with Barclays Bank PLC, or Barclays, pursuant to which Barclays has committed, subject to certain customary conditions, to provide (i) \$500 million under a six year term loan facility, and (ii) \$100 million under a five year revolving loan facility. The commitment to provide the loan facilities is subject to certain conditions, including the negotiation of definitive documentation and other customary closing conditions consistent with the EUSA Merger Agreement. We expect to finance the EUSA Acquisition with a combination of cash on hand and proceeds from the \$500 million term loan. The EUSA Acquisition is not subject to a financing contingency, and we are therefore contractually obligated to complete the EUSA Acquisition, regardless of whether the loan facilities described in the commitment letter are available to us.

The Azur Merger represented a significant change in our business and has required, and will continue to require, significant efforts and expenditures. As a result of the transaction, Jazz Pharmaceuticals, Inc. transitioned from a standalone public Delaware corporation to being part of a combined company organized in Ireland. The proposed EUSA Acquisition would create numerous additional uncertainties and risks and would require additional significant efforts and expenditures. Upon closing of the EUSA Acquisition, which is anticipated to occur in June 2012, we would further transition to a company operating in an additional therapeutic area with a pan-European presence and a distribution network in numerous additional territories. The transition activities associated with the Azur Merger and the proposed EUSA Acquisition are complex, and we may encounter unexpected difficulties or incur unexpected costs, including those discussed in Part II Item 1A of this Quarterly Report on Form 10-Q under the heading "The combination of the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma has created, and the acquisition of EUSA Pharma would create, numerous risks and uncertainties, which could adversely affect our operating results or prevent us from realizing the expected benefits of the transactions." Our future financial results will be impacted by our ability to integrate the operations of the companies to the extent required successfully and on a timely basis and by our ability to realize the anticipated synergies, business opportunities and growth prospects from combining the businesses.

Results of Operations

The following table presents revenues and expenses for the three months ended March 31, 2012 and 2011:

	Three Months Ended		Increase/ (Decrease) (2)
	March 31,		
	2012	2011	
	(In thousands)		
Product sales, net	\$ 107,336	\$ 49,903	115%
Royalties and contract revenues	1,078	978	10%
Cost of product sales (excluding amortization of acquired developed technology)	10,758	2,809	283%
Selling, general and administrative	46,999	19,911	136%
Research and development	3,959	3,695	7%
Intangible asset amortization	13,513	1,862	626%
Interest income and other, net	71	-	N/A(1)
Interest expense	58	777	N/A(1)
Provision for income tax expense	5,517	-	N/A(1)

- (1) Comparison to prior period is not meaningful.
- (2) Subsequent to the completion of the Azur Merger on January 18, 2012, our financial results include the financial results of the historic Azur Pharma business. The historical financial statements of Jazz Pharmaceuticals, Inc. are included in the comparative prior period.

Table of Contents*Product Sales, Net*

	Three Months Ended		Increase/ (Decrease)
	March 31,		
	2012	2011	
	(In thousands)		
Xyrem	\$ 73,437	\$ 42,778	72%
Psychiatry:			
Luvox CR	9,558	7,125	34%
FazaClo LD (2)	5,579	-	N/A(1)
FazaClo HD (2)	2,561	-	N/A(1)
Prialt (2)	9,522	-	N/A(1)
Women's health and other (2)	6,679	-	N/A(1)
Product sales, net	\$ 107,336	\$ 49,903	115%

(1) Comparison to prior period is not meaningful.

(2) Represents net sales of products from the historic Azur Pharma business since January 18, 2012, the effective time of the Azur Merger. Xyrem product sales increased in the three months ended March 31, 2012 compared to the same period in 2011, primarily due to price increases and to a lesser extent increases in sales volume of 10%. Luvox CR product sales increased in the three months ended March 31, 2012 compared to the same period in 2011 due to price increases, partially offset by a small decrease in sales volumes. Other product sales increased by \$24.3 million in the three months ended March 31, 2012 compared to the same period in 2011 due to the inclusion of products from the historic Azur Pharma business, of which Prialt product sales included sales of \$4.6 million related to a supply agreement to provide Prialt to Eisai Co. Limited for distribution and sale in Europe. We expect total product sales will increase in 2012 over 2011 due to growth in sales of Xyrem and due to the inclusion of product sales from our expanded product portfolio resulting from the Azur Merger. If the EUSA Acquisition is completed as anticipated, we expect product sales to increase further.

Royalties and Contract Revenues

An increase in royalties accounted for the modest increase in royalty and contract revenues in the three months ended March 31, 2012 compared to the same period in 2011. We expect royalty and contract revenue to decrease slightly in 2012 as compared to 2011.

Cost of Product Sales

Cost of product sales increased in the three months ended March 31, 2012 compared to the same period in 2011 primarily due to \$6.4 million of cost of product sales from the products added to our portfolio as a result of the Azur Merger, including \$2.4 million related to purchase accounting inventory step up adjustments. Gross margin as a percentage of product sales was 90% in the three months ended March 31, 2012, compared to 94% for the same period in 2011. We expect our gross margin percentage to decrease in 2012 compared to 2011 because of the effect of the Azur Merger.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three months ended March 31, 2012 compared to the same period in 2011 primarily due to higher professional service fees and expenses of \$9.9 million (including transaction and integration costs of \$6.1 million), an increase in salary and benefit related headcount expenses of \$7.2 million, and other expenses related to the increase in the size of the organization including our increased commercial presence. We expect that selling, general and administrative expenses will be higher in 2012 than in 2011 due to the inclusion of expenses of the historic Azur Pharma business subsequent to the effective time of the Azur Merger on January 18, 2012. If the EUSA Acquisition is completed as anticipated, we expect selling, general and administrative expense sales to increase further.

Table of Contents

Research and Development Expenses

Research and development expenses were slightly higher in the three months ended March 31, 2012 compared to the same period in 2011. The primary reason for the increase was an increase in direct development project costs, which consist of formulation development costs, consulting fees and out-sourced study costs, including investigator payments. Headcount-related expenses incurred in the research and development organization were relatively flat from period to period. We expect research and development expenses to be higher in 2012 than in 2011 as we expect to increase our development activities.

Intangible Asset Amortization

In connection with the Azur Merger, we acquired finite-lived intangible assets with a fair value of \$323.0 million, which are expected to be amortized over their useful economic lives of two to fifteen years. We recorded amortization related to these intangibles of \$11.7 million in the three months ended March 31, 2012 which accounted for all of the increase in the amortization expense. We expect amortization expense in 2012 to increase substantially from 2011 due to amortization of intangibles related to the Azur Merger. If the EUSA Acquisition is completed as anticipated, we expect intangible asset amortization to increase further.

Interest Income and Other, Net

Interest income was marginally higher in the three months ended March 31, 2012 compared to the same period in 2011 as a result of higher cash, cash equivalents and marketable securities.

Interest Expense

Interest expense decreased in the three months ended March 31, 2012 compared to the same period in 2011 as a result of the repayment of our term loan in July 2011. We expect to finance the EUSA Acquisition, in part, through debt financing and as a result we expect interest expense to increase significantly.

Provision for Income Tax Expense

Our effective tax rate was 16.6% in the three months ended March 31, 2012 as compared to no provision for income tax expense in the same period in 2011. The increase in the effective tax rate is due to taxable profits for the quarter in excess of available net operating losses, or NOLs, after taking account of limitations imposed on current year utilization of NOLs. We expect our effective tax rate for the full year 2012 to be in the range of 14% to 18%.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we use the non-GAAP measures adjusted net income and adjusted net income per diluted share as shown in the table below. We believe these non-GAAP financial measures are helpful in understanding our past financial performance and our potential future results. They are not meant to be considered in isolation or as a substitute for comparable GAAP measures, and should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP. Our management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate our business and make operating decisions. Compensation of our executives is based in part on the performance of our business based on these non-GAAP measures. In addition, we believe that the use of these non-GAAP measures enhances the ability of investors to compare our results from period to period. Adjusted net income and adjusted net income per diluted share, as used by us, may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by our competitors and other companies. These measures exclude the following: amortization of intangible assets, share-based compensation, purchase accounting inventory fair value step up adjustments, transaction and integration costs and other non-cash items.

Table of Contents

A reconciliation of GAAP net income to adjusted net income, a non-GAAP financial measure, and related per share amounts is as follows:

	Three Months Ended March 31,	
	2012	2011
	(In thousands, except per share amounts)	
GAAP net income	\$ 27,681	\$ 21,827
Intangible asset amortization	13,513	1,862
Share-based compensation expense	3,281	3,148
Purchase accounting inventory fair value step-up	2,369	-
Transaction and integration costs	6,095	-
Other non-cash expense/(income)	42	(79)
Adjusted net income	\$ 52,981	\$ 26,758
GAAP net income per diluted share (1)	\$ 0.48	\$ 0.48
Adjusted net income per diluted share (1)	\$ 0.91	\$ 0.59
Shares used in computing GAAP and adjusted net income per diluted share amounts (1)	58,084	45,697

(1) All references to shares in the comparative prior year period were replaced with references to ordinary shares to reflect the capital structure of Azur Pharma, the legal acquirer in the Azur Merger. Our net income per diluted share in the comparative prior year period was not impacted by the Azur Merger because of the one-for-one merger exchange ratio.

Liquidity and Capital Resources

As of March 31, 2012, we had cash, cash equivalents and marketable securities of \$244.2 million. We generated cash flows from operations of \$24.3 million in the first quarter of 2012. We believe that our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and to meet our existing obligations, other than pursuant to the EUSA Merger Agreement, for the foreseeable future. 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, if we are not able to maintain or increase sales of Xyrem, it would have a material adverse effect on our business, financial condition, results of operations and growth prospects, If generic products that compete with Xyrem or any of our other products are approved and launched, sales of that product would be adversely affected, We may not complete our anticipated loan financing prior to the contractually required time for closing of the proposed EUSA Acquisition or otherwise secure favorable terms for such financing, and 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.

We do not currently have sufficient capital to complete the EUSA Acquisition. In connection with entering into the EUSA Merger Agreement, we entered into a commitment letter with Barclays, pursuant to which Barclays has committed to provide \$500 million under a six year term loan facility and \$100 million under a five year revolving loan facility. The commitment to provide the loan facilities is subject to certain conditions, including the negotiation of definitive documentation and other customary closing conditions consistent with the EUSA Merger Agreement. The funding under the loan facilities is not a condition to our obligations under the terms of the EUSA Merger Agreement. We cannot assure you that either the loan facilities will be available prior to the contractually required time for the closing of the proposed EUSA Acquisition or that the terms of the definitive documentation for the loan facilities will be consistent with the terms anticipated by the

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

commitment letter or will otherwise be favorable to us. In the event that the loan facilities contemplated by the commitment letter are not available at the required time, in order to complete the EUSA Acquisition, we would be required to raise capital through an alternative transaction or transactions, which could include an alternative loan facility, public or private debt or equity financings or other arrangements, and we may be unable to raise such additional funds in a timely manner or at all. Any equity financing could be dilutive to our shareholders.

Table of Contents

To grow our business over the longer-term, we will need to commit substantial resources to one or all of product acquisition and in-licensing, expensive and time-consuming product development and clinical trials of product candidates, and expanding our commercial operations. We may need to raise additional funds to license or acquire additional products, product candidates or companies or seek to raise additional funds 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.

The following table shows a summary of our cash flows for the periods indicated:

	Three Months Ended	
	March 31,	
	2012	2011
	(In thousands)	
Net cash provided by operating activities	\$ 24,295	\$ 24,448
Net cash provided by (used in) investing activities	82,508	(1,191)
Net cash used in financing activities	(18,225)	(2,990)
Net increase in cash and cash equivalents	\$ 88,578	\$ 20,267

Net cash provided by operating activities decreased slightly in 2012 primarily due to a net decrease in working capital of \$18.2 million, partially offset by an increase in non-cash adjustments of \$12.2 million primarily related to the amortization of intangible assets and an increase in net income of \$5.9 million.

Net cash provided by investing activities in 2012 primarily related to cash acquired in the Azur Merger.

Net cash used in financing activities in 2012 included payments totaling \$25.3 million for employee withholding tax related to net share exercises, partially offset by proceeds from other employee stock option exercises and warrant exercises.

Contractual Obligations

The table below presents a summary of our contractual obligations as of March 31, 2012 and includes contractual obligations assumed as a result of the Azur Merger.

Contractual Obligations (1)	Total	Payments due by period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
	(In thousands)				
Purchased product rights liability (2)	\$ 15,250	\$ 15,250	\$ -	\$ -	\$ -
Operating lease obligations (3)	20,520	3,696	7,033	5,330	4,461
Purchase obligations (4)	9,756	9,756	-	-	-
Total	\$ 45,526	\$ 28,702	\$ 7,033	\$ 5,330	\$ 4,461

- (1) We have not included milestone or royalty payments or contractual payment obligations in the table above if the amount and timing of such obligations are unknown or uncertain.
- (2) This amount represents amounts due under a product license agreements with Elan Pharma International Limited related to Prialt (\$12.0 million) and with Abbott Laboratories, or Abbott, related to Luvox CR (\$3.3 million). These amounts exclude \$5.0 million we may owe to

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

Abbott if net sales of Luvox CR reach a cumulative amount of \$100.0 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the United States as of December 31, 2014, because we do not know if we will have to pay it. These amounts also exclude payments totaling \$5.3 million we may owe to Douglas Pharmaceuticals American Limited under a product license and supply agreement related to an oral suspension formulation of clozapine which are dependent on regulatory approval and various sales milestones.

- (3) Includes the minimum lease payments for our office buildings and automobile lease payments for our sales force. In May 2012 we amended and extended the operating lease for our Philadelphia office and as a result, we are obligated to make additional payments of at least \$1.3 million through 2016 which are not included in the above table. In May 2012, we entered into an operating lease agreement for a new office in Dublin and as a result, we are obligated to make additional payments of \$4.5 million through 2022 which are not included in the table above. We have an option to terminate the new Dublin office lease on May 8, 2017, with no less than six months prior written notice and the payment of a termination fee in the amount of approximately \$0.2 million.
- (4) This includes non-cancelable commitments to third party manufacturers.

Table of Contents

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 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, the determination of excess and obsolete inventory, share-based compensation, accrued expenses and income taxes. 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. Please refer to Part II, Item 7 of the Annual Report on Form 10-K that we filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. under the heading **Critical Accounting Policies and Significant Estimates** for a discussion of our critical accounting estimates.

In connection with the Azur Merger on January 18, 2012, we acquired a number of intangible assets including intangible assets related to currently marketed products (developed technology) and intangible assets related to product candidates (in-process research and development, or IPR&D). When significant identifiable intangible assets are acquired, we engage an independent third-party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to:

estimating the timing of and expected costs to complete, the in-process projects;

projecting regulatory approvals;

estimating future cash flows from product sales resulting from completed products and in-process projects; and

developing appropriate discount rates and probability rates by project.

We believe the fair values that we assign to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates. No assurance can be given, however, that the underlying assumptions used to estimate expected cash flows will transpire as estimated. In addition, we are required to estimate the period of time over which to amortize the intangible assets, which requires significant judgment. Please refer to the footnotes to the condensed consolidated financial statements included elsewhere in this Form 10-Q for information about the remaining useful lives of our intangible assets as of March 31, 2012.

In connection with the Azur Merger, we recorded goodwill of \$201.5 million, which represented the excess cost of our investment in the net assets of the acquired Azur Pharma business over the fair value of the underlying identifiable net assets at the date of acquisition. This resulted in total goodwill recorded of \$239.7 million as of March 31, 2012. We assess our goodwill balance within our single reporting unit annually and whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then in the second step, the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Cautionary Note Regarding Forward-Looking Statements

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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, estimate, project, predict, intend, potential and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under Part II Item 1A. Risk Factors. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-

Table of Contents

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 actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2012, 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 the Annual Report on Form 10-K that we filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. for the year ended December 31, 2011.

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, 2012.

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, on January 18, 2012, a wholly-owned subsidiary of Jazz Pharmaceuticals plc (formerly known as Azur Pharma Public Limited Company) merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger and becoming a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Jazz Pharmaceuticals, Inc. is treated as the acquiring company in the Azur Merger for accounting purposes, and the Azur Merger was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the historical financial statements of Jazz Pharmaceuticals plc reflect the financial position, results of operations and cash flows of Jazz Pharmaceuticals, Inc. only. Following the Azur Merger, the financial statements of the current period reflect the financial position, results of operations and cash flows of Jazz Pharmaceuticals plc. The results of operations of the acquired Azur Pharma business are included in the results of operations of Jazz Pharmaceuticals plc beginning on January 18, 2012. Also, as a result of the Azur Merger, the internal control over financial reporting utilized by Jazz Pharmaceuticals, Inc. prior to the Azur Merger became the internal control over financial reporting of our company, and we are currently in the process of evaluating and integrating Azur Pharma's historical internal controls over financial reporting with ours.

During the quarter ended March 31, 2012, other than continuing changes to our internal control processes resulting from the Azur Merger as discussed above, there have been no material 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**

Throughout this report, unless otherwise indicated or the context otherwise requires, references to Jazz Pharmaceuticals, we, us, and our refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, including its predecessor, Jazz Pharmaceuticals, Inc. All references to Azur Pharma are references to Jazz Pharmaceuticals plc (f/k/a Azur Pharma Public Limited Company) and its consolidated subsidiaries prior to the effective time of the Azur Merger on January 18, 2012.

Item 1. Legal Proceedings

On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleged that all five patents listed for Xyrem in the FDA's approved drug products with therapeutic equivalence evaluation documents, or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States District Court for the District of New Jersey. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) April 18, 2013, which is 30 months from our October 18, 2010 receipt of Roxane's Paragraph IV certification notice, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. An additional method of use patent covering the distribution system for Xyrem issued in December 2010 and is listed in the Orange Book, and we amended our lawsuit against Roxane on February 4, 2011 to include the additional patent in the litigation in response to Roxane's Paragraph IV Certification against this patent. An additional method of use patent covering the distribution system for Xyrem issued in February 2011 and is listed in the Orange Book, and we amended our lawsuit on May 2, 2011 to include this additional patent in response to Roxane's Paragraph IV Certification against it. The District Court held a Markman hearing, a pretrial hearing in which the trial judge construes the claims of a patent, on April 26, 2012, and the discovery phase of the proceeding is ongoing. No trial date has been scheduled. We cannot predict the outcome of this matter.

In August 2009, we received a Paragraph IV Certification from Actavis Elizabeth, LLC, or Actavis, advising that Actavis had filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. Actavis' Paragraph IV Certification alleged that the United States patent covering Luvox CR, which is owned by Elan Pharma International Limited, or Elan, which has subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes, and licensed to us, is invalid on the basis that the inventions claimed therein were obvious. On October 6, 2009, we and Elan, as plaintiffs, filed a lawsuit against Actavis in the United States District Court for the District of Delaware claiming infringement of the Alkermes patent. On September 10, 2011, we received a Paragraph IV Certification from Torrent Pharma Limited, or Torrent, advising us that it had filed an ANDA with the FDA requesting approval to market a generic version of Luvox CR. On October 21, 2011, we and Alkermes, as plaintiffs, filed a lawsuit against Torrent in the United States District Court for the District of Delaware asserting infringement of the Alkermes patent. On April 5, 2012 and April 10, 2012, we and Alkermes entered into settlement agreements with Actavis and Torrent, respectively. Under the agreements, we, Alkermes and each of Actavis and Torrent agreed to dismiss all of the claims brought in the litigation without prejudice, each of Actavis and Torrent agreed not to contest the validity or enforceability of the Alkermes patent in the United States, and we, Alkermes and each of Actavis and Torrent agreed to release each other from all claims arising in the litigation or relating to the product each of Actavis and Torrent intends to market under its ANDA. In addition, we granted a sublicense to each of Actavis and Torrent of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicenses are non-transferable, non-sublicensable and royalty-free and are exclusive even as to us and Alkermes (except with respect to Luvox CR) for a period of time. The sublicenses will commence on April 15, 2014 or earlier upon the occurrence of certain events.

Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD. Azur Pharma and CIMA Labs Inc., a subsidiary of Teva, or CIMA, 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 in the U.S. District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, Inc., entered into an agreement settling the patent litigation and granted a sublicense of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD. The sublicenses will commence in July 2012 and May 2015 for FazaClo LD and FazaClo HD, respectively, or earlier upon the occurrence of certain events. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in California Superior Court in the County of Los Angeles. The complaint, among other

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

things, alleges that Azur Pharma and its subsidiary breached certain contractual obligations relating to contingent payments in respect of FazaClo. 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 owing to Dr. Cutler in relation to FazaClo. The complaint further alleges that certain contingent payments are due because sales thresholds have

Table of Contents

been achieved, entitling Dr. Cutler to either \$10.5 million or \$25.0 million, plus unspecified punitive damages and attorneys' fees. Azur Pharma denied the allegations in the complaint, moved to quash the summons for lack of jurisdiction by the California state court, and requested that the court send the dispute to arbitration under the contract under which Azur Pharma was sued. On March 14, 2012, the Superior Court denied the motion to quash but granted our petition to compel arbitration in New York and stayed the litigation. We intend to vigorously defend ourselves in connection with this litigation; however, this, like all litigation, carries certain risks and there can be no assurance of the outcome.

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

Item 1A. Risk Factors

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

We have marked with an asterisk () those risks described below that reflect substantive changes from, or additions to, the risks described in the Annual Report on Form 10-K for the year ended December 31, 2011 that we filed on behalf of and as successor to Jazz Pharmaceuticals, Inc.*

Risks Relating to Our Dependence on Xyrem

*Xyrem is our largest selling product, and, if we are not able to maintain or increase sales of Xyrem, it would have a material adverse effect on our business, financial condition, results of operations and growth prospects.**

Xyrem is our largest selling product. We are substantially dependent on sales of Xyrem to generate most of the cash necessary to operate our business and to meet our ongoing financial obligations, and our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2010 to 2011, we cannot assure you that Xyrem sales will continue to grow. We have periodically significantly increased the price of Xyrem, most recently in February 2012, and we cannot assure you that price adjustments we have taken or may take in the future have not, or will not in the future, negatively affect Xyrem sales volumes.

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

the potential introduction of a generic version of Xyrem;

our manufacturing partners' ability to obtain sufficient quota from the U.S. Drug Enforcement Administration, or 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;

changed or increased regulatory restrictions, including changes to our risk management program for Xyrem, or regulatory actions by the FDA as a result of a warning letter we received in October 2011;

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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

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

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.

These and the other risks described in these risk factors 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 prescriptions and revenue from sales of Xyrem do not continue or increase as expected, we may be required to reduce our operating expenses or to seek to raise additional funds, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects, or we may not be able to acquire, in-license or develop new products to grow our business.

Table of Contents

Risks Relating to the Proposed Acquisition of EUSA Pharma

Failure to consummate the proposed acquisition of EUSA Pharma could negatively impact our share price and our future business and financial results.*

On April 26, 2012, we, an indirect wholly-owned subsidiary of ours, or Merger Sub, EUSA Pharma Inc., or EUSA Pharma, and the representatives of the equity holders of EUSA Pharma entered into an Agreement and Plan of Merger, or the EUSA Merger Agreement. The EUSA Merger Agreement provides that, upon the terms and subject to the conditions set forth in the EUSA Merger Agreement, Merger Sub will merge with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly owned subsidiary of ours, which we refer to in this report as the EUSA Acquisition. If the proposed EUSA Acquisition is not consummated, our ongoing business may be adversely affected and, without realizing any of the benefits of having consummated the EUSA Acquisition, we will be subject to a number of risks, including the following:

we may be required to reimburse EUSA Pharma for certain expenses incurred by EUSA Pharma in connection with certain transaction matters;

the current price of our ordinary shares may reflect a market assumption that the EUSA Acquisition will occur, such that a failure to complete the EUSA Acquisition could result in a decline in the price of our ordinary shares; and

matters relating to the EUSA Acquisition have required and will continue to require substantial commitments of time and resources by our management and other employees, which could otherwise have been devoted to other opportunities that may have been beneficial to us.

We also could be subject to litigation related to any failure to consummate the EUSA Acquisition or to perform our obligations under the EUSA Merger Agreement or related to any enforcement proceeding commenced against us. If the EUSA Acquisition is not consummated, these risks may materialize and may adversely affect our business, financial results and share price.

EUSA Pharma's business relationships may be subject to disruption due to uncertainty associated with the EUSA Acquisition.*

Parties with which EUSA Pharma currently conducts business or may conduct business in the future, including customers and suppliers, may experience uncertainty associated with the EUSA Acquisition, including with respect to current or future business relationships with us or EUSA Pharma. As a result, EUSA Pharma's business relationships may be subject to disruptions if customers, suppliers and others attempt to negotiate changes in existing business relationships or consider entering into business relationships with parties other than us or EUSA Pharma. These disruptions could have an adverse effect on our businesses, financial condition, results of operations or prospects following the closing. The adverse effect of such disruptions could be exacerbated by a delay in the consummation of the EUSA Acquisition.

Loss of key personnel could impair the integration of the two businesses, lead to loss of customers and a decline in revenues, adversely affect the progress of pipeline product candidates or otherwise adversely affect our operations and the operations of EUSA Pharma.*

Our success after the completion of the EUSA Acquisition will depend, in part, upon our ability to retain key employees, especially during the integration phase of the two businesses. Current and prospective employees of ours and EUSA Pharma might experience uncertainty about their future roles with us following completion of the EUSA Acquisition, which might adversely affect our ability to retain key managers and other employees. In addition, competition for qualified personnel in the biotechnology industry is very intense. If we or EUSA Pharma lose key personnel or we are unable to attract, retain and motivate qualified individuals or the associated costs to us increase significantly, our business could be adversely affected.

Obtaining required approvals necessary to satisfy the conditions to the completion of the EUSA Acquisition may delay or prevent completion of this acquisition, result in additional expenditures of money and resources and/or reduce the anticipated benefits of the EUSA Acquisition.*

The EUSA Acquisition is subject to customary closing conditions. These closing conditions include, among others, the expiration or termination of the waiting period under the HSR Act and compliance with antitrust-related filing requirements in certain other countries. The governmental

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

agencies from which the parties will seek approvals have broad discretion in administering the governing regulations. As a condition to their approval, agencies may impose requirements, limitations or costs or require divestitures or place restrictions on the conduct of our business after the closing. These requirements, limitations, costs, divestitures or restrictions could jeopardize or delay the consummation of the EUSA Acquisition or may reduce the anticipated benefits of this acquisition. If we and EUSA Pharma agree to any material requirements, limitations, costs or restrictions in order to obtain any approvals required to consummate the EUSA Acquisition, these requirements, limitations, costs or restrictions could adversely affect the anticipated benefits of this acquisition. This could result in a failure to consummate these transactions or have a material adverse effect on our business and results of operations.

Table of Contents

We may not complete our anticipated loan financing prior to the contractually required time for closing of the proposed EUSA Acquisition or otherwise secure favorable terms for such financing.*

We do not currently have sufficient capital to complete the EUSA Acquisition. In connection with entry into the EUSA Merger Agreement, we entered into a commitment letter with Barclays Bank PLC, or Barclays, pursuant to which Barclays has committed to provide \$500 million under a six year term loan facility and \$100 million under a five year revolving loan facility. The commitment to provide the loan facilities is subject to certain conditions, including the negotiation of definitive documentation and other customary closing conditions consistent with the EUSA Merger Agreement. The funding under the loan facilities is not a condition to our obligations under the terms of the EUSA Merger Agreement. We cannot assure you that either the loan facilities will be available prior to the contractually required time for the closing of the proposed EUSA Acquisition or that the terms of the definitive documentation for the loan facilities will be consistent with the terms anticipated by the commitment letter or will otherwise be favorable to us. In the event that the loan facilities contemplated by the commitment letter are not available at the required time, in order to complete the EUSA Acquisition, we would be required to raise capital through an alternative transaction or transactions, which could include an alternative loan facility, public or private debt or equity financings or other arrangements, and we may be unable to raise such additional funds in a timely manner or at all. Any equity financing could be dilutive to our shareholders.

The terms of our anticipated loan facilities could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.*

The terms of our anticipated loan facilities are expected to include customary restrictive covenants that would impose operating and financial restrictions on us, including restrictions on our ability to take actions that could be in our best interests. These restrictive covenants are expected to include operating covenants restricting, among other things, our ability to incur additional indebtedness, effect certain acquisitions or make other fundamental changes. The anticipated loan facilities are also expected to include financial covenants relating to minimum interest coverage, maximum total senior secured leverage and maximum capital expenditures. Our failure to comply with any of the covenants that are included in our anticipated loan facilities could result in a default under the terms of the facilities, 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 anticipated revolving loan facility, which could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.

If goodwill or other intangible assets that we record in connection with the EUSA Acquisition become impaired, we could be required to take significant charges against earnings.*

In connection with the accounting for the EUSA Acquisition, it is expected that we will record a significant amount of goodwill and other intangible assets. Under the U.S. generally accepted accounting principles, or GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets has been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Risks Relating to the Integration of the Azur Pharma and EUSA Pharma Businesses

The combination of the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma has created, and the acquisition of EUSA Pharma would create, numerous risks and uncertainties, which could adversely affect our operating results or prevent us from realizing the expected benefits of the transactions.*

The merger transaction between Jazz Pharmaceuticals and Azur Pharma, or the Azur Merger, which was completed on January 18, 2012, created numerous uncertainties and risks, and has required, and will continue to require, significant efforts and expenditures. In the Azur Merger, Jazz Pharmaceuticals transitioned from a standalone public Delaware corporation to being part of a combined company organized in Ireland. This combination entails many changes, including the integration of Azur Pharma and its personnel with those of Jazz Pharmaceuticals and changes in systems. The proposed EUSA Acquisition would also create numerous additional uncertainties and risks and require additional significant efforts and expenditures. Upon closing of the EUSA Acquisition, which is anticipated to occur in June 2012, we would further transition to a company operating in an additional therapeutic area, oncology, with a pan-European presence and a distribution network in numerous additional territories. The transition activities associated with the Azur Merger and the proposed EUSA Acquisition are complex, and we may encounter unexpected difficulties or incur unexpected costs, including:

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

the diversion of our management's attention to integration of operations and corporate and administrative infrastructures;

difficulties in achieving anticipated business opportunities and growth prospects from the Azur Merger and the proposed EUSA Acquisition;

difficulties in the integration of operations and systems;

difficulties in the assimilation of employees and corporate cultures, as well as managing employees in geographically disparate locations;

increased complexity and costs of managing international operations;

challenges in harmonizing our promotional review process and other compliance activities and meeting our ongoing U.S. and foreign regulatory obligations for our expanded product portfolio;

Table of Contents

challenges in integrating sale forces and building and maintaining a strong sales organization;

increased exposure to foreign currency exchange rate fluctuations;

challenges in keeping existing customers and obtaining new customers; and

challenges in attracting and retaining key personnel.

If any of these factors impairs our ability to integrate the acquired businesses successfully or on a timely basis, we may not be able to realize the anticipated synergies, business opportunities and growth prospects from combining the businesses. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business.

In addition, the market price of our ordinary shares may decline if the integration of the businesses is unsuccessful, takes longer than expected or fails to achieve financial benefits to the extent anticipated by financial analysts or investors, or the effect of the business combinations on the financial results of the combined company is otherwise not consistent with the expectations of financial analysts or investors.

Risks Relating to Our Business

*If generic products that compete with Xyrem or any of our other products are approved and launched, sales of that product would be adversely affected.**

Although Xyrem is covered by patents covering its formulation, distribution system and method, and certain of our other products are covered by patents covering their respective formulations, distributions systems or methods of use, we cannot assure you that third parties will not attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and introduce generic equivalents of Xyrem or any other products. Once orphan drug exclusivity for Xyrem in the United States for the treatment of excessive daytime sleepiness in patients with narcolepsy expires in November 2012 and exclusivity has expired for the other products, other companies could possibly introduce generic equivalents of these products if they do not infringe our patents or can demonstrate that our patents are invalid or unenforceable.

On October 18, 2010, we received notice from Roxane Laboratories, Inc., or Roxane, that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. If the application 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 forms of Xyrem; if those applications for generics were approved and the generics were launched, sales of Xyrem would further decrease. Roxane has sent us Paragraph IV certifications with respect to our patents listed in the FDA's approved drug products with therapeutic equivalence evaluation documents, or Orange Book, covering Xyrem for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy. A Paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product. The FDA will not approve an ANDA for a generic form of a product unless the submitting manufacturer either files a Paragraph IV certification with respect to the patents listed in the FDA's Orange Book for that product or all of those patents expire. We have sued Roxane, but we cannot assure you that the lawsuit will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all.

A generic manufacturer would need to obtain quota from the DEA in order to manufacture the active pharmaceutical ingredient and finished product for a generic version of Xyrem. The DEA has historically published an annual overall quota that is less than we need, and we have engaged in costly and time consuming legal efforts to obtain the needed quotas, and our suppliers have historically obtained substantially all of the aggregate quota, for use in the manufacture of Xyrem. The aggregate quota published for 2012 is significantly higher than the amounts requested by our suppliers to meet our needs for Xyrem. As a result, it may be easier for a generic manufacturer to obtain DEA quota than it would have been in prior years.

We received Paragraph IV certification notices relating to three generic versions of Luvox CR, two in 2009 and one in 2011. We filed lawsuits against all of these companies after receipt of their certifications. We and Elan Pharma International Limited, which has subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes, entered into settlement agreements with all three of the companies, granting to each company a sublicense of its rights to have manufactured, market and sell a generic version of Luvox CR, with one sublicense commencing in February 2013, or earlier upon the occurrence of certain events, and the other two commencing in April 2014, or earlier upon the occurrence of certain events.

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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 Labs Inc., a subsidiary of Teva, or CIMA, our licensor and whose drug-delivery technology is incorporated into FazaClo LD, filed lawsuits in response to each certification. In July 2011, Azur Pharma, CIMA, Barr Laboratories (one of the three generic manufacturers) and Teva, which had acquired Barr Laboratories, entered into an agreement settling the patent litigation and granting a license of our rights to have manufactured, market and sell a generic version of FazaClo LD and FazaClo HD. The sublicenses will commence in July 2012 and May 2015 for FazaClo LD and FazaClo HD,

Table of Contents

respectively, or earlier upon the occurrence of certain events. In August 2011, Azur Pharma received a Paragraph IV certification notice from Teva advising that Teva had filed an ANDA with the FDA seeking approval to market a generic version of FazaClo HD. As noted above, FazaClo HD was covered under the July 2011 settlement agreement with Teva. In the July 2011 settlement agreement, we granted Teva an option, subject to certain conditions, to have us supply it with an authorized generic of FazaClo LD starting in July 2012. Teva exercised the option in February 2012. We are working with the FDA to address any applicable regulatory requirements in connection with the supply of an authorized generic of FazaClo LD to Teva. We cannot assure you that the lawsuits against the other generic manufacturers, or any other lawsuit we may bring, will prevent the introduction of generic versions of FazaClo LD and FazaClo HD for any particular length of time, or at all.

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

After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product generally may be filled with the generic version, resulting in a loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. 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 equivalent is available. Generic competition for Xyrem and our other products could 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 restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.*

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 current and any potential new suppliers of sodium oxybate, as well as our 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 and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate or Xyrem exceed our suppliers' and product manufacturer's DEA quotas, our suppliers and product manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. We cannot assure you that our suppliers will receive sufficient quota from the DEA to meet our needs, and if we and our suppliers cannot obtain as much quota as is needed, on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem. The risk management plan includes unique features that provide information about adverse events, including deaths, that is generally not available for other products that are not subject to a similar risk management plan. Information concerning adverse events that may not be related to the use of Xyrem is likely to be collected under the risk management plan. This information, which we are required to report regularly to the FDA, 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.

The Xyrem risk management plan adopted with the approval of the product in 2002 is not in the same form as required under the newer Risk Evaluation and Mitigation Strategy, or REMS, structure pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The FDA has required that pre-existing risk management programs be converted to the newer REMS structure. The Xyrem risk management program is a deemed REMS in the view of the FDA. While we have been in discussions with the FDA about converting our deemed REMS to a REMS under the new structure, those discussions have not been completed. We cannot assure you that the FDA will not impose new and onerous requirements under the new REMS structure that could make it more difficult or expensive for us to distribute Xyrem or could adversely affect our sales or make competition easier.

Under our existing risk management plan, 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 the Xyrem risk management program is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, Inc. 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

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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

Table of Contents

with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under the risk management plan approved by the FDA. Transitioning to a new central pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the United States, result in additional costs and expenses for us, and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In late 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 as required. Promptly after learning of them, we reported to the FDA all of the previously unreported cases that we and ESSDS had identified. We also began immediately taking specific steps to strengthen our own procedures, and those between us and ESSDS, to seek to ensure that all adverse events are reported to us, and to the FDA, in an appropriate and timely manner.

In early May 2011, we received a Form 483 as a result of an FDA inspection, which included the inspector's observations concerning our adverse event reporting system. That document discussed the failure to report serious adverse events, including certain cases of deaths as described above, and also noted deficiencies in certain of our drug safety procedures. After receipt of the Form 483, we continued our efforts to improve our systems, and those used by us and ESSDS, to ensure that we correct the deficiencies noted in the Form 483, and those efforts are continuing. In October 2011, we received a warning letter from the FDA relating to the matters covered by the Form 483. We have responded to the warning letter, advising the FDA of the efforts we have taken to date and are continuing to take, and we are continuing to strengthen our procedures and take appropriate corrective actions to address all of the matters covered in the warning letter. While we have responded to the warning letter in a timely manner and we intend to demonstrate our compliance to the FDA's satisfaction, we cannot assure you that we will be able to adequately address the FDA's requirements pursuant to the warning letter, and the failure to do so could have a material and adverse effect on our business, financial condition and results of operations.

The information we initially received concerning the cases discussed above did not specify the cause of death in most cases. We have gathered additional information and completed our analysis with respect to these cases under a plan that we discussed with the FDA. The analysis showed that the mortality rates in patients receiving a Xyrem prescription have not increased over time since product launch, and, overall, the inclusion of the new cases does not change the known mortality risks observed among patients prescribed Xyrem. We are continuing to work with the FDA on both the product label and an updated risk management plan to further enhance and promote the safe use of Xyrem. We cannot assure you that the FDA will agree with our proposed updates to the Xyrem label or risk management plan, whether the FDA will open an evaluation based on the FDA's Adverse Event Reporting System database, or whether the FDA will take or require us to take other actions that could be costly or time-consuming and/or negatively affect the commercial success of Xyrem. We cannot assure you that regulatory authorities in other countries where Xyrem is sold will not take similar actions.

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, ads which 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.

The manufacture, distribution and sale of FazaClo LD and FazaClo HD are, and we expect Clozapine OS and Clozapine QD if approved would be, subject to the requirements of a patient registry program and other restrictions under the requirements of its risk management plan, and these requirements will subject us to increased risks and uncertainties, any of which could negatively impact sales of those products.*

The FDA requires a risk management plan in the form of a patient registry for all clozapine-containing products, including FazaClo LD and FazaClo HD. The FazaClo risk management plan provides a database for monitoring patients (white blood cell and absolute neutrophil counts) treated with FazaClo LD and FazaClo HD to permit early detection of clozapine-induced leucopenia or agranulocytosis, provides a confidential registration and reporting process for patients treated with the products, and provides ongoing updating of the Clozapine National Non-Rechallenge Masterfile with patients previously treated with clozapine products who can no longer be prescribed clozapine products including FazaClo. White blood cell counts of patients taking FazaClo products must be monitored weekly for the first six months of treatment, bi-weekly for the next six months and monthly thereafter (for patients having 12 months of acceptable blood test results).

The risk management plan for FazaClo, which was adopted in 2004, is not in the same form as required under the newer REMS structure under the FDAAA. The FDA views the existing risk management program for FazaClo LD and FazaClo HD as a deemed REMS and has required that this deemed REMS be converted to its current REMS structure. Azur Pharma submitted a supplement for a new REMS plan, which, once approved, will replace the current risk management plan for FazaClo LD and FazaClo HD. We also have two clozapine product candidates: an oral suspension formulation of clozapine, Clozapine OS, and a once-daily formulation of clozapine, Clozapine QD. We expect these two product candidates if approved would be subject to the REMS requirements. We cannot assure you that the FDA will not impose new and onerous

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

requirements under the new REMS structure that could make it more difficult or expensive for us to distribute FazaClo or could adversely affect our sales or make competition easier.

Table of Contents

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

We depend on single source suppliers and manufacturers for each of our products and product candidates. 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 do not have, and do not intend to establish in the near term, our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. In part due to the limited market size for our approved products, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. If our suppliers and contract manufacturers, including any new suppliers without a track record of meeting our supply needs, do not manufacture our products or product candidates without interruption or do not 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.

The availability of our products for commercial sale depends upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product 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 product 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, packaging materials 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 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 approval of a new active pharmaceutical ingredient supplier or product manufacturer. For Xyrem or sodium oxybate, any new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. Our new supplier of sodium oxybate, Siegfried (USA) Inc., or Siegfried, was approved by the FDA in late 2011 and became our sole commercial supplier in 2012.

Our FazaClo supplier, CIMA, is in the process of transferring manufacturing of FazaClo LD and FazaClo HD from its Eden Prairie site to the Salt Lake City site of its parent company, Teva. While we expect this transition to be completed in 2012, we cannot be certain this will occur. FDA approval is required for this change and we cannot be certain this will be obtained.

Pursuant to our supply agreement with Abbott Laboratories, or Abbott, we are responsible for purchasing, and Abbott is responsible for providing us with, fluvoxamine maleate, the active pharmaceutical ingredient necessary to manufacture Luvox CR. Abbott (through its predecessor Solvay which it acquired in 2010) assigned to us its rights and obligations under its license and supply agreement with Alkermes. Pursuant to the license and supply agreement with Alkermes, we are responsible for providing the active pharmaceutical ingredient free of charge to Alkermes, and Alkermes has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. Abbott has purchased the fluvoxamine maleate it supplied to us from Lonza, Inc., or Lonza, and, therefore, Lonza, through Abbott, was our sole supplier of fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR. Lonza sold its United States facility where it manufactured fluvoxamine maleate to a third party that currently continues to supply Abbott, and therefore us, with fluvoxamine maleate. Any new manufacturer or new site would need to be approved by the FDA.

We are in the process of changing suppliers for Prialt finished product and for ziconotide, the active ingredient in Prialt. We have identified and commenced the transfer of ziconotide to a new manufacturer. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for a number of years, by which time we expect supply to be available from a new manufacturer. We have also identified and begun the transfer of Prialt finished product manufacturing to a new manufacturer. Final

Table of Contents

batches are scheduled for manufacture at the current manufacturer with supply expected to be sufficient to meet commercial requirements through the end of 2013, by which time we expect a new manufacturer to be approved as a supplier by the FDA. However, there can be no assurance that such new manufacturers of ziconotide and Prialt finished product or any other manufacturer will be approved by the FDA, or that our supplies of ziconotide and Prialt will be sufficient until such manufacturers or other manufacturers have been approved, and any failure to obtain sufficient commercial supplies of Prialt would have a material adverse effect on our business, financial condition and results of operations.

If there are delays in qualifying the new manufacturers or facilities or the new manufacturer is unable to obtain a sufficient quota from the DEA or otherwise meet the FDA requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both.

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

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 in the United States and our partners' needs outside the United States, or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

We may not be able to successfully identify and acquire, in-license or develop additional products or product candidates to grow our business, and, even if we are able to do so, we may not be able to successfully identify and manage the risks associated with integrating acquisitions, including acquisitions of a company or business unit, or other new products or product candidates.

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. Any growth through acquisition or in-licensing will depend upon the availability of suitable acquisition or in-license products and product candidates on acceptable prices, terms and conditions, and 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.

In addition, integrating an acquisition, including the acquisition of a company such as EUSA Pharma or a business unit, or an in-licensed product or product candidate, may create unforeseen operating difficulties and expenses for us, including:

the diversion of management time and focus from operating our current business;

unanticipated liabilities for activities of or related to an acquired company or product before the acquisition;

failure to retain employees or to smoothly integrate related departments; and

failure to successfully develop and commercialize acquired products and product candidates.

We cannot assure you that we will be able to successfully manage these risks or other anticipated and unanticipated problems in connection with integrating an acquisition, including the acquisition of a company or business unit, or in-licensed product or product candidate, and, if we are not successful in identifying and managing these risks and uncertainties effectively, it could have a material adverse effect on our business.

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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. Market acceptance of any of our products by physicians, patients, third party payors and the medical community depends on:

the clinical indications for which a product is approved, including any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry or labeling restrictions;

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;

Table of Contents

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.

From time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Patients, physicians and regulators may therefore view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of its connection to GHB. Xyrem's label includes information about adverse events from GHB. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients.

Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects. Negative publicity resulting from our receipt of a Form 483 observation in May 2011 or the related warning letter from the FDA in October 2011, or other related regulatory actions could adversely affect sales of Xyrem.

Sales of our products may be adversely affected by the consolidation among wholesale drug distributors.

The network through which we sell our products has undergone significant consolidation through mergers and acquisitions among wholesale distributors. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drugstore chains has decreased. Three large wholesale distributors and one of their subsidiaries accounted for an aggregate of 25% of our total revenue during the quarter ended March 31, 2012. If any of our major distributors reduces its inventory levels or otherwise reduces purchases of our products, it could lead to periodic and unanticipated future reductions in revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug companies, including us.

We face substantial competition from other companies, including companies with greater resources than we have.

With respect to all of our existing and future products, we may compete with companies selling or working to develop products that may be more effective, safer or less costly than our products. The markets for which we are developing products are competitive and include generic and branded products, some of which are marketed by major pharmaceutical companies that have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing and marketing and selling approved products than we do.

Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunities may be reduced or eliminated if our competitors develop and commercialize generic or branded products that are safer or more effective, have fewer side effects or are less expensive than our products.

Many of our competitors have far greater financial resources and a larger number of personnel to market and sell their products than we do. 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. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to other therapies, we may not generate meaningful revenues from the sales of our products.

We currently have a relatively small sales organization compared with most other pharmaceutical companies with marketed products. If our specialty sales forces and sales organization is not appropriately sized to adequately promote any current or potential future products, the commercial opportunity for our current or potential future products may be diminished.*

We 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 commercial products may require expansion of our sales force and sales support organization, 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.

Table of Contents

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.

Significant additional research and development, financial resources and additional personnel will be required to obtain necessary regulatory approvals for our current and any future product candidates and to develop them into commercially viable products. As a condition to regulatory approval, each product candidate must undergo extensive and expensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. If a product candidate fails at any stage of development, we will not be able to commercialize it and we will not receive any return on our investment from that product candidate.

We and our partners have conducted, and we may in the future conduct, additional clinical trials for our product candidates including: an oral suspension formulation of clozapine, Clozapine OS, and a once-daily formulation of clozapine, Clozapine QD. Clinical testing can take many years to complete, especially for product candidates that are in Phase II, or earlier, clinical trials, and failure can occur any time during the clinical trial process. 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. 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. Our product candidates are subject to competition for clinical study sites and patients from other therapies under development that may delay the enrollment in or initiation of our clinical trials. Many of these companies have far greater financial and human resources than we do.

To grow our sodium oxybate business, we have and may in the future conduct additional studies in different diseases or conditions or with additional or different doses or dosage forms. We cannot assure you that adverse events or other information obtained during the course of any of these studies will not result in action by the FDA or otherwise that could have a material adverse effect on the Xyrem commercial product as well as the candidate we are studying.

We rely on third parties to conduct clinical trials for our product candidates, 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 our licensors, contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out clinical trials for our product candidates, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as FDA's and foreign 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 enforces good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our licensors, contract research organizations 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 may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA 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. Our failure, or the failure of our contract 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.

If we fail to attract, retain and motivate key personnel, or to retain our executive management team, or if we cannot provide additional resources to perform important tasks, we may be unable to successfully sustain or grow our business.*

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 key personnel, all of whom work on many complex matters that are critical to our success. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry key person insurance. Any employee may terminate his or her employment at any time without notice (or, in the case of certain employees who entered into employment agreements with Azur Pharma, with up to three months

notice) and without cause or good reason.

Table of Contents

In addition, to grow our company we will need additional personnel. Competition for qualified personnel in the life sciences industry has historically been intense. If we lose key personnel or cannot timely attract, retain and motivate quality personnel on acceptable terms, our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

Risks Related to Our Intellectual Property

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our products and product candidates, their use and the methods used to manufacture and, in some cases, distribute them, as well as successfully defending these patents against third party challenges. 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 for which important legal principles remain unresolved. 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. For example, even though we have patents covering Xyrem, an ANDA was filed requesting permission from the FDA to market a generic form of Xyrem, and we have received notices from the company that filed the ANDA stating that the ANDA included Paragraph IV certifications with respect to our Xyrem patents listed in the FDA's Orange Book. In the case of Luvox CR, we received three Paragraph IV certifications which allege that the Alkermes patent listed in the Orange Book for Luvox CR was invalid. Similarly, three ANDAs were filed requesting approval from the FDA to market a generic form of FazaClo LD and one ANDA has been filed requesting approval from the FDA to market a generic form of FazaClo HD. Azur Pharma received notices from the companies that filed the ANDAs stating that such ANDAs included Paragraph IV certifications with respect to the patents listed in the FDA's Orange Book.

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 United States patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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 make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;

we or our licensors or partners might not have been the first to file patent applications for these inventions;

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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;

Table of Contents

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

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

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

We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Certain of the women's health and other products we sell, including Urelle, Natelle, Gesticare and Gastrocrom, have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. The introduction of competing products could materially adversely affect our sales of these products. For example, in October 2011 an ANDA from Pack Pharmaceuticals LLC, seeking to manufacture and sell a generic version of Gastrocrom, was approved by the FDA, and a generic version of Gastrocrom has since been launched.

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 patent 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 foreign counterparts, and may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, in part because of prior research performed and patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents, our licensed patents or our partners' patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or 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 Jazz Pharmaceuticals, Inc. or Azur Pharma with respect to Xyrem and FazaClo LD. See Part II Item 1. Legal Proceedings. We cannot assure you that these, or other lawsuits we may file in the future, will be successful in stopping the infringement of our patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for us.

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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.

Table of Contents

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

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, 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 U.S. Patent and Trademark Office 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.

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.

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 by FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, generally of a new drug application, or an NDA. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process, and the FDA has substantial discretion in the approval process. 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.

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

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which is referred to in this report as the Healthcare Reform Act or the PPACA. 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, 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.

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. In addition, under the Healthcare Reform Act, the minimum Medicaid rebate has been increased from 15.1% to 23.1% of the average manufacturer price for our products.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014 and thereafter, and their details will be shaped significantly by implementing regulations that have yet to be proposed. The constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act have been challenged. These challenges are pending final adjudication in several jurisdictions, including the United States Supreme Court. Congress has also proposed a number of legislative initiatives, including possible repeal of the Healthcare Reform Act. As a result of these uncertainties as well as others unknown to us at this time, it is unclear whether there will be any

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

changes made to the Healthcare Reform Act, whether to certain provisions or in its

Table of Contents

entirety. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates or could limit or eliminate our future spending on development projects.

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third-party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem voucher program and coupon programs for certain products. Coupon programs, including our program for Xyrem, have received some negative publicity, and it is possible that new legislation could be enacted to restrict or otherwise negatively affect these programs. The enactment and implementation of any future healthcare reform legislation or policies 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.

We are subject to significant ongoing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products are, and any of our product candidates that may be approved by the FDA will be, subject to extensive and ongoing regulatory requirements. If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities 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 previously unknown 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.

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

Some of our women's health and other products, such as Urelle and prenatal vitamin products Natelle and Gesticare, have not been approved by the FDA, and the FDA may view them as unapproved new drugs. These products have historically been the subject of FDA enforcement discretion under which the FDA has generally prioritized action against marketed unapproved drugs that the FDA considers to present a potential safety risk, lack evidence of effectiveness, or be deceptively promoted, among other enforcement priority reasons. However, in a September 19, 2011 Compliance Policy Guide, the FDA announced a change to its enforcement policy for marketed unapproved drugs. In this guidance, the FDA informed marketers of unapproved drugs that all unapproved drugs introduced into the market after September 19, 2011 are subject to immediate enforcement action at any time, without prior notice. In addition, any formulation or labeling changes to a pre-September 19, 2011 product could potentially subject the manufacturer to immediate FDA enforcement action to remove such product from the market. We cannot assure you that the FDA will continue to permit marketing of any of our women's health and other products that have not been approved by the FDA in their existing formulations, or at all, without submission and approval of an NDA. Moreover, under the recent FDA guidance, any formulation or labeling changes to these products may also subject them to FDA enforcement action to remove them from the market.

The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. For example, a predecessor company to Jazz Pharmaceuticals, Inc. was investigated for off-label promotion of Xyrem, and, while Jazz Pharmaceuticals, Inc. was not prosecuted, as part of the settlement Jazz Pharmaceuticals, Inc. entered into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services with a term extending through mid-2012. The investigation resulted in significant fines and penalties, which Jazz Pharmaceuticals, Inc. guaranteed and has been paying; the final payment was made in January 2012. The corporate integrity agreement requires us to maintain a comprehensive compliance program. In the event of an uncured material breach or deliberate violation, as the case may be, of the corporate integrity agreement or the other definitive settlement agreements Jazz Pharmaceuticals, Inc. entered into, we could be excluded from participation in Federal healthcare programs and/or subject to

prosecution.

Table of Contents

In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to other administrative or judicially imposed sanctions, including warning letters, untitled letters, other civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production, withdrawal of the products from the market and refusal to approve pending NDAs or supplements to approved NDAs. We are also subject to regulation by regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, the U.S. Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we commercialize our products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state 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 manufacturing partners are subject to many of the same requirements, which include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. 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 federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations of our products may be subject to scrutiny if they do not qualify for an exemption or safe harbor. We seek to comply with the exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under these laws for a variety of alleged marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. Companies have been prosecuted for causing false claims to be submitted because of the marketing of their products for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other healthcare companies have also been prosecuted on other legal theories of Medicare and Medicaid fraud.

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. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals.

Compliance with various federal and state laws 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 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. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations and, as required by the Physician Payment Sunshine provisions, extensive tracking of physician payments and maintenance of a payments database scheduled to begin after January 1, 2013 and public reporting of the physician payment data scheduled to start in March 2013, which may be postponed to a later date. While it is too early to predict what effect these changes will have on

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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.

Table of Contents

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 or our partners' ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

If we fail to comply with our reporting and payment obligations under the Medicaid 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 federal Medicaid 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 programs. Under the Medicaid rebate program, we 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 under a fee-for-service arrangement, 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 the Centers for Medicare and Medicare Services, or CMS, the federal agency that administers the Medicaid rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug.

The PPACA made significant changes to the Medicaid rebate program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organizations. With regard to the amount of the rebates owed, the PPACA increased the minimum Medicaid rebate for innovator drugs; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and caps the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the PPACA and subsequent legislation changed the definition of average manufacturer price. Finally, the PPACA requires pharmaceutical manufacturers of branded prescription drugs to pay a new branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of \$2.8 billion in 2012 (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.

The CMS has yet to issue regulations to implement any of the PPACA's changes to the Medicaid rebate program, although regulations have been proposed to implement the Medicaid rebate provisions of the enacted statutory changes. We cannot assure you that there will not be additional increases in rebates or other costs and charges associated with participating in the Medicaid rebate program. Regulations continue to be issued and coverage expanded by various governmental agencies relating to these rebate programs, increasing the cost and complexity of compliance.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B ceiling price for the manufacturer's covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. To the extent the PPACA, as discussed above, changes the statutory and regulatory definitions of average manufacturer price and the Medicaid rebate amount, these changes also will affect our 340B ceiling price calculations.

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 PPACA 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 PPACA. Except for children's hospitals, the PPACA exempts orphan drugs—those designated under section 526 of the Federal Food Drug and Cosmetic Act—from the ceiling price requirements for these newly-eligible entities.

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 the CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for prior quarters was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed 12 quarters from the quarter in which the data originally were due. Such restatements and recalculations serve to increase our costs for complying with the laws and regulations governing the Medicaid rebate program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the price that we are required to charge certain safety-net providers under the Public Health Service 340B drug discount program.

Table of Contents

In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted false average manufacturer 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 and best price data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the submission is late beyond the due date. In the event that the 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, the CMS and the Office of the Inspector General indicated that they intend more aggressively to pursue companies who fail to report this 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. The CMS recently published information stating that many companies' monthly and quarterly submissions are incomplete or incorrect. We cannot assure you that our submissions will not be found by the CMS to be incomplete or incorrect.

The PPACA also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the program and to update the agreement that manufacturers must sign to participate in the program to obligate manufacturers to sell to covered entities if they sell to any other purchaser and to report to the government the ceiling prices for its drugs. In addition, Congress is currently considering legislation that, if passed, would further expand the 340B program to require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting by certain covered entity hospitals, where those drugs are used for the covered entity's uninsured inpatients.

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 foreign markets, our ability to commercialize our products successfully and to attract strategic partners for our products depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because Luvox CR, FazaClo LD and FazaClo HD each compete in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to effectively commercialize our products.

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. For example, a final rule published by the U.S. Department of Defense, or DoD, in March 2009 (and reissued in October 2010), implementing the terms of Section 703 of the National Defense Authorization Act for Fiscal Year 2008, established a program under which the DoD expects rebates from pharmaceutical manufacturers on all prescriptions of covered drugs (including innovator drugs and biologics) filled under the TRICARE retail pharmacy program from January 28, 2008 forward, unless the DoD agrees to a waiver or compromise of amounts due. Additionally, under the final rule, to remain eligible for inclusion on the DoD Uniform Formulary, a pharmaceutical manufacturer must enter into a pricing agreement under which it agrees to pay rebates to the DoD on TRICARE retail pharmacy utilization on a prospective basis. These rebates are meant to enable the DoD to access pricing that is either close to or equal to Federal Ceiling Prices, as defined under the Veterans Health Care Act of 1992. Pursuant to the final rule, Jazz Pharmaceuticals, Inc. and Azur Pharma entered into separate pricing agreements with the DoD in July 2009 and June 2009, respectively. These legislative and regulatory changes, including our DoD pricing agreements, 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 rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. 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.

Table of Contents

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products entail significant risk of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could result in exacerbation of a patient's condition, serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Xyrem, FazaClo, Luvox CR, Prialta, and Elestrin have boxed warnings in their labels.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class. 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 when a company receives a warning letter. 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. Partly as a result of product liability lawsuits related to pharmaceutical products, product liability and other types of insurance have become more difficult and costly for pharmaceutical companies to obtain. 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.

Risks Relating to Our Financial Condition

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.

To grow our business over the longer-term, we will need to commit substantial 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 will also need to continue to invest in our commercial operations. Our future capital requirements will depend on many factors, including many of those discussed above, such as:

the revenues from our commercial products and the costs of our commercial operations;

the extent of generic competition for our products;

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;

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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 activities and third-party claims; and

changes in laws and regulations, including, for example, healthcare reform legislation.

One of our corporate goals is to continue to expand our business through the licensing, acquisition and/or development of additional products and product candidates. We cannot assure you that our funds will be sufficient to fund these activities if opportunities arise, and 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 addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, including in connection with the proposed EUSA Acquisition, 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 successfully maintain our low tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.

We are incorporated in Ireland and maintain subsidiaries in the United States 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 a substantially similar structure and arrangements. Taxing authorities, such as the U.S. Internal Revenue Service, or the

Table of Contents

IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. The IRS may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

It is possible that the IRS could disagree with the position that the ownership test is satisfied and assert that Section 7874 of the Code applies to treat us as a U.S. corporation following the Azur Merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. Moreover, 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 likely will limit 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 taxable transactions following the Azur Merger for a period of time following the Azur Merger.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, it is currently expected that this limitation should apply to us. As a result, it is not currently expected that Jazz Pharmaceuticals, Inc. or its U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions following the Azur Merger. 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.

Jazz Pharmaceuticals, Inc. and its 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 limited if they do not generate taxable income in a timely manner or if an ownership change pursuant to Section 382 of the Code is triggered.

Jazz Pharmaceuticals, Inc. and its U.S. affiliates have a significant amount of NOLs. Their ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon their generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, Jazz Pharmaceuticals, Inc. and its U.S. affiliates will generate sufficient taxable income to use all of their NOLs. In addition, realization of their NOLs to offset potential future taxable income and related income taxes that would otherwise be due could be restricted by annual limitations on use of NOLs triggered by an ownership change under Section 382 of the Code and similar state provisions. In general, an ownership change will occur if, during a three-year rolling period,

there is a change of 50% or more in the percentage ownership of

Table of Contents

a company by 5% shareholders (and certain persons treated as 5% shareholders), as defined in the Code and Treasury Regulations. Section 382 of the Code is an extremely complex provision with respect to which there are many uncertainties. We have not requested a ruling from the IRS to confirm that Jazz Pharmaceuticals, Inc. and its U.S. affiliates have not experienced an ownership change for the purposes of Section 382 of the Code, and, therefore, we have not established whether the IRS agrees with our analysis regarding the application of Section 382 of the Code.

*If goodwill or other intangible assets that we recorded in connection with Azur Merger become impaired, we could have to take significant charges against earnings.**

In connection with the accounting for the Azur Merger, we recorded a significant amount of goodwill and other intangible assets. Under U.S. GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets has been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

As a result of the Azur Merger, we have and will continue to incur additional direct and indirect costs.

We have and will continue to incur additional costs and expenses in connection with and as a result of the Azur Merger. These costs and expenses include professional fees to comply with Irish corporate and tax laws and financial reporting requirements, costs and expenses incurred in connection with holding a majority of the meetings of our board of directors and certain executive management meetings in Ireland, as well as any additional costs we may incur going forward as a result of our new corporate structure. There can be no assurance that these costs will not exceed the costs historically borne by Jazz Pharmaceuticals, Inc. and Azur Pharma.

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 Jazz Pharmaceuticals, Inc.'s common stock has fluctuated significantly from time to time and increased substantially during the past year, and we cannot predict if the price of our ordinary shares will continue to do so. The risk factors described above relating to our business and products could cause the price of our ordinary shares 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. In addition, our stock price may be dependent upon the valuations and recommendations of the analysts who cover our business, and if our results do not meet our analysts' forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise. In the past, following periods of volatility in the market, 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 integration of the acquired Azur Pharma business and if the EUSA Acquisition is consummated, the acquired EUSA Pharma business, is unsuccessful, takes longer than expected or fails to achieve financial benefits to the extent anticipated by financial analysts or investors, or the effect of the business combination on the financial results of our combined company is otherwise 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 shares of our ordinary shares in the public market or the perception that these sales might occur, could depress the market price of our ordinary shares, and could impair our ability to raise capital through the sale of additional equity securities. As of April 30, 2012, we had 56,732,899 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.

As of April 30, 2012, the holders of up to approximately 8,000,000 ordinary shares, based on shares outstanding as of that date, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, or the Securities Act, under an amended and restated investor rights agreement that Jazz Pharmaceuticals, Inc. entered into with these holders in June 2007, which we assumed

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

at the closing of the Azur Merger. Certain of our executive officers are entitled to rights under the amended and restated investor rights agreement with respect to registration of the ordinary shares acquired on exercise of their stock options. If such holders, 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. If in the future we file a registration statement and include shares held by

Table of Contents

these holders pursuant to the exercise of their registration rights or otherwise, these sales may impair our ability to raise capital. In addition, we have filed a registration statement on Form S-8 under the Securities Act to register our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

Pursuant to the terms of an investor rights agreement dated July 7, 2009 Jazz Pharmaceuticals, Inc. entered into in connection with a private placement completed on July 7, 2009, which agreement we assumed at the closing of the Azur Merger, we agreed to file a registration statement under the Securities Act registering the resale of 1,895,734 ordinary shares held by the investors in the July 2009 private placement, as well as the 947,867 ordinary shares now underlying the warrants held by such investors. In addition, if we propose to register any of our securities under the Securities Act after February 14, 2012, either for our own account or for the account of others, the investors in the private placement are entitled to notice of the registration and are entitled to include, at our expense, their ordinary shares in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration.

Pursuant to the terms of a registration rights agreement dated January 13, 2012 we entered into with the holders of the Azur Pharma s outstanding ordinary shares as of that date, we filed a shelf registration statement with the SEC covering the resale of 12,020,616 ordinary shares held by these holders following the closing of the Azur Merger to permit these holders to immediately resell their ordinary shares.

Our executive officers and directors, together with their respective affiliates, own a significant percentage of our shares and may be able to exercise significant influence over matters subject to shareholder approval.*

As of April 30, 2012, our executive officers and directors, together with the shareholders with which our executive officers and directors are affiliated or associated, beneficially owned approximately 29% of our ordinary shares. Accordingly, our executive officers and directors, together with their respective affiliates or associates, may be able to significantly influence matters subject to shareholder approval and will continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our ordinary shares, and may prevent attempts by our shareholders to replace or remove our board of directors or management.

Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.

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

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

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

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

permit our board of directors to issue one or more series of preferred shares with rights and preferences designated by our board;

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

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; and

require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally in the election of directors for shareholders to amend or repeal our articles of association.

Table of Contents

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.

We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs. Even if we propose to pay dividends in the future, we may be unable to do so under Irish law. Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, distributable reserves. 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 and other factors our board of directors deems relevant. Holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future.

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

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

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

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the United States, European Union member states (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.

Item 5. Other Information

2012 Annual General Meeting of Shareholders

Our 2012 annual general meeting of shareholders, or the Annual Meeting, will be held on July 27, 2012 in Dublin, Ireland. Shareholders of record as of the close of business on May 25, 2012 shall be entitled to notice of and to vote at the Annual Meeting. This announcement constitutes public announcement of the date of the Annual Meeting for purposes of Article 98 of our articles of association. In accordance with Article 98 of our articles of association, for your proposal to be considered for inclusion in the proxy materials for our Annual Meeting, your proposal must be submitted in writing to our company secretary at 45 Fitzwilliam Square, Dublin 2, Ireland within a reasonable time prior to the time we begin to print and mail our proxy materials, and in any event no later than May 18, 2012, being the 10th day following the first public announcement of the date for our Annual Meeting.

Dublin Lease

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-Q

On May 8, 2012, we entered into a Lease with John Ronan and Castle Cove Property Development Limited for our new headquarters in Dublin, Ireland, which is referred to in this report as the Dublin Lease. Under the Dublin Lease, we will occupy approximately 12,000 square feet of office space. The term of the Dublin Lease is 10 years from and including May 8, 2012. Under the terms of the Dublin Lease, the initial yearly rent will be approximately 369,000, to be paid quarterly in advance on the first day of each quarter, and the first payment of rent will be in respect of the quarter commencing February 8, 2013. The initial yearly rent is subject to review on the fifth anniversary of the commencement of the Dublin Lease term. We have an option to terminate the Dublin Lease on May 8, 2017, with no less than six months prior written notice and the payment of a termination fee in the amount of approximately 184,500.

Table of Contents

The foregoing description of the material terms of the Dublin Lease does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the Dublin Lease that will be filed as an exhibit to our quarterly report on Form 10-Q for the period ending June 30, 2012.

Table of Contents

Item 6. Exhibits.

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 21, 2011, by and among Azur Pharma Public Limited Company (formerly Azur Limited Company), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan as Indemnitors Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s quarterly 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 quarterly report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A*	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B*	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C*	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D*	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Series BB Preferred Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

Table of Contents

Exhibit Number	Description of Document
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.4 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.5	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 Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.6 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.7A*	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.7B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.8	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1	Form of Indemnification Agreement between Jazz Pharmaceuticals plc and its officers and directors (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.2	Escrow Agreement made and entered into as of January 18, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., Seamus Mulligan, solely in his capacity as Indemnitors Representative, and Deutsche Bank National Trust Association, as escrow agent (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.3+	Separation Agreement, dated January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Carol Gamble (incorporated herein by reference to Exhibit 10.27 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.4	Second Amendment of Lease, dated February 25, 2012, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.31 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.5+	Non-Employee Director Compensation Arrangements (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, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

Table of Contents

Exhibit Number	Description of Document
10.6A+	Jazz Pharmaceuticals plc Cash Bonus Plan (incorporated herein by reference to Exhibit 10.33 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.6B+	Jazz Pharmaceuticals plc Cash Bonus Plan (incorporated herein by reference to Exhibit 10.33 in Jazz Pharmaceuticals plc's annual report on Form 10-K, as amended (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.7A+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.34 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.7B+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.34 in Jazz Pharmaceuticals plc's annual report on Form 10-K, as amended (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.8A+*	Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.21 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.8B+*	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.22 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.8C+*	Form of Letter, amending outstanding options granted under Jazz Pharmaceuticals, Inc.'s 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.60 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
10.9+	Jazz Pharmaceuticals plc 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.5 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.10A+*	Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.23 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.10B+*	Form of Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.24 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007).
10.10C+*	Form of Stock Award Grant Notice and Stock Award Agreement under Jazz Pharmaceuticals, Inc.'s 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.73 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008).
10.11A+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.3 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.11B+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.3B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

Table of Contents

Exhibit Number	Description of Document
10.11C+	Form of Option Grant Notice and Form of Stock Option Agreement under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.35 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.11D+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.36 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.11E+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.37 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.11F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.38 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12A+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.1 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.12B+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.39B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12C+	Form of Option Grant Notice and Form of Stock Option Agreement under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.40 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12D+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.41 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12E+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.42 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.43 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.13A+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.13B+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan Offering Document, as amended and restated (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).

Table of Contents

Exhibit Number	Description of Document
10.14A+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 99.2 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.14B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document (incorporated herein by reference to Exhibit 10.19 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.14C+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Sub-Plan Governing Purchase Rights to Participants in the Republic of Ireland.
10.14D+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document (Designated U.S. Related Corporations).
10.14E+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document (Jazz Pharmaceuticals plc and Designated Non-U.S. Related Corporations).
10.15A+*	Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.25 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.15B+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.26 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.15C+*	Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.15D+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.16+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 99.4 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.17+*	Jazz Pharmaceuticals, Inc. Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.18+	Jazz Pharmaceuticals plc Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 99.6 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.19+	Offer Letter from Jazz Pharmaceuticals, Inc. to Suzanne Sawochka Hooper.
10.20+	Amendment to Employment Agreement by and between Jazz Pharmaceuticals plc and Seamus Mulligan.
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 an instrument, agreement or compensatory arrangement or plan assumed by Jazz Pharmaceuticals plc in the merger and no longer binding on Jazz Pharmaceuticals, Inc.

+ Indicates management contract or compensatory plan.

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

++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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.

Dated: May 8, 2012

Jazz Pharmaceuticals Public Limited Company

(Registrant)

/s/ Bruce C. Cozadd

Bruce C. Cozadd

Chairman and Chief Executive Officer and Director

(Principal Executive Officer)

/s/ Kathryn E. Falberg

Kathryn E. Falberg

Executive Vice President and Chief Financial Officer

(Principal Financial Officer)

/s/ Karen J. Wilson

Karen J. Wilson

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 21, 2011, by and among Azur Pharma Public Limited Company (formerly Azur Limited Company), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan as Indemnitors Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s quarterly 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 quarterly report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A*	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B*	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C*	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D*	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Series BB Preferred Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

Table of Contents

Exhibit Number	Description of Document
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.4 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.5	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 Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.6 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.7A*	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.7B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.8	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1	Form of Indemnification Agreement between Jazz Pharmaceuticals plc and its officers and directors (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.2	Escrow Agreement made and entered into as of January 18, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., Seamus Mulligan, solely in his capacity as Indemnitors Representative, and Deutsche Bank National Trust Association, as escrow agent (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.3+	Separation Agreement, dated January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Carol Gamble (incorporated herein by reference to Exhibit 10.27 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.4	Second Amendment of Lease, dated February 25, 2012, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.31 in Jazz Pharmaceuticals plc s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.5+	Non-Employee Director Compensation Arrangements (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, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

Table of Contents

Exhibit Number	Description of Document
10.6A+	Jazz Pharmaceuticals plc Cash Bonus Plan (incorporated herein by reference to Exhibit 10.33 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.6B+	Jazz Pharmaceuticals plc Cash Bonus Plan (incorporated herein by reference to Exhibit 10.33 in Jazz Pharmaceuticals plc's annual report on Form 10-K, as amended (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.7A+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.34 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.7B+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.34 in Jazz Pharmaceuticals plc's annual report on Form 10-K, as amended (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.8A+*	Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.21 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.8B+*	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.22 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.8C+*	Form of Letter, amending outstanding options granted under Jazz Pharmaceuticals, Inc.'s 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.60 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
10.9+	Jazz Pharmaceuticals plc 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.5 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.10A+*	Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.23 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.10B+*	Form of Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.24 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007).
10.10C+*	Form of Stock Award Grant Notice and Stock Award Agreement under Jazz Pharmaceuticals, Inc.'s 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.73 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008).
10.11A+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.3 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.11B+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.3B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

Table of Contents

Exhibit Number	Description of Document
10.11C+	Form of Option Grant Notice and Form of Stock Option Agreement under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.35 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.11D+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.36 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.11E+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.37 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.11F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.38 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12A+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.1 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.12B+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.39B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12C+	Form of Option Grant Notice and Form of Stock Option Agreement under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.40 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12D+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.41 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12E+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.42 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.12F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.43 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.13A+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.13B+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan Offering Document, as amended and restated (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).

Table of Contents

Exhibit Number	Description of Document
10.14A+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 99.2 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.14B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document (incorporated herein by reference to Exhibit 10.19 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.14C+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Sub-Plan Governing Purchase Rights to Participants in the Republic of Ireland.
10.14D+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document (Designated U.S. Related Corporations).
10.14E+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document (Jazz Pharmaceuticals plc and Designated Non-U.S. Related Corporations).
10.15A+*	Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.25 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.15B+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.26 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.15C+*	Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.15D+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.16+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 99.4 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.17+*	Jazz Pharmaceuticals, Inc. Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.18+	Jazz Pharmaceuticals plc Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 99.6 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.19+	Offer Letter from Jazz Pharmaceuticals, Inc. to Suzanne Sawochka Hooper.
10.20+	Amendment to Employment Agreement by and between Jazz Pharmaceuticals plc and Seamus Mulligan.
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 an instrument, agreement or compensatory arrangement or plan assumed by Jazz Pharmaceuticals plc in the merger and no longer binding on Jazz Pharmaceuticals, Inc.

+ Indicates management contract or compensatory plan.

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

++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.