Jazz Pharmaceuticals plc
Form 10-Q
August 07, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

Ireland	98-1032470
(State or other jurisdiction of incorporation or organization)	(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 x 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 x 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 x	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 x

As of July 31, 2012, 57,536,632 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

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JAZZ PHARMACEUTICALS PLC

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2012

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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), Prialt® (ziconotide) intrathecal infusion, Elestrin® (estradiol gel), Urelle® (urinary antiseptic), Gesticare® (prenatal vitamin), Natelle® (prenatal vitamin), Gastrocrom® (cromolyn sodium oral concentrate), Niravam® (alprazolam), Parcopa® (carbidopa/levodopa), AVC Cream (sulfanilamide), Erwinaze® (asparaginase *Erwinia chrysanthemi*), Erwinase®, Asparec® (mPEG-r-crisantaspase), Leukotac (inolimomab), ProstaScint® (capromab pendetide) and Quadramet® (Samarium Sm 153 Lexidronam Injection). This report also includes trademarks, service marks, and trade names of other companies.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

JAZZ PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	June 30, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 154,543	$ 82,076
Marketable securities	-	75,822
Accounts receivable, net of allowances	78,130	34,374
Inventories	48,355	3,909
Prepaid expenses	5,906	1,690
Other current assets	13,508	1,260
Total current assets	300,442	199,131
Property and equipment, net	4,631	1,557
Intangible assets, net	927,409	14,585
Goodwill	446,236	38,213
Other long-term assets	19,226	87
Total assets	$ 1,697,944	$ 253,573
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 34,505	$ 5,129
Accrued liabilities	125,080	34,783
Current portion of long-term debt	23,750	-
Purchased product rights liability	6,972	4,500
Liability under government settlement	-	7,320
Deferred revenue	2,011	1,138
Total current liabilities	192,318	52,870
Deferred revenue, non-current	7,356	7,915
Long-term debt, less current portion	444,190	-
Contingent consideration	35,300	-
Deferred tax liability	185,706	-
Other non-current liabilities	1,615	-
Commitments and contingencies (Note 8)		
Shareholders equity:		
Ordinary shares	6	4
Non-voting euro deferred shares	55	-
Capital redemption reserve	471	-
Additional paid-in capital	1,126,371	542,697

Accumulated other comprehensive loss	(388)	(31)
Accumulated deficit	(295,056)	(349,882)
Total shareholders equity	831,459	192,788
Total liabilities and shareholders equity	$ 1,697,944	$ 253,573

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

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JAZZ PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues:				
Product sales, net	$ 128,310	$ 63,464	$ 235,646	$ 113,367
Royalties and contract revenues	1,229	1,103	2,307	2,081
Total revenues	129,539	64,567	237,953	115,448
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	15,370	3,370	26,128	6,179
Selling, general and administrative	60,638	22,094	107,637	42,005
Research and development	2,321	3,382	6,280	7,077
Intangible asset amortization	15,751	1,862	29,264	3,724
Total operating expenses	94,080	30,708	169,309	58,985
Income from operations	35,459	33,859	68,644	56,463
Interest expense, net	(1,481)	(657)	(1,450)	(1,434)
Other expense	(240)	-	(258)	-
Income before provision for income tax expense	33,738	33,202	66,936	55,029
Provision for income tax expense	6,593	-	12,110	-
Net income	$ 27,145	$ 33,202	$ 54,826	$ 55,029
Net income per ordinary share:				
Basic	$ 0.48	$ 0.81	$ 0.99	$ 1.35
Diluted	$ 0.45	$ 0.71	$ 0.92	$ 1.19
Weighted-average ordinary shares used in computing net income per share:				
Basic	56,952	41,209	55,437	40,788
Diluted	60,554	46,601	59,319	46,238

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

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JAZZ PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net income	$ 27,145	$ 33,202	$ 54,826	$ 55,029
Other comprehensive income (loss):				
Foreign currency translation adjustments	(388)	-	(388)	-
Available-for-sale securities:				
Net unrealized (loss) gain on available-for-sale securities, net of income taxes	(20)	-	8	-
Reclassification adjustments for gains included in earnings, net of income taxes	17	-	23	-
Other comprehensive loss	(391)	-	(357)	-
Total comprehensive income	$ 26,754	$ 33,202	$ 54,469	$ 55,029

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

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JAZZ PHARMACEUTICALS PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2012	**2011**
Operating activities		
Net income	$ 54,826	$ 55,029
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	415	189
Amortization of intangible assets	29,264	3,724
Loss on disposal of property and equipment	139	15
Share-based compensation expense	8,539	6,563
Excess tax benefit from share-based compensation	(6,238)	-
Purchase accounting inventory fair value step-up	6,380	-
Change in fair value of contingent consideration	200	-
Other non-cash transactions	309	394
Changes in assets and liabilities:		
Accounts receivable	(7,427)	(2,918)
Inventories	806	352
Prepaid expenses and other current assets	(5,390)	(1,820)
Other assets and liabilities	(1,191)	51
Accounts payable	11,363	1,616
Accrued liabilities	16,339	3,141
Deferred revenue	250	(476)
Liability under government settlement	(7,320)	(3,976)
Net cash provided by operating activities	101,264	61,884
Investing activities		
Acquisitions, net of cash acquired	(542,531)	-
Purchases of marketable securities	(37,443)	-
Proceeds from sale of marketable securities	81,246	-
Proceeds from maturities of marketable securities	31,988	-
Purchases of property and equipment	(2,494)	(161)
Purchase of product rights	(9,500)	(2,250)
Decrease in restricted cash	-	400
Net cash used in investing activities	(478,734)	(2,011)
Financing activities		
Net proceeds from issuance of debt	450,916	-
Proceeds from employee stock purchases, exercise of stock options and warrants	18,573	9,411
Payment of employee withholding taxes upon exercise of share-based awards	(25,299)	-
Excess tax benefit from share-based compensation	6,238	-
Repayment of long-term debt	-	(8,332)
Net repayments under revolving credit facility	-	(3,350)

Net cash provided by (used in) financing activities	450,428	(2,271)
Effect of exchange rates on cash and cash equivalents	(491)	-
Net increase in cash and cash equivalents	72,467	57,602
Cash and cash equivalents, at beginning of period	82,076	44,794
Cash and cash equivalents, at end of period	$ 154,543	$ 102,396

See Note 2 for supplemental disclosures of non-cash investing activities related to acquisitions.

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

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JAZZ PHARMACEUTICALS PLC

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. The Company and Summary of Significant Accounting Policies

Jazz Pharmaceuticals Public Limited Company, or Jazz Pharmaceuticals plc, a public limited company formed under the laws of Ireland, is a specialty biopharmaceutical company dedicated to improving patients lives through the identification, development and commercialization of pharmaceutical products that address 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 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. only are included in the comparative prior periods. For additional information regarding the Azur Merger see Note 2.

On June 12, 2012, we completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, which we refer to as the EUSA Acquisition. As part of the EUSA Acquisition, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc. For additional information regarding the EUSA Acquisition 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., except that all such references prior the effective time of the Azur Merger on January 18, 2012 are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. 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. The disclosures in this report relating to the pre-Azur 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 Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the annual consolidated financial statements and accompanying notes of Jazz Pharmaceuticals, 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 and EUSA Pharma businesses, along with the estimated fair values of the assets acquired and liabilities assumed in each transaction, have been included in our condensed consolidated financial statements since the effective dates of the Azur Merger and the EUSA Acquisition, respectively.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements 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 and six months ended June 30, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012, 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

Our financial results are significantly influenced by sales of Xyrem, and maintaining and increasing sales of Xyrem is subject to a number of risks and uncertainties, including the potential introduction of generic competition, and changed or increased regulatory restrictions. During 2010, an abbreviated new drug application, or ANDA, was filed with the United States Food and Drug Administration, or FDA, by a third party seeking to market a generic form of Xyrem. We have sued that third party for infringement

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of our patents, and the litigation is ongoing. If an ANDA for Xyrem is approved and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. In addition, we are continuing our ongoing work with the FDA on both changes to our Xyrem product label and our risk management and distribution system for Xyrem. The FDA may take, or require us to take, actions that could make it more difficult or expensive for us to distribute Xyrem, make competition easier and/or negatively affect the commercial success of Xyrem.

In addition to risks related specifically to Xyrem, we are subject to risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including: the need to successfully integrate and grow our combined business after the EUSA Acquisition and Azur Merger; the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging environment; the ongoing regulation and oversight by the FDA, the U.S. Drug Enforcement Administration, and similar foreign regulatory agencies; the challenges of achieving and maintaining commercial success of our products; the dependence on key customers and sole source suppliers; the protection of intellectual property rights; and the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval.

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 hospitals, pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company, primarily in the United States, and to other international distributors. Customer creditworthiness is monitored and collateral is not required. We monitor deteriorating economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of June 30, 2012, five customers accounted for 71% of gross accounts receivable and one customer, Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, accounted for 46% of gross accounts receivable. As of December 31, 2011, Express Scripts accounted for 79% of gross accounts receivable.

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

Foreign Currency

Our functional and reporting currency is the U.S. dollar. The assets and liabilities of our subsidiaries that have a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date with the results of operations of subsidiaries translated at the average exchange rate for the reporting period. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders equity.

Transactions in foreign currencies are translated into the functional currency of the relevant subsidiary at the rate of exchange prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the relevant functional currency at exchange rates

prevailing at the balance sheet date. Gains and losses as a result of translation adjustments are recorded within Other expense in the accompanying condensed consolidated statements of income.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Numerator:				
Net income	$ 27,145	$ 33,202	$ 54,826	$ 55,029
Denominator:				
Weighted-average ordinary shares - basic	56,952	41,209	55,437	40,788
Dilutive effect of employee equity incentive and purchase plans	1,440	2,821	1,633	2,844
Dilutive effect of warrants	2,162	2,571	2,249	2,606
Weighted-average ordinary shares - diluted	60,554	46,601	59,319	46,238
Net income per ordinary share:				
Basic	$ 0.48	$ 0.81	$ 0.99	$ 1.35
Diluted	$ 0.45	$ 0.71	$ 0.92	$ 1.19

Potentially dilutive ordinary shares from employee equity plans and warrants are determined by applying the treasury stock method to the assumed exercise of warrants and share options, the assumed vesting of outstanding restricted stock units, or RSUs, and the assumed issuance of ordinary shares under our employee stock purchase plan. The following table represents the weighted-average ordinary shares that were excluded from the computation of diluted net income per ordinary share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Options to purchase ordinary shares and RSUs	1,522	1,372	1,079	1,016

All references to ordinary shares in the discussion and table above refer to Jazz Pharmaceuticals, Inc. s common stock with respect to the comparative prior year periods and to Jazz Pharmaceuticals plc s ordinary shares with respect to the current year periods. Our earnings per share in the comparative prior year periods 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 became the right to receive one ordinary share upon the consummation of the Azur Merger. This one-for-one conversion ratio is referred to in this report as the Azur exchange ratio.

2. Business Combinations

Merger with Azur Pharma

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. We believe the Azur Merger 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.

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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 as a reverse acquisition under 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 estimated fair values as of the date of the Azur Merger and added to those of Jazz Pharmaceuticals, Inc., including an amount for goodwill representing the difference between the acquisition consideration and the estimated fair value of the identifiable net assets. The results of operations of the acquired Azur Pharma business and the estimated fair values of the assets acquired and liabilities assumed have been included in our condensed consolidated financial statements since the date of the Azur Merger.

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.

During the three and six months ended June 30, 2012, we incurred $0 and $2.4 million, respectively, 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 and six months ended June 30, 2012, the contribution of the acquired Azur Pharma business to our total revenues was $20.8 million and $45.2 million, respectively. The portion of total expenses and net income associated with the acquired Azur Pharma business was not separately identifiable due to the integration with our operations.

The preliminary 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 estimated 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 Azur Merger has been prepared on a preliminary basis and we will finalize these amounts as we obtain the information necessary to complete the measurement process. Any changes resulting from facts and circumstances that existed as of the date of the Azur Merger may result in retrospective adjustments to the amounts recorded. These changes could be significant. We expect to finalize these amounts no later than one year from the date of the Azur Merger. Through June 30, 2012, we

have not recorded any measurement period adjustments related to the Azur Merger.

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The intangible assets as of 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. 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.

Acquisition of EUSA Pharma

On June 12, 2012, pursuant to an Agreement and Plan of Merger dated as of April 26, 2012, or the EUSA Acquisition Agreement, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc. The EUSA Acquisition has contributed to our expanded portfolio of specialty pharmaceutical products and product candidates, including in particular, Erwinaze, as well as given us a strengthened management team and an enhanced commercial platform, adding EUSA Pharma s specialty commercial infrastructure in the United States and Europe and its international distribution network to our existing U.S. specialty product platform.

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

At the closing of the EUSA Acquisition, we made an upfront cash payment of $678.4 million. Under the EUSA Acquisition Agreement, we also agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze achieves U.S. net sales of $124.5 million in 2013. $50.0 million of the amount paid at closing was deposited in an escrow account, to be held for 12 months as partial security for our indemnification rights under the EUSA Acquisition Agreement. $25.0 million of the potential 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. The initial estimate of fair value of the contingent consideration was $35.1 million, which was recorded as a non-current liability and included in the total purchase price as summarized below:

Base payment	$ 650,000
Cash acquired	54,117
Working capital and other adjustments	(25,719)
Upfront payment in accordance with agreement	678,398
Estimated fair value of contingent consideration	35,100
Total purchase price	$ 713,498

During the three months and six months ended June 30, 2012, we incurred $8.9 million and $10.1 million, respectively, in transaction costs related to the EUSA Acquisition, which primarily consisted of banking, legal, accounting and valuation-related expenses. These expenses were recorded in selling, general and administrative expense in the accompanying condensed consolidated statements of income.

During both the three and six months ended June 30, 2012 periods, our statements of income included revenues of $8.0 million and a net loss of $1.6 million from the acquired EUSA Pharma business, as measured from the date of the EUSA Acquisition.

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

Cash and cash equivalents	$ 54,117
Accounts receivable (1)	23,354
Inventories	36,360
Prepaid assets	6,212
Property and equipment	764
Intangible assets	616,970
Goodwill	206,452
Other assets	436
Accounts payable and accrued liabilities	(44,502)
Deferred tax liability	(186,591)
Other liabilities	(74)
Total purchase price	$ 713,498

(1) The estimated fair value of trade receivables acquired was $23.4 million. The gross contractual amount of trade receivables was $25.1 million and was recorded net of allowances for wholesaler chargebacks related to government rebate programs, cash discounts for prompt payment and doubtful accounts. We expect that $1.7 million of the gross contractual amount of trade receivables will be uncollectible.

Categories acquired in the EUSA Acquisition 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 EUSA Acquisition has been prepared on a preliminary basis and we will finalize these amounts as we obtain the information necessary to complete the measurement process. Any changes resulting from facts and circumstances that existed as of the date of the EUSA Acquisition may result in retrospective adjustments to the amounts recorded. These changes could be significant. We expect to finalize these amounts no later than one year from the date of the EUSA Acquisition. Through June 30, 2012, we have not recorded any measurement period adjustments related to the EUSA Acquisition since the date of acquisition.

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

Acquired developed technologies	$ 584,470
In-process research and development	32,500
Total intangible assets	$ 616,970

Intangible assets related to acquired developed technologies reflect the estimated fair value of the rights we acquired to those products in the EUSA Acquisition. 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 fourteen 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. 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 and a platform for developing 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.

Pro forma financial information (unaudited)

The following unaudited supplemental pro forma information presents the combined historical results of operations of Jazz Pharmaceuticals, Inc., Azur Pharma and EUSA Pharma for the three and six months ended June 30, 2012 and 2011, respectively, as if the Azur Merger and the EUSA Acquisition had each been completed on January 1, 2011. The pro forma financial information includes adjustments to reflect one time charges and amortization of fair value adjustments in the appropriate pro forma periods as though the companies were combined as of the beginning of 2011. These adjustments include:

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An increase in amortization expense of $4.3 million and $10.2 million for the three and six months ended June 30, 2012, respectively, and $18.2 million and $36.6 million, respectively, for the three and six months ended June 30, 2011 related to the fair value of acquired identifiable intangible assets.

The exclusion of transaction-related expenses of $17.5 million and $33.3 million for the three and six months ended June 30, 2012, respectively, and $0.3 million for both the three and six months ended June 30, 2011.

A decrease in interest expense of $3.9 million and $1.1 million for the three and six months ended June 30, 2012, respectively, and an increase of $3.2 million and $7.3 million for the three and six months ended June 30, 2011, respectively, incurred on additional borrowings made to fund the acquisition of EUSA, as if the borrowings had occurred on January 1, 2011, offset by the elimination of actual interest expense incurred by EUSA during the periods presented.

The exclusion of other non-recurring expenses of $37.1 million and $47.0 million for the three and six months ended June 30,2012, respectively, and the inclusion of $5.7 million and $14.7 million for the three and six months ended June 30, 2011, primarily related to the fair value step-up to acquired inventory, share-based compensation incurred from the acceleration of stock option vesting upon closing of the Azur Merger and the EUSA Acquisition, a share-based liability granted to certain former Azur Pharma shareholders and integration-related expenses.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues	$ 166,289	$ 109,490	$ 320,848	$ 202,515
Net income (loss)	$ 40,074	$ 1,137	$ 75,694	$ (11,071)
Net income (loss) per ordinary share - basic	$ 0.70	$ 0.02	$ 1.34	$ (0.21)
Net income (loss) per ordinary share - diluted	$ 0.66	$ 0.02	$ 1.25	$ (0.21)

3. Inventories

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

	June 30, 2012	December 31, 2011
Raw materials	$ 4,102	$ 1,937
Work in process	6,078	524
Finished goods	38,175	1,448
Total inventories	$ 48,355	$ 3,909

As of June 30, 2012, inventories included $18.4 million related to purchase accounting inventory fair value step-up.

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4. Fair Value

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

	June 30, 2012					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	$ 154,242	$ -	$ -	$ 154,242	$ 154,242	$ -
Money market funds	201	-	-	201	201	-
Certificates of deposit	100	-	-	100	100	-
Totals	$ 154,543	$ -	$ -	$ 154,543	$ 154,543	$ -

	December 31, 2011					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Marketable Securities
Cash	$ 33,307	$ -	$ -	$ 33,307	$ 33,307	$ -
Money market funds	48,518	-	-	48,518	48,518	-
Certificates of deposit	7,300	-	(6)	7,294	-	7,294
Corporate debt securities	50,371	7	(34)	50,344	-	50,344
Obligations of U.S. government agencies	18,433	3	(1)	18,435	251	18,184
Totals	$ 157,929	$ 10	$ (41)	$ 157,898	$ 82,076	$ 75,822

Collectively, cash and cash equivalents and marketable securities are considered available-for-sale. We use the specific-identification method for calculating realized gains and losses on securities sold and include them in interest expense, net in the condensed consolidated statements of income. Proceeds from sales of available-for-sale securities during the six months ended June 30, 2012 were $81.2 million and were used to partially fund the EUSA Acquisition. Gross realized gains and losses during the three and six months ended June 30, 2012 were insignificant. All available-for-sale securities held as of June 30, 2012 were cash and cash equivalents.

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

	June 30, 2012			December 31, 2011		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:						
Available-for-sale securities						
Money market funds	$ 201	$ -	$ 201	$ 48,518	$ -	$ 48,518
Certificates of deposit	100	-	100	-	7,294	7,294
Corporate debt securities	-	-	-	-	50,344	50,344
	-	-	-	-	18,435	18,435

Obligations of U.S. government agencies						
Total available-for-sale securities at fair value	$ 301	$ -	$ 301	$ 48,518	$ 76,073	$ 124,591
Liabilities:						
Contingent consideration	$ -	$ 35,300	$ 35,300	$ -	$ -	$ -

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

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As of December 31, 2011, our available-for-sale securities included corporate debt securities, obligations of U.S. government agencies, money market funds and certificates of deposit which were measured at fair value using Level 2 inputs. We reviewed 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. As of December 31, 2011, the aggregate fair value of available-for-sale securities which had unrealized losses was $43.6 million.

As part of the EUSA Acquisition, we agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze achieves U.S. net sales of $124.5 million in 2013. The fair value measurement of this contingent consideration obligation is determined using unobservable (Level 3) inputs. These inputs include the probability of 2013 U.S. net sales of Erwinaze exceeding the $124.5 million threshold and the discount rate. A significant increase or decrease in the estimated probability of exceeding the milestone threshold would result in a significantly higher or lower fair value measurement, respectively. The range of the estimated contingent payment is from zero if 2013 U.S. net sales of Erwinaze are less than $124.5 million to $50.0 million if 2013 U.S. net sales of Erwinaze exceed $124.5 million. The fair value of the contingent consideration payable was estimated to be $35.1 million at June 12, 2012, the date of the EUSA Acquisition, and $35.3 million at June 30, 2012.

As of June 30, 2012, the estimated fair value of our $475.0 million term loan was $477.4 million and the carrying amount was $467.9 million. The fair value was determined using quotes from the administrative agent of our credit facility that are based on bid/ask prices of our term loan (Level 2). For additional information regarding our term loan see Note 7.

5. Certain Balance Sheet Items

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

	June 30, 2012	December 31, 2011
Computer software	$ 4,164	$ 4,010
Computer equipment	2,923	2,046
Furniture and fixtures	871	556
Leasehold improvements	1,058	763
Construction-in-progress	2,461	689
Machinery and equipment	94	76
Subtotal	11,571	8,140
Less accumulated depreciation	(6,940)	(6,583)
Property and equipment, net	$ 4,631	$ 1,557

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Accrued liabilities consisted of the following (in thousands):

	June 30, 2012	December 31, 2011
Employee compensation and benefits	$ 35,947	$ 11,643
Rebates and other sales deductions	31,713	12,378
Sales returns reserve	25,690	4,302
Taxes payable	7,175	-
Professional fees	5,682	4,021
Other	18,873	2,439
Total accrued liabilities	$ 125,080	$ 34,783

6. Goodwill and Intangible Assets

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

	June 30, 2012	December 31, 2011
Goodwill	$ 446,236	$ 38,213

We recorded goodwill of $201.5 million in January 2012 in connection with the Azur Merger and $206.5 million in June 2012 in connection with the EUSA Acquisition. There were no changes to the initial carrying amounts of goodwill during the six months ended June 30, 2012.

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

		June 30, 2012			December 31, 2011		
	Remaining Weighted-Average Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies	12.4	$ 956,946	$ (64,716)	$ 892,230	$ 49,400	$ (35,634)	$ 13,766
Trademarks	2.5	2,600	(1,917)	683	2,600	(1,781)	819
Total finite-lived intangible assets		959,546	(66,633)	892,913	52,000	(37,415)	14,585
Acquired IPR&D assets		34,496	-	34,496	-	-	-
Total intangible assets		$ 994,042	$ (66,633)	$ 927,409	$ 52,000	$ (37,415)	$ 14,585

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Based on finite-lived intangible assets recorded as of June 30, 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)	$ 45,247
2013	87,313
2014	82,140
2015	75,190
2016	69,118
Thereafter	533,905
Total	$ 892,913

7. Long-Term Debt

Term Loan and Revolving Credit Facility

On June 12, 2012, Jazz Pharmaceuticals plc, as guarantor, and Jazz Pharmaceuticals, Inc., as borrower, entered into a $575.0 million credit agreement with Barclays Bank PLC, as administrative agent and certain other lenders. The credit agreement provides for a six-year $475.0 million term loan and a five-year $100.0 million revolving credit facility, which includes a $10.0 million swing line loan sub facility and a $10.0 million letter of credit sub facility. The proceeds from the term loan were used to partially finance the EUSA Acquisition. Borrowings under the term loan bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.25% per annum (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 3.25% per annum (subject to a 2.0% prime rate floor). Borrowings under the revolving credit facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum, or the prime lending rate, plus an applicable margin equal to 3.00% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio.

The obligations of Jazz Pharmaceuticals, Inc. under the credit agreement and any hedging or cash management obligations entered into with a lender are guaranteed by Jazz Pharmaceuticals plc and certain of its subsidiaries and are secured by substantially all of their assets.

We may make prepayments of principal without premium or penalty, except that a 1% premium would apply to a repayment via a repricing of the loan under the term loan effected on or prior to June 12, 2013. We are required to make mandatory prepayments of borrowings under the term loan (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), (3) beginning with the fiscal year ending December 31, 2013, 50% of our excess cash flow as defined in the credit agreement (subject to increase to 75% if our secured leverage ratio exceeds 2.25 to 1.0, or decrease to 25% or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.0 or 0.75 to 1.0, respectively), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the term loan are due quarterly beginning in September 2012 and are equal to 5% of the original principal amount in the first year, 7.5% in the second year, 10% in each of the third and fourth years and 15% in each of the fifth and sixth years, with any remaining balance payable on the final maturity date.

The credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to Jazz Pharmaceuticals plc and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement contains a financial covenant that requires Jazz Pharmaceuticals plc and its restricted subsidiaries to maintain a maximum secured leverage ratio beginning with the quarter ending September 30, 2012.

The $475.0 million principal amount of the term loan was recorded net of an original issue discount of $7.1 million. We incurred $15.0 million of debt issuance costs associated with the term loan which are recorded under the caption Other long-term assets in the accompanying condensed consolidated balance sheets. Unpaid debt issuance costs amounted to $1.6 million at June 30, 2012. As of June 30, 2012, the interest rate on the

term loan was 5.25%. Interest expense associated with the term loan is recorded using the interest method and includes non-cash interest related to the debt discount and debt issuance costs. The effective interest rate on the term loan is 6.7%. The current portion of the carrying amount of the term loan was $23.8 million as of June 30, 2012.

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Financing costs of $3.5 million associated with the revolving credit facility were deferred and are being amortized to interest expense on a straight-line basis over the life of the facility. As of June 30, 2012, we had not borrowed under the revolving credit facility.

8. Commitments and Contingencies

Indemnification

In the normal course of business, we enter into agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. Our exposure under these agreements is unknown because it involves future claims that may be made but have 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 June 30, 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 and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force. Future minimum lease payments under our noncancelable operating leases at June 30, 2012 were as follows (in thousands):

Year Ending December 31,	Lease Payments
2012 (remainder)	$ 2,807
2013	6,668
2014	5,713
2015	4,957
2016	4,158
Thereafter	5,755
Total	$ 30,058

In May 2012, we entered into an operating lease agreement for our new headquarters in Dublin for a term of ten years, we amended and extended the operating lease for our existing Philadelphia office building for a term of four years and we entered into a new operating sublease for additional office space in Palo Alto near our existing office location for a term of five years. As a result of the EUSA Acquisition, we have additional operating leases which are included in the table above.

As of June 30, 2012, we had $45.7 million of noncancelable purchase commitments under agreements with contract manufacturers, $42.5 million of which is due within one year.

Legal Proceedings

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

Xyrem ANDA Matter: 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 ANDA with the United States 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 then listed for Xyrem in the FDA s publication Approved Drug Products with Therapeutic Equivalence Evaluations , or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane s proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane s Paragraph IV Certification in the United States

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District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem in violation of our patents. 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, as well as another patent which is not listed in the Orange Book. Another 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 against Roxane on May 2, 2011 to include this additional patent in response to Roxane s Paragraph IV Certification against it. On April 26, 2012, the District Court held a Markman hearing, a pretrial hearing in which the trial judge construes the claims of a patent, and the discovery phase of the proceeding is ongoing. No trial date has been scheduled. We cannot predict the outcome of this matter.

On May 18, 2012, we submitted a Citizen Petition to the FDA addressing the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem and requesting that the FDA: publish in the Orange Book bioequivalence requirements specifying whether in vitro or in vivo bioequivalence studies, or both, are required for ANDAs referencing Xyrem; not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs; and require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants.

On July 10, 2012, we submitted a second Citizen Petition to the FDA addressing the requirements for submission of any ANDA referencing Xyrem. This petition asks the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, that did not contain a proposed risk management system at the time it was accepted for review, because such ANDA would not have demonstrated, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. This petition further requests that the FDA (i) not accept for review any ANDA referencing Xyrem that does not contain, at the time of its submission, a proposed risk management system sufficient to demonstrate that the new generic drug product has the same labeling and conditions of use as Xyrem; and (ii) determine that if any sponsor, including Roxane, of an ANDA referencing Xyrem that did not contain, at the time it was accepted for review, a proposed risk management system later submits, or resubmits, an ANDA that contains a proposed risk management system sufficient to demonstrate that the new generic drug product would have the same labeling and conditions of use of Xyrem, such ANDA should not be approved for a period of up to thirty months beginning on the date we receive notice of any Paragraph IV certifications contained in such new ANDA, to the extent that we avail ourselves of our right to initiate a patent infringement action based on such notice. We believe that the FDA s acceptance of Roxane s ANDA caused the thirty-month stay under the Hatch-Waxman Act and the related patent litigation between the parties to begin prematurely in a manner contrary to applicable law. We cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, either of our Citizen Petitions, or the effect of any such response or action on the timing of the potential introduction of a generic version of Xyrem or on the ongoing litigation between us and Roxane.

Luvox CR ANDA Matters. 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 will commence on April 15, 2014 or earlier upon the occurrence of certain events.

FazaClo ANDA Matters: Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo

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LD, filed a lawsuit in response to each certification claiming infringement based on such certification in the United States District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, Inc., entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma s rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015 or earlier upon the occurrence of certain events. Teva has exercised its option for supply of an authorized generic product for Fazaclo LD, and we are addressing the FDA requirements to permit a launch of the authorized generic product. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in the suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in California Superior Court in the County of Los Angeles. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma s subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to either a $10.5 million or $25.0 million contingent payment, plus unspecified punitive damages and attorneys fees. On March 14, 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. We submitted a complaint in arbitration alleging that Dr. Cutler s suit had been improperly filed in Los Angeles and seeking a declaratory judgment that we have complied with all contractual obligations to Dr. Cutler. On July 25, 2012, the arbitrator dismissed the arbitration on the grounds that the parties dispute falls outside the scope of the arbitration clause in the applicable contract. This matter, like all litigation, carries certain risks, and there can be no assurance of the outcome.

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

9. Shareholders Equity

Shares and Additional Paid-In Capital

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 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 reports in the discussion and table 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 Azur 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, by creating a capital redemption reserve of $0.5 million as required by Irish company law, to preserve permanent capital in the company; and by increasing our additional paid-in capital by $575.9 million.

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

	Six Months Ended June 30, 2012		Six Months Ended June 30, 2011	
	Shares	Cash	Shares	Cash
Azur Merger	12,360	$ -	-	$ -
Employee withholding taxes related to share option exercises (1)	-	(25,299)	-	-
Employee stock purchase program, option and warrant exercises	2,678	18,573	1,716	9,411
Directors deferred compensation plan	29	-	13	-
Totals	15,067	$ (6,726)	1,729	$ 9,411

(1) During the six months ended June 30, 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.

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Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as at June 30, 2012 and December 31, 2011 were as follows (in thousands):

	Net Unrealized Gains (Losses) On Available-For-Sale Securities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2011	$ (31)	$ -	$ (31)
Other comprehensive income (loss)	31	(388)	(357)
Balance at June 30, 2012	$ -	$ (388)	$ (388)

10. Share-Based Compensation

Share-based compensation expense related to share options, restricted stock units, 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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Selling, general and administrative	$ 4,442	$ 2,418	$ 6,847	$ 4,830
Research and development	522	848	1,037	1,504
Cost of product sales	294	149	655	229
Total share-based compensation expense	$ 5,258	$ 3,415	$ 8,539	$ 6,563

Share Options

The table below shows (i) the number of shares 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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Shares underlying options granted (in thousands)	96	81	921	1,251
Weighted-average grant date fair value	$ 27.64	$ 19.00	$ 27.87	$ 17.67
Black-Scholes option pricing model assumption information:				
Weighted-average volatility	66%	71%	63%	74%
Weighted-average expected term (years)	5.2	5.6	5.2	5.6
Range of risk-free rates	0.7-1.1%	1.9-2.6%	0.7-1.1%	1.9-2.7%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

Restricted Stock Units

In the six months ended June 30, 2012, we granted 452,793 RSUs covering an equal number of our ordinary shares to employees with a weighted-average grant date fair value of $51.59. The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares as of that date. The fair value of the RSUs is recognized as expense ratably over the vesting period of four years.

As of June 30, 2012, total compensation cost not yet recognized related to unvested share options and RSUs was $48.5 million, which is expected to be recognized over a weighted-average period of 2.8 years.

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11. 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 $0.1 million in the six months ended June 30, 2012. There were no amounts unpaid at June 30, 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. Effective July 2012, we terminated the agreement at no cost.

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 at the time of the agreement. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering, and we agreed to pay expenses of approximately $0.4 million in connection with this offering.

12. 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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Xyrem	$ 89,097	$ 56,178	$ 162,534	$ 98,956
Erwinaze/Erwinase	6,007	-	6,007	-
Prialt	5,555	-	15,077	-
Psychiatry:				
Luvox CR	10,471	7,286	20,029	14,411
FazaClo LD	5,956	-	11,535	-
FazaClo HD	3,362	-	5,922	-
Other	7,862	-	14,542	-
Product sales, net	128,310	63,464	235,646	113,367
Royalties and contract revenues	1,229	1,103	2,307	2,081
Total revenues	$ 129,539	$ 64,567	$ 237,953	$ 115,448

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
United States	$ 124,748	$ 62,931	$ 226,902	$ 112,830
Europe	3,172	1,314	9,086	2,292
All other	1,619	322	1,965	326
Total revenues	$ 129,539	$ 64,567	$ 237,953	$ 115,448

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Express Scripts	69%	86%	68%	85%

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

	June 30, 2012	December 31, 2011
Ireland	$ 202,856	$ -
France	718,019	-
Bermuda	301,696	-
United States	136,754	54,442
Other	38,177	-
Total long-lived assets	$ 1,397,502	$ 54,442

13. Income Tax

Our provision for income taxes was $6.6 million and $12.1 million for the three and six months ended June 30, 2012, respectively, compared to zero for the same periods in 2011. Our effective tax rate was 19.5% and 18.1% for the three and six months ended June 30, 2012, respectively, compared to our effective tax rate of zero for the same periods in 2011. The provision for income taxes for the three and six months ended June 30, 2012 was for taxes in foreign jurisdictions. During 2011, we had operations only in the U.S. and made no provision for income taxes due to our utilization of federal net operating loss carryforwards to offset both regular taxable income and alternative minimum taxable income and to our utilization of deferred state tax benefits. The 2012 effective tax rates were higher than the Irish statutory rate of 12.5% due to income taxable at a rate higher than the Irish statutory rate partially offset by a valuation allowance release in connection with the utilization of current year net operating losses.

We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of our assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. Our deferred tax assets are composed primarily of U.S. federal net operating loss carryforwards and tax credit carryforwards. Based on available objective evidence, management believes it is more likely than not that these deferred tax assets are not recognizable and will not be recognizable until we have sufficient taxable income because of the risks and uncertainties described in Note 1. Accordingly, net deferred tax assets have been fully offset by a valuation allowance. We will continue to evaluate the need for a valuation allowance by jurisdiction on our deferred tax assets during each reporting period. If and when we reverse the valuation allowance, we will record a tax benefit in our consolidated statement of income. As of June 30, 2012, our deferred tax liability of $185.7 million primarily related to intangible assets and IPR&D acquired in the EUSA Acquisition.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that 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 see the Cautionary Note Regarding Forward-Looking Statements that appears at the end of this discussion. These statements, like all statements in this report, speak only as of their date (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Throughout this discussion, unless otherwise indicated or the context otherwise requires, references to Jazz Pharmaceuticals, we, us, and our refer to Jazz Pharmaceuticals Public Limited Company, or 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 (described below).

Recent Transactions

In January 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction, or the Azur Merger. In June 2012, we completed the acquisition of EUSA Pharma, or the EUSA Acquisition. In connection with the EUSA Acquisition, we entered into a $575.0 million credit agreement consisting of a $475.0 million term loan, which partially financed the EUSA Acquisition, and a $100.0 million revolving credit facility.

Merger with Azur Pharma

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in the Azur Merger, which was 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 Azur Pharma are included in our condensed consolidated financial statements since the effective date of the Azur Merger, 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, Jazz Pharmaceuticals, Inc. was an independent specialty pharmaceutical company incorporated in Delaware.

Acquisition of EUSA Pharma

On June 12, 2012, we completed the acquisition of EUSA Pharma. As part of the EUSA Acquisition, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc. At the closing of the EUSA Acquisition, we paid $678.4 million in cash, and agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze (asparaginase *Erwinia chrysanthemi*), a product acquired in the EUSA Acquisition, achieves U.S. net sales of $124.5 million in 2013. The operating results of EUSA Pharma are included in our condensed consolidated financial statements since the effective date of the EUSA Acquisition on June 12, 2012.

Term Loan and Revolving Credit Facility

In connection with the EUSA Acquisition, we entered into a $575.0 million credit agreement with Barclays Bank PLC and certain other lenders. The credit agreement provides for a six-year $475.0 million term loan and a five-year $100.0 million revolving credit facility. The proceeds from the term loan were used to partially finance the EUSA Acquisition. Our obligations are secured by substantially all of the assets of certain of our subsidiaries. For a more detailed discussion, see Liquidity and Capital Resources below.

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Business and Financial Overview

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

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

We made substantial progress in the execution of our strategy during the first half of 2012. Sales of our lead product, Xyrem (sodium oxybate) oral solution, increased 59% and 64% in the three and six months ended June 30, 2012, respectively, compared to the same periods in 2011. In addition, as a result of the EUSA Acquisition and Azur Merger, we significantly increased the number of products that we market and added products in therapeutic areas that are new to us, such as oncology and pain. Our marketed products now address medical needs in the following five therapeutic areas and include the following products:

Narcolepsy: Xyrem (sodium oxybate) oral solution, 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;

Oncology: Erwinaze (asparaginase *Erwinia chrysanthemi*), called Erwinase in ex-U.S. markets, a treatment for patients with acute lymphoblastic leukemia, and other products, including products for oncology supportive care;

Pain: Prialt (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for refractory severe chronic pain;

Psychiatry: FazaClo (clozapine, USP) LD and FazaClo HD, orally disintegrating clozapine tablets indicated for treatment resistant schizophrenia, and Luvox CR (fluvoxamine maleate) Extended-Release Capsules marketed for the treatment of obsessive compulsive disorder; and

Other: a portfolio of other products led by Elestrin (estradiol gel), indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause.

Our development pipeline currently includes clinical testing of the intravenous administration of Erwinaze for potential approval in the United States, as well as the clinical testing of the product candidates Asparec (mPEG-r-crisantaspase), a pegylated recombinant *Erwinia* asparaginase for patients with *E. coli* asparaginase hypersensitivity, and Leukotac (inolimomab), an anti-CD25 monoclonal antibody being studied for the treatment of steroid-refractory acute graft vs. host disease. In addition, we are continuing to pursue development of Clozapine OS, an oral suspension formulation of clozapine. We expect research and development expenses to be higher in 2012 compared to 2011 as we expect to increase our development activities.

With completion of the EUSA Acquisition and the Azur Merger this year, we gained not only an expanded portfolio of specialty pharmaceutical products and product candidates, but also a strengthened management team and an enhanced commercial platform, adding EUSA Pharma s specialty commercial infrastructure in the United States and Europe and its international distribution network to our existing U.S. specialty product platform. Our international footprint now includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 650 employees in ten countries. Going forward, we intend that our strengthened operations will function as an efficient platform for further growth, leveraging our commercial, medical and scientific experience to seek to maximize the potential of our existing products and expand our product portfolio through a combination of internal development, acquisition and in-licensing. We view the operations of the businesses acquired in the EUSA Acquisition and the Azur Merger as complementary to our prior business, and therefore we do not expect to realize significant operating cost synergies.

During the remainder of 2012, we expect to focus on executing on our strategy, as described above, as well as on completing the integration of our acquired businesses. Both this year and going forward, we anticipate that we will continue to face a number of challenges and risks to our

business and the execution of our strategy. For example, while we now have a more diversified product portfolio, our financial results are significantly influenced by sales of Xyrem, which accounted for 69% of our net product sales for both the three and six months ended June 30, 2012. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product, and enforcing our intellectual property rights.

Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, including those discussed in Part II Item 1A of this Quarterly Report on Form 10-Q. In particular, during 2010, an abbreviated new drug application, or ANDA, was filed with the United States Food and Drug Administration, or 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.

In May 2012, we received a Form FDA 483 at the conclusion of an FDA inspection conducted in May 2012 and in October 2011, we received a warning letter from the FDA (which followed a Form FDA 483 that we received earlier in 2011) related to certain aspects of our adverse event reporting system for Xyrem, our review and investigation of adverse events and our drug safety procedures. In June 2012, we responded to the May 2012 Form FDA 483 with our plan to address the observations made in the May 2012

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Form FDA 483, and we believe that we have now substantially completed the review, investigation and documentation that are necessary to fully address the observations. In particular, we have completed our review of information from the single central pharmacy, Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or ESSDS, through which all Xyrem sold in the United States is shipped directly to patients, related to potential Xyrem-related adverse events over an approximately nine-year period from late 2002 through May 2011. As a result of this 2012 review, over the entire period that was reviewed, we identified fewer than 80 previously unreported serious adverse events that are required to be reported to the FDA. Of these events, approximately one-half were serious and unexpected cases (including a small number of deaths) that require expedited reporting to the FDA, which we completed in July 2012. We plan to submit the balance of the previously unreported adverse events in our periodic safety update report (PSUR) that is due to be filed with the FDA in September 2012. We have also completed the actions that we believe are required to address the other observations in the May 2012 FDA Form 483. In addition, we are near completion of the actions that we believe are necessary to fully address the matters raised in the October 2011 warning letter.

In April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us as required. We promptly reported to the FDA all of the previously unreported cases identified by us and ESSDS and began our investigation of the related data from ESSDS, as well as additional data we gathered. Earlier in 2012, we completed and submitted to the FDA an analysis with respect to these cases under a plan that we had 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 data did not change the known risks associated with the use of Xyrem. In July 2012, we held a telephonic meeting with the FDA with respect to our analysis. As a result of that meeting, we believe that the FDA does not require any further analysis with respect to mortality during the historical period that was covered by our investigation and evaluation.

Our ongoing review of Xyrem safety information has not, in our view, resulted in any significant change in the overall safety profile of the product. We are continuing our ongoing work with the FDA on both changes to the product label and our risk management and distribution system for Xyrem, called the Xyrem Success Program, to further enhance and promote the safe use of Xyrem. We do not know whether the FDA will agree with our proposed updates to the Xyrem label or to the Xyrem Success Program, whether the FDA will take further action, or require us to take further action, with respect to our adverse event reporting, whether the FDA will otherwise conclude we have not taken all appropriate corrective actions with respect to the May 2012 Form FDA 483 or the October 2011 warning letter, or whether the FDA will agree with our analysis of the previously unreported mortality data and other data, or require additional analysis. The FDA may take, or require us to take, actions that could make it more difficult or expensive for us to distribute Xyrem, make competition easier and/or negatively affect the commercial success of Xyrem.

The implementation of our strategy is also subject to other challenges and risks specific to our business, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations. In addition to risks related to Xyrem, other key challenges and risks that we face include risks and uncertainties related to:

- the need to successfully integrate and grow our combined business after the EUSA Acquisition and Azur Merger, which subjects us to the risks attendant to the increased complexity and diversity of our business and product lines;
- the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to health care cost containment and other austerity measures in the U.S. and worldwide;
- the ongoing regulation and oversight by the FDA, the U.S. Drug Enforcement Administration, and similar foreign regulatory agencies, including with respect to product labeling, requirements for distribution, marketing and promotional activities and product recalls or withdrawals;
- the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors;
- our dependence on key customers and sole source suppliers and protection of intellectual property rights; and

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

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

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Results of Operations

The following table presents revenues and expenses for the three and six months ended June 30, 2012 and 2011, respectively:

	Three Months Ended June 30,		Increase/ (Decrease) (2)	Six Months Ended June 30,		Increase/ (Decrease) (2)
	2012	2011		2012	2011	
	(In thousands)			(In thousands)		
Product sales, net	$ 128,310	$ 63,464	102%	$ 235,646	$ 113,367	108%
Royalties and contract revenues	1,229	1,103	11%	2,307	2,081	11%
Cost of product sales (excluding amortization of acquired developed technologies)	15,370	3,370	356%	26,128	6,179	323%
Selling, general and administrative	60,638	22,094	174%	107,637	42,005	156%
Research and development	2,321	3,382	(31%)	6,280	7,077	(11%)
Intangible asset amortization	15,751	1,862	746%	29,264	3,724	686%
Interest expense, net	1,481	657	125%	1,450	1,434	1%
Other expense	240	-	N/A(1)	258	-	N/A(1)
Provision for income tax expense	6,593	-	N/A(1)	12,110	-	N/A(1)

(1) Comparison to prior period is not meaningful.

(2) Subsequent to the completion of the Azur Merger on January 18, 2012 and the EUSA Acquisition on June 12, 2012, our financial results include the financial results of the historic Azur Pharma and EUSA businesses, respectively. The historical financial statements of Jazz Pharmaceuticals, Inc. only are included in the comparative prior periods.

Product Sales, Net

	Three Months Ended June 30,		Increase/ (Decrease)	Six Months Ended June 30,		Increase/ (Decrease)
	2012	2011		2012	2011	
	(In thousands)			(In thousands)		
Xyrem	$ 89,097	$ 56,178	59%	$ 162,534	$ 98,956	64%
Erwinaze/Erwinase	6,007	-	N/A(1)	6,007	-	N/A(1)
Prialt	5,555	-	N/A(1)	15,077	-	N/A(1)
Psychiatry:						
Luvox CR	10,471	7,286	44%	20,029	14,411	39%
FazaClo LD	5,956	-	N/A(1)	11,535	-	N/A(1)
FazaClo HD	3,362	-	N/A(1)	5,922	-	N/A(1)
Other	7,862	-	N/A(1)	14,542	-	N/A(1)
Product sales, net	128,310	63,464		235,646	113,367	
Royalties and contract revenues	1,229	1,103		2,307	2,081	
Total revenues	$ 129,539	$ 64,567		$ 237,953	$ 115,448	

(1) Comparison to prior period is not meaningful.

Xyrem product sales increased in the three and six months ended June 30, 2012 compared to the same periods in 2011, primarily due to price increases and to a lesser extent increases in sales volume of 11% in both periods. Luvox CR product sales increased in the three and six months ended June 30, 2012 compared to the same periods in 2011 due to price increases. Sales of products other than Xyrem and Luvox CR increased by $28.7 million and $53.1 million in the three and six months ended June 30, 2012, respectively, compared to the same periods in 2011 due to the inclusion of products from the Azur Merger and to a lesser extent, the inclusion of products from the EUSA Acquisition from the June 12, 2012 acquisition date. Prialt product sales included sales of $4.6 million in the six months ended June 30, 2012 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 Luvox CR and due to the inclusion of product sales from our expanded product portfolio resulting from the Azur Merger and the EUSA Acquisition.

Royalties and Contract Revenues

An increase in royalties accounted for the modest increases in royalty and contract revenues in the three and six months ended June 30, 2012 compared to the same periods in 2011. We expect royalty and contract revenue to decrease slightly in 2012 as compared to 2011 due to a sales milestone payment received in 2011.

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Cost of Product Sales

Cost of product sales increased in the three and six months ended June 30, 2012 compared to the same periods in 2011 primarily due to cost of product sales from the Azur Merger of $7.8 million and $14.2 million in the three and six months ended June 30, 2012, respectively, including purchase accounting inventory fair value step-up adjustments of $2.8 million and $5.2 million in the three and six months ended June 30, 2012, respectively. Cost of product sales related to products added to our portfolio as a result of the EUSA Acquisition from the June 12, 2012 acquisition date were not significant. Gross margin as a percentage of product sales was 88.0% and 88.9% in the three and six months ended June 30, 2012, respectively, compared to 94.7% and 94.5% for the same periods in 2011. We expect our gross margin percentage to decrease in 2012 compared to 2011 because of the effect of the Azur Merger and the EUSA Acquisition.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in the three and six months ended June 30, 2012 compared to the same periods in 2011 primarily due to an increase in professional service fees and expenses of $14.1 million and $23.9 million, respectively, (including transaction and integration costs of $10.6 million and $16.7 million, respectively), an increase in salary and benefit related headcount expenses of $12.0 million and $19.2 million, respectively, and other expenses related to expansion of our 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 Azur Pharma business subsequent to the Azur Merger on January 18, 2012 and the EUSA Pharma business subsequent to the EUSA Acquisition on June 12, 2012. We do not expect synergies as a result of these two acquisitions to contribute to any significant reduction in operating expenses.

Research and Development Expenses

Research and development expenses were slightly lower in the three and six months ended June 30, 2012 compared to the same periods in 2011. 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 and the EUSA Acquisition, we acquired finite-lived intangible assets with a fair value of $942.0 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 $14.1 million and $25.8 million in the three and six months ended June 30, 2012, respectively, which accounted for all of the increase in the amortization expense. We expect amortization expense in 2012 to increase substantially from 2011 as a result of the intangible assets we acquired in 2012.

Interest Expense, Net

Interest expense increased in the three and six months ended June 30, 2012 primarily due to a larger debt balance as compared to the same periods in 2011. In June 2012, we entered into a new credit agreement which provides for a term loan in an aggregate principal amount of $475.0 million which bears interest at a variable interest which was 5.25% as of June 30, 2012. In July 2011 we fully repaid a term loan outstanding at that time. As a result of the increase in average debt outstanding, we expect interest expense to increase significantly in 2012.

Other Expense

Other expense represents foreign currency exchange losses. As a result of the EUSA Acquisition foreign exchange gains/(losses) may become significant in future periods, the amount of which is difficult to predict.

Provision for Income Tax Expense

Our provision for income taxes was $6.6 million and $12.1 million for the three and six months ended June 30, 2012, respectively, compared to zero for the same periods in 2011. Our effective tax rate was 19.5% and 18.1% for the three and six months ended June 30, 2012, respectively, compared to our effective tax rate of zero for the same periods in 2011. The provision for income taxes for the three and six months ended June 30, 2012 was for taxes in foreign jurisdictions. During 2011, we had operations only in the U.S. and made no provision for income taxes due to our utilization of federal net operating loss carryforwards to offset both regular taxable income and alternative minimum taxable income and to our utilization of deferred state tax benefits. The 2012 effective tax rates were higher than the Irish statutory rate of 12.5% due to income taxable at a rate higher than the Irish statutory rate partially offset by a valuation allowance release in connection with the utilization of current year net operating losses.

We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of our assets and liabilities, as measured by enacted jurisdictional tax rates assumed to be in effect when these differences reverse. Our deferred tax assets are composed primarily of U.S. federal net operating loss carryforwards and tax credit carryforwards. Based on available

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objective evidence, management believes it is more likely than not that these deferred tax assets are not recognizable and will not be recognizable until we have sufficient taxable income because of the risks and uncertainties described in Part II Item 1A Risk Factors included elsewhere in this report. Accordingly, net deferred tax assets have been fully offset by a valuation allowance. We will continue to evaluate the need for a valuation allowance by jurisdiction on our deferred tax assets during each reporting period. If and when we reverse the valuation allowance, we will record a tax benefit in our consolidated statement of income. As of June 30, 2012, our deferred tax liability of $185.7 million primarily related to intangible assets and in-process research and development, or IPR&D, acquired in the EUSA Acquisition.

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, change in the fair value of contingent consideration, other non-cash items and income tax adjustments.

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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
	(In thousands, except per share amounts)			
GAAP net income	$ 27,145	$ 33,202	$ 54,826	$ 55,029
Intangible asset amortization	15,751	1,862	29,264	3,724
Share-based compensation expense	5,258	3,415	8,539	6,563
Purchase accounting inventory fair value step-up	4,011	-	6,380	-
Transaction and integration costs	10,641	-	16,736	-
Change in fair value of contingent consideration	200	-	200	-
Other non-cash expense (income)	267	(96)	309	(175)
Income tax adjustments (1)	2,897	-	2,897	-
Adjusted net income	$ 66,170	$ 38,383	$ 119,151	$ 65,141
GAAP net income per diluted share (2)	$ 0.45	$ 0.71	$ 0.92	$ 1.19
Adjusted net income per diluted share (2)	$ 1.09	$ 0.82	$ 2.01	$ 1.41
Shares used in computing GAAP and adjusted net income per diluted share amounts (2)	60,554	46,601	59,319	46,238

(1) Tax related to acquisition restructuring of $5.9 million, partially offset by $3.0 million for tax effect of non-GAAP pre-tax adjustments.

(2) All references to share or shares in the table above refer to Jazz Pharmaceuticals, Inc. s common stock with respect to the comparative prior year periods and to Jazz Pharmaceuticals plc s ordinary shares with respect to the current year periods. GAAP net income per diluted share and non-GAAP adjusted net income per diluted share in the comparative prior year periods 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 became the right to receive one ordinary share upon the consummation of the Azur Merger.

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Liquidity and Capital Resources

In June 2012, in order to partially finance the EUSA Acquisition, we entered a new credit agreement which provides for a term loan in an aggregate principal amount of $475.0 million which matures in June 2018, and a $100.0 million revolving credit facility which matures in June 2017. Net proceeds from the term loan were $450.9 million after deducting an original issue discount of $7.1 million, fees paid to the lenders and issuance costs.

As of June 30, 2012, we had cash, cash equivalents and marketable securities of $154.5 million and borrowing availability under the revolving credit facility of $100.0 million. We generated cash flows from operations of $101.3 million in the first half of 2012 and we expect to continue to generate positive cash flow from operations. We believe that our existing cash balances, cash we expect to generate from operations and funds available under our revolving credit facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future, including our obligations under the credit agreement and a potential contingent payment of $50.0 million which we agreed to under the EUSA Acquisition Agreement if Erwinaze achieves U.S. net sales of $124.5 million in 2013. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses as well as the other factors set forth in Part II Item 1A of this Quarterly Report on Form 10-Q under the headings Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects, If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected, The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem, and To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

As of June 30, 2012, $475.0 million principal amount was outstanding on our term loan which is repayable in quarterly installments beginning in September 2012 equal to 5% of the original principal amount in the first year, 7.5% in the second year, 10% in each of the third and fourth years and 15% in each of the fifth and sixth years, with any remaining balance payable on the final maturity date. Borrowings under the term loan bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.25% per annum (subject to a 1.0% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 3.25% per annum (subject to a 2.0% prime rate floor). As of June 30, 2012, the interest rate on the term loan was 5.25%. Borrowings under the revolving credit facility bear interest, at our option, at a rate equal to either the LIBOR rate, plus an applicable margin of 4.00% per annum, or the prime lending rate, plus an applicable margin equal to 3.00% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. We may make prepayments of principal without premium or penalty, except that a 1% premium would apply to a repayment via a repricing of the loan under the term loan effected on or prior to June 12, 2013. We are required to make mandatory prepayments of borrowings under the term loan (without payment of a premium) with net cash proceeds from certain non-ordinary course asset sales, issuances of debt (other than certain permitted debt) and casualty proceeds and condemnation awards; and, beginning with the fiscal year ending December 31, 2013, with 50% of our excess cash flow, as defined in the credit agreement (subject to increase to 75% if our secured leverage ratio exceeds 2.25 to 1.0, or decrease to 25% or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.0 or 0.75 to 1.0, respectively).

Borrowings under the credit agreement are guaranteed by Jazz Pharmaceuticals plc and certain of its subsidiaries and are secured by substantially all of their assets. The credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to us, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement contains a financial covenant that requires us to maintain a maximum secured leverage ratio beginning with the quarter ending September 30, 2012. Our failure to comply with any of the operating and financial covenants contained in the credit agreement would constitute an event of default under the credit agreement. The credit agreement contains other customary events of default. If one or more events of default occurs and continues beyond any applicable cure period, the administrative agent may, with the consent of the lenders holding a majority of the loans and commitments under the facilities, or will, at the request of such lenders, terminate the commitments of the lenders to make further loans and declare all of the obligations under the credit agreement to be immediately due and payable. In such event, we would not have sufficient cash resources to repay the full amount of the obligations. We are currently in compliance with all material covenants under the credit agreement.

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To continue 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, product development and clinical trials of product candidates, and expanding our commercial operations. We may seek to raise additional funds to license or acquire additional products, product candidates or companies or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders, and the consent of the lenders under our credit agreement could be required for certain potential financings.

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

	Six Months Ended June 30,	
	2012	2011
	(In thousands)	
Net cash provided by operating activities	$ 101,264	$ 61,884
Net cash used in investing activities	(478,734)	(2,011)
Net cash provided by (used in) financing activities	450,428	(2,271)
Effect of foreign currency exchange rates on cash and cash equivalents	(491)	-
Net increase in cash and cash equivalents	$ 72,467	$ 57,602

Net cash provided by operating activities increased in 2012 compared to 2011 due to increase in net income, after adjusting for non-cash items, in addition to the favorable effect of changes in working capital.

Net cash used in investing activities in 2012 primarily related to cash used in the EUSA Acquisition offset by cash received as a result of the EUSA Acquisition and the Azur Merger and by net proceeds from the sale of marketable securities.

Net cash provided by financing activities in 2012 primarily related to net proceeds of $450.9 million from our new term loan and proceeds of $18.6 million from employee share purchases and exercises of options and warrants partially offset by payments totaling $25.3 million for employee withholding tax related to net share exercises.

Contractual Obligations

The table below presents a summary of our contractual obligations as of June 30, 2012 and includes contractual obligations assumed as a result of the Azur Merger and the EUSA Acquisition.

	Payments Due By Period				
Contractual Obligations (1)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
			(In thousands)		
Term loan principal	$ 475,000	$ 23,750	$ 83,125	$ 118,750	$ 249,375
Term loan interest (2)	116,246	24,859	44,694	34,648	12,045
Purchase obligations (3)	45,662	42,494	3,168	-	-
Operating lease obligations (4)	30,058	6,195	11,510	8,690	3,663
Purchased product rights liability (5)	7,000	7,000	-	-	-
Revolving credit facility (6)	2,536	532	1,014	990	-
Other	2,160	40	360	400	1,360
Total	$ 678,662	$ 104,870	$ 143,871	$ 163,478	$ 266,443

(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 including an additional contingent payment of $50.0 million which we agreed to make under the EUSA Acquisition Agreement if Erwinaze achieves U.S. net sales of $124.5 million in 2013.

(2) In June 2012, we entered into a new credit agreement which provides for a term loan in an aggregate principal amount of $475.0 million which matures in June 2018 and a $100.0 million revolving credit facility which matures in June 2017. On June 12, 2012, we borrowed $475.0 million under the new term loan. The interest rate was 5.25% at June 30, 2012 which we used to estimate interest owed on the term loan until the final maturity date.

(3) This includes non-cancelable commitments to third party manufacturers.

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(4) Includes the minimum lease payments for our office buildings and automobile lease payments for our sales force. In May 2012, we entered into an operating lease agreement for our new headquarters in Dublin for a term of ten years, we amended and extended the operating lease for our existing Philadelphia office building for a term of four years and we entered into a new operating sublease for additional office space in Palo Alto near our existing office location for a term of five years. This amount also includes additional operating leases acquired as a result of the EUSA Acquisition.

(5) This amount represents amounts due under a product license agreements with Elan Pharma International Limited related to Prialt ($5.0 million) and with Abbott Laboratories, or Abbott, related to Luvox CR ($2.0 million). These amounts exclude $5.0 million we may owe to 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.

(6) The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.50% and assumed undrawn amounts of $100.0 million to estimate commitment fees owed. No amount was borrowed under the revolving credit facility as of June 30, 2012.

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 and the EUSA Acquisition on June 12, 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 (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 June 30, 2012. We also recorded a deferred tax liability of $185.7 million at June 30, 2012 primarily related to the difference between the book basis and tax basis of the intangible assets and identifiable IPR&D acquired in the EUSA Acquisition. The difference between the book basis and tax basis was based on enacted jurisdictional

tax rates assumed to be in effect when these differences reverse. The deferred tax liability amount is based on a variety of significant estimates and assumptions.

In connection with the Azur Merger and the EUSA Acquisition, we recorded goodwill of $408.0 million, which represented the excess cost of our investment in the net assets of the acquired Azur Pharma and EUSA Pharma businesses over the fair value of the underlying identifiable net assets at the date of acquisition. This resulted in total goodwill recorded of $446.2 million as of June 30, 2012. We assess our goodwill balance within our single reporting unit annually and whenever events or changes in circumstances

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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

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-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

Market risks related to our cash equivalents and marketable securities, and the ways we manage such risks, are 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. During the six months ended June 30, 2012, there were no material changes to the market risks relating to cash equivalents. We did not hold any marketable securities at June 30, 2012.

Interest Rate Risk. In June 2012, we entered into a credit agreement which provides for a six-year $475.0 million term loan and a five-year $100.0 million revolving credit facility. On June 12, 2012, we borrowed $475.0 million under the term loan. We are exposed to risks associated with changes in interest rates as a result of borrowings under our term loan. Our indebtedness outstanding under our term loan is subject to a LIBOR floor of 1.0%. Currently LIBOR rates are below the floor of 1% and therefore an increase in interest rates would only impact our net interest expense to the extent it exceeds the floor of 1%. Based on variable rate debt levels of $475.0 million as of June 30, 2012, a 1.0% change in interest rates, above the LIBOR floor, would impact net interest expense by approximately $1.2 million per quarter.

Foreign Exchange Risk. Following the acquisition of EUSA, we now have significant operations in Europe as well as in the United States. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the local currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposures are related to our subsidiaries that have functional currencies denominated in the Euro and the British Pound Sterling, or GBP. A 10% movement in the rates used to translate the results of our foreign subsidiaries would not have had a material impact on our net income for the three and six months ended June 30, 2012.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the

appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are included within Other expense in the condensed consolidated statements of income. At June 30, 2012, our primary

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exposures to transaction risk related to GBP net monetary liabilities held by subsidiaries with a functional currency other than GBP and U.S dollar net monetary assets held by subsidiaries with a Euro functional currency. At June 30, 2012, a 10% strengthening/(weakening) in the U.S. dollar against GBP would have increased/(decreased) net income by approximately $1.5 million. At June 30, 2012, a 10% strengthening/ (weakening) in the U.S. dollar against the Euro would have increased / (decreased) net income by approximately $3.4 million.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 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, we completed the Azur Merger on January 18, 2012, which was accounted for as a reverse acquisition under the acquisition method of accounting, with Jazz Pharmaceuticals, Inc. treated as the acquirer in the Azur Merger for accounting purposes. The results of operations of the acquired Azur Pharma business have been included in the results of operations of Jazz Pharmaceuticals plc beginning on January 18, 2012. We are currently integrating Azur Pharma s historical internal controls over financial reporting with ours.

Also as discussed above, we completed the EUSA Acquisition on June 12, 2012. The EUSA Acquisition was accounted for using the acquisition method of accounting. The results of operations of the acquired EUSA Pharma business have been included in the results of operations of Jazz Pharmaceuticals plc since June 12, 2012, and we are currently in the process of evaluating and integrating EUSA Pharma s historical internal controls over financial reporting with ours.

During the quarter ended June 30, 2012, other than continuing changes to our internal control processes resulting from the Azur Merger and the EUSA Acquisition as discussed above, there have been no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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., except that all such references prior the effective time of the merger with Azur Pharma on January 18, 2012 are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. 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. The disclosures in this report relating to the pre-Azur 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.

Item 1. Legal Proceedings

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

Xyrem ANDA Matter: 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 United States 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 then listed for Xyrem in the FDA s publication Approved Drug Products with Therapeutic Equivalence Evaluations , or Orange Book, on the date of the

Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane s proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane s Paragraph IV Certification in the United States District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem in violation of our patents. 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

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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, as well as another patent which is not listed in the Orange Book. Another 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 against Roxane on May 2, 2011 to include this additional patent in response to Roxane s Paragraph IV Certification against it. On April 26, 2012, the District Court held a Markman hearing, a pretrial hearing in which the trial judge construes the claims of a patent, and the discovery phase of the proceeding is ongoing. No trial date has been scheduled. We cannot predict the outcome of this matter.

On May 18, 2012, we submitted a Citizen Petition to the FDA addressing the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem and requesting that the FDA: publish in the Orange Book bioequivalence requirements specifying whether in vitro or in vivo bioequivalence studies, or both, are required for ANDAs referencing Xyrem; not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs; and require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants.

On July 10, 2012, we submitted a second Citizen Petition to the FDA addressing the requirements for submission of any ANDA referencing Xyrem. This petition asks the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, that did not contain a proposed risk management system at the time it was accepted for review, because such ANDA would not have demonstrated, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. This petition further requests that the FDA (i) not accept for review any ANDA referencing Xyrem that does not contain, at the time of its submission, a proposed risk management system sufficient to demonstrate that the new generic drug product has the same labeling and conditions of use as Xyrem; and (ii) determine that if any sponsor, including Roxane, of an ANDA referencing Xyrem that did not contain, at the time it was accepted for review, a proposed risk management system later submits, or resubmits, an ANDA that contains a proposed risk management system sufficient to demonstrate that the new generic drug product would have the same labeling and conditions of use of Xyrem, such ANDA should not be approved for a period of up to thirty months beginning on the date we receive notice of any Paragraph IV certifications contained in such new ANDA, to the extent that we avail ourselves of our right to initiate a patent infringement action based on such notice. We believe that the FDA s acceptance of Roxane s ANDA caused the thirty-month stay under the Hatch-Waxman Act and the related patent litigation between the parties to begin prematurely in a manner contrary to applicable law. We cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, either of our Citizen Petitions, or the effect of any such response or action on the timing of the potential introduction of a generic version of Xyrem or on the ongoing litigation between us and Roxane.

Luvox CR ANDA Matters. 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 will commence on April 15, 2014 or earlier upon the occurrence of certain events.

FazaClo ANDA Matters: Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc.; Novel Laboratories, Inc.; and Mylan Pharmaceuticals, Inc., indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification in the United States District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, Inc., entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma s rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of

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authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015 or earlier upon the occurrence of certain events. Teva has exercised its option for supply of an authorized generic product for Fazaclo LD, and we are addressing the FDA requirements to permit a launch of the authorized generic product. The Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc. matters have been stayed pending reexamination of the patents in the suit. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc., the reexamination proceedings, or when the stays will be lifted.

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in California Superior Court in the County of Los Angeles. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma s subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to either a $10.5 million or $25.0 million contingent payment, plus unspecified punitive damages and attorneys fees. On March 14, 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. We submitted a complaint in arbitration alleging that Dr. Cutler s suit had been improperly filed in Los Angeles and seeking a declaratory judgment that we have complied with all contractual obligations to Dr. Cutler. On July 25, 2012, the arbitrator dismissed the arbitration on the grounds that the parties dispute falls outside the scope of the arbitration clause in the applicable contract. This matter, like all litigation, carries certain risks, and there can be no assurance of the outcome.

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

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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 Xyrem and the Significant Impact of Xyrem Sales

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

Xyrem is our largest selling product and our financial results are significantly influenced by sales of Xyrem, which accounted for 69% of our net product sales for both the three and six months ended June 30, 2012 and 88% of our net product sales for the year ended December 31, 2011, and our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2010 to 2011 and in the first two quarters of 2012, we cannot assure you that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in August 2012, and we cannot assure you that price adjustments we have taken or may take in the future have not already negatively affected, or will not in the future negatively affect, Xyrem sales volumes.

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

- the potential introduction of a generic version of Xyrem;
- changed or increased regulatory restrictions, including changes to our risk management program for Xyrem, or regulatory actions by the FDA as a result of, or related to the matters raised in, the warning letter we received from the FDA in October 2011 or the Form FDA 483 we received in May 2012;
- 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;
- 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 below related to Xyrem product sales and protection of our proprietary rights could have a material adverse effect on our ability to maintain or increase sales of Xyrem.

If sales of Xyrem were to decline significantly, we could need 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 might not be able to acquire, in-license or develop new products in the future to grow our business.

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

Although Xyrem is covered by patents covering its formulation, distribution system and method of use, a third party is seeking to introduce a generic version of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem. Once orphan drug exclusivity in the United States for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy expires in November 2012, other companies could possibly introduce generic versions of Xyrem if they do not infringe our patents or if they can demonstrate that our patents are invalid or unenforceable, and they receive FDA approval.

On October 18, 2010, we received notice from Roxane that it had filed an ANDA with the 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

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decrease. We have sued Roxane seeking to prevent Roxane from introducing a generic version of Xyrem in violation of our patents, 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. On May 18, 2012, we submitted a Citizen Petition to the FDA requesting that the FDA include in the Orange Book bioequivalence requirements specifying whether *in vitro* bioequivalence studies, or *in vivo* bioequivalence studies, or both, are required for ANDAs referencing Xyrem. In this Citizen Petition, we also asked the FDA not to accept for review, review or approve any ANDA referencing Xyrem until such requirements are published in the Orange Book, and to require *in vivo* bioequivalence studies for any sodium oxybate drug product seeking approval under an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On July 10, 2012, we submitted a second Citizen Petition to the FDA asking the FDA to rescind acceptance of any previously filed ANDA referencing Xyrem, and not to accept any future ANDA referencing Xyrem, unless such ANDA contains, at the time of acceptance for review, a proposed risk management system demonstrating that the proposed generic product would have the same labeling and condition of use of Xyrem. We cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, either of our Citizen Petitions, or the effect of any such response or action on the timing of the potential introduction of a generic version of Xyrem or the ongoing litigation between us and Roxane.

A generic manufacturer would need to obtain quota from the DEA in order to manufacture both the active pharmaceutical ingredient and the finished product for a generic version of Xyrem. The DEA has historically published an annual overall quota that is less than we needed for our projected supply of Xyrem, and we have had to engage in costly and time consuming legal efforts to obtain the needed quotas. When the quotas were obtained, our suppliers historically obtained substantially all of the aggregate quota for use in the manufacture of Xyrem. However, the aggregate quota published by the DEA 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.

After the introduction of a generic competitor, a significant percentage of the prescriptions written for Xyrem may be filled with the generic version, resulting in a loss in sales of Xyrem, including for indications for which the generic version may not have 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 version is available. Generic competition for Xyrem 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 regulatory oversight and 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.*

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management and distribution system that was implemented at the time Xyrem was approved, called the Xyrem Success Program, to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse or diversion of sodium oxybate. The Xyrem Success Program includes unique features that provide information about adverse events, including deaths, which is generally not available for other products that are not subject to a similar risk management plan. As required by the FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to the FDA and could result in the FDA requiring changes to the Xyrem label or taking or requiring us to take other actions that could have an adverse effect on Xyrem s commercial success.

While the Xyrem Success Program, adopted in 2002, is deemed to be an approved Risk Evaluation and Mitigation Strategy, or REMS, pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA, it is not in the form that is now required for REMS. The FDA is requiring product risk management programs that existed prior to the adoption of the FDAAA, including the Xyrem Success Program, to be updated to comply with the current requirements for REMS. We have filed a supplement conforming the elements of the Xyrem Success Program to the new REMS formatting requirements and seeking approval of the document. We have had communications with the FDA with respect to our submitted REMS document, but we cannot assure you that the FDA will agree with the updated REMS document we submitted, and we cannot predict the timing of the FDA s response. The FDA may impose new and onerous requirements under the new REMS structure that could make it more difficult or expensive for us to distribute Xyrem, make competition easier and/or negatively affect the commercial success of Xyrem. In addition, the regulatory scheme that governs REMS programs is complex, and includes provisions that favor operation of a single shared REMS for the holder of the new drug application, or NDA, and related generic products, and that encourages generic companies to seek a license if the NDA holder s REMS program is protected by intellectual property. The FDAAA further specifies that a REMS should not prevent generic drugs from entering the market and includes provisions that provide considerable relief for generic drug makers. Accordingly, we may face pressure to license or share the Xyrem Success Program with generic competitors in the future. We cannot predict the impact that any changes to the Xyrem Success Program would have on our business.

Currently, we operate under our Xyrem Success Program, which requires that all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under our Xyrem Success Program is cumbersome. While we have an exclusive 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

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fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem and our sales would be adversely affected. If we change our central pharmacy, new contracts might be required with government and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under our Xyrem Success Program or any REMS that we are subject to in the future. 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 April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us as required. We promptly reported to the FDA all of the previously unreported cases identified by us and ESSDS and began our investigation of the related data from ESSDS, as well as additional data we gathered. Earlier this year, we completed and submitted to the FDA an analysis with respect to these cases under a plan that we had discussed with the FDA. In July 2012, we held a telephonic meeting with the FDA with respect to our analysis and, as a result of that meeting, we believe that the FDA does not require any further analysis with respect to mortality during the historical period that was covered by our investigation and evaluation. However, we cannot predict whether the FDA will ultimately agree with our analysis of the previously unreported mortality data and other data, or require additional analysis. The FDA may take, or require us to take, actions that may be costly or time consuming and/or that negatively affect the commercial success of Xyrem.

In October 2011, we received a warning letter from the FDA following a 2011 Form FDA 483 covering certain aspects of our adverse event reporting system for Xyrem and drug safety procedures. In May 2012, we received a Form FDA 483 at the conclusion of an FDA inspection conducted in May 2012, which noted the FDA investigators observations with respect to our incomplete review of information from ESSDS related to potential Xyrem-related adverse events prior to 2011 and determination of whether there are additional adverse events that are required to be reported to the FDA based on such review; our investigation of serious unexpected adverse drug experiences, including insufficient documentation to demonstrate the past investigation; and our lack of written procedure relating to one administrative aspect of our current drug safety monitoring procedures. While we have substantially completed the actions that we believe are required to address the observations in the May 2012 Form FDA 483 and are also near completion of the actions that we believe are necessary to fully address the matters raised in the warning letter, we cannot predict either the timing or the final outcome of the FDA s regulatory compliance review. We do not know whether the FDA will take further action, or require us to take further action, with expect to our adverse event reporting, or whether the FDA will otherwise conclude we have not taken all appropriate corrective actions with respect to the May 2012 Form FDA 483 or the warning letter.

We are continuing our ongoing work with the FDA on both changes to the Xyrem label and our deemed REMS to further enhance and promote the safe use of Xyrem. We do not know whether the FDA will agree with our proposed updates to the Xyrem label or our deemed REMs. The FDA may impose requirements that could make it more difficult or expensive for us to distribute Xyrem, make competition easier and/or negatively affect the commercial success of Xyrem.

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

The FDA has required that Xyrem s label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. In addition, Xyrem s FDA approval under the FDA s Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. We cannot predict whether the FDA will require additional warnings, including black box warnings, to be included on Xyrem s label. Warnings in our label and any limitations on our ability to advertise and promote Xyrem may have affected, and could in the future negatively affect, Xyrem sales and therefore our business, financial condition, results of operations and growth prospects.

Risks Relating to Our Business

We may not realize the anticipated financial and strategic benefits from the Azur Merger and/or the EUSA Acquisition or be able to successfully integrate the acquired businesses.*

The Azur Merger, which was completed in January 2012, and the EUSA Acquisition, which was completed in June 2012, created numerous uncertainties and risks, and have required, and will continue to require, significant efforts and expenditures, including with respect to integrating the acquired businesses with our historical business. We may encounter unexpected difficulties, or incur unexpected costs, in connection with

our transition activities and integration efforts, which include:

- the potential disruption of our historical core business;

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- the risk that our lack of experience in new markets, including the oncology market, will not allow us to achieve growth in, or maintain current levels of, sales of our products in such markets;

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

- the strain on, and need to expand, our existing operational, technical, financial and administrative infrastructure, including our financial controls and reporting systems and procedures and disaster recovery procedures, in connection with integrating three different businesses and operations;

- the difficulties in assimilating employees and corporate cultures, including successfully integrating sales forces and building and maintaining a strong sales organization;

- the potential failure to retain key managers and other personnel, including the employees from the acquired Azur Pharma or EUSA Pharma businesses who might experience uncertainty about their future roles with us;

- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisitions, including professional fees to comply with corporate and tax laws and financial reporting requirements in a number of countries in the European Union, or EU, costs and expenses incurred in connection with travel, and additional costs we may incur going forward as a result of our corporate structure that includes an increased number of subsidiaries in multiple additional countries;

- the potential disruption to our existing business relationships with suppliers, distributors and customers, including those of EUSA Pharma, who may experience uncertainty associated with the acquisitions and consider terminating or negotiating changes in existing agreements; and

- any unanticipated liabilities for activities of or related to Azur Pharma or EUSA Pharma or any of their operations, products or product candidates that occurred prior to the closing of the respective acquisitions.

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 financial and strategic benefits from combining the businesses. In addition, we may be required to spend additional time or money on integration activities that otherwise would be spent on the development and expansion of our business. If we fail to integrate the acquired businesses successfully and in a timely manner, resulting operating inefficiencies could increase costs and expenses more than we planned, could negatively impact the market price of our ordinary shares and otherwise distract us from execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures could also impact our ability to produce timely and accurate financial statements.

As a result of the transactions, we have grown rapidly, and our business and corporate structure has become substantially more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage the increased complexity of the combined business and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

As a result of the Azur Merger and the EUSA Acquisition, we are headquartered in Dublin, Ireland and have multiple offices in the United States, the United Kingdom, and other countries in Europe. Our headcount has grown from approximately 260 employees at the end of 2011 to approximately 650 employees in July 2012. This includes employees in approximately ten countries in the EU, a European commercial presence, and a complex distribution network of products in the EU and additional territories. Prior to these transactions, our core business had very limited exposure to international risks. In addition, we may expand our international operations into other countries in the future, either

organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, because we are conducting a larger portion of our business outside of the United States, we are now subject to a variety of risks and complexities that may materially and adversely affect our business, results of operations and financial condition, including, among other things:

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

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Failure to effectively manage these risks could have a material adverse effect on our business.

In recent years, the global economy has been impacted by the effects of an ongoing global financial crisis, including the European sovereign debt crisis, which have has caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in the EU, could adversely affect our revenues, financial condition or results of operations, if, for example, our customers in Europe fail to pay or delay payments owed to us for our products.

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

In addition to Xyrem, we have a portfolio of marketed products, primarily acquired through the Azur Merger and the EUSA Acquisition. EUSA Pharma s lead oncology product, Erwinaze (called Erwinase in ex-U.S. markets), has been added to our portfolio. Erwinaze, a biologic product, is used in conjunction with chemotherapy to treat patients with acute lymphoblastic leukemia, or ALL, with hypersensitivity to *E. coli*-derived asparaginase. Erwinaze is exclusively licensed to us, and manufactured for us, by the U.K. Health Protection Agency, or HPA, a public body company, and was approved by the FDA under a biological license application, or BLA, in November 2011 and launched in the U.S. market the same month. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in the EU and elsewhere.

Erwinaze represents an important part of our strategy to grow sales of our existing products. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of challenges, including our need to apply for and receive marketing authorizations in additional countries so we can launch promotional efforts in those countries and the limited population of patients with ALL and the incidence of hypersensitivity reactions to *E. coli*-derived asparaginase within that population. We face numerous risks that may impact Erwinaze sales, including manufacturing risks, regulatory risks, the development of new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL, the development of new treatment protocols for ALL that may not include asparaginase-containing regimens, difficulties with obtaining and maintaining profitable pricing and reimbursement arrangements and potential competition from biosimilar products. If we fail to comply with our obligations under our agreement with the HPA and lose exclusive rights to Erwinaze, or otherwise fail to maintain and grow sales of Erwinaze, our growth prospects could be negatively affected.

In the Azur Merger, we acquired our lead pain product, Prialt, an intrathecal infusion of ziconotide, approved by the FDA in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. We face many challenges in maintaining and growing sales of Prialt, including acceptance of intrathecal administration by patients and physicians and challenges for physicians with timely reimbursement for use of Prialt, due in part to its current distribution system. We are assessing the distribution system for Prialt and are considering implementing a new distribution strategy. If we do so, we could experience a disruption in delivery of Prialt, which could negatively affect product sales.

Failure to maintain or increase prescriptions and revenue from sales of our marketed products other than Xyrem, including Erwinaze and Prialt, could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We may choose to increase the price of our other marketed products, and we cannot assure you that price adjustments will not negatively affect our sales volumes. In addition, sales of Erwinaze, which was launched in the United States in the last year, may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the dosing requirements of treated patients and other factors, and it may be difficult for us to estimate Erwinaze revenue until we have more experience selling the product. The market price of our ordinary shares may decline if the sales of our products do not continue or grow at the rates anticipated by financial analysts or investors.

In addition, if we fail to obtain approvals for certain of our existing products in new indications or formulations, or if we fail to successfully develop and receive approval for new product candidates, including our product candidate Asparec, we will be unable to commercialize our products in new indications or formulations and will be unable to obtain any financial benefit from such product candidates, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredient and the finished product in sufficient quantities and meeting detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with specifications and strictly enforced U.S., state and foreign regulations.

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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. The availability of our products for commercial sale depends upon our ability to procure the ingredients, packaging materials and finished products we need from third parties. In part due to the limited market size for our products and product candidates, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers.

We maintain limited inventories of certain of our products. If our suppliers and contract manufacturers, including any new suppliers without a track record of meeting our supply needs, for any reason do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, if one of our suppliers or 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 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 or similar international regulatory body approval of a new active pharmaceutical ingredient supplier or product manufacturer.

The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem, sodium oxybate, is a Schedule I controlled substance, our supplier of sodium oxybate, as well as our finished product manufacturer, must each obtain separate DEA quotas in order to supply us with sodium oxybate and Xyrem. Since the DEA typically grants quotas on an annual basis 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 sufficient quota will be received 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.

In addition, the FDA and similar international regulatory bodies must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. If there are delays in qualifying new manufacturers or facilities or a new manufacturer is unable to obtain a sufficient quota from the DEA, if required, or to otherwise meet FDA or similar international regulatory body s requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates.

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

We are in the process of changing our supplier for ziconotide, the active ingredient in Prialt, and our supplier of the finished Prialt product. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for finished product for a number of years. We have also identified and begun the transfer of Prialt finished product manufacturing to a new manufacturer. The current manufacturer has completed the manufacture of final batches of Prialt, and our current supply is expected to be sufficient to meet commercial requirements for Prialt through the end of 2013, by which time we expect a new manufacturer to be approved as a supplier by the FDA. Similarly, 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, which we expect to be completed in 2012. There can be no assurance that the new manufacturers of ziconotide, Prialt, FazaClo LD and FazaClo HD, or any other manufacturer, will be approved by the FDA, or that our commercial supplies of such products will be sufficient until such manufacturers or other manufacturers have been approved, and any failure to obtain and maintain sufficient commercial supplies would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Erwinaze is licensed to us, and manufactured for us, by the HPA, which is our sole supplier for Erwinaze. During the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma agreed to a number of post marketing commitments related to the manufacture of Erwinaze by HPA. In the past, there has been a disruption of supply of Erwinase in the European market due to manufacturing challenges.

Failure by HPA to comply with regulatory requirements, including post marketing commitments, could adversely affect its ability to supply Erwinaze to us and could result in FDA approval being revoked or product recalls, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of

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the market for this product. We cannot assure you that HPA will be able to continue to supply our ongoing commercial needs of Erwinaze in a timely manner, or at all. We do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as uncured material breach by the HPA or the cessation of its business. Any failure of HPA to supply necessary quantities of Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, if the FDA or any foreign regulatory authority mandates any changes to the specifications for Erwinaze, we may face challenges having product produced to meet such specifications, and HPA may charge us more to supply Erwinaze meeting such specifications, which may result in additional costs to us and may decrease any profit we would otherwise achieve with Erwinaze.

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 and similar authorities in foreign jurisdictions. Failure to comply with applicable legal requirements subjects the suppliers to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need. Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products, or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

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

We intend to grow our business over the long term by acquiring or in-licensing and developing additional products and product candidates that we believe have significant commercial potential. Future growth through acquisition or in-licensing will depend upon the availability of suitable acquisition or in-license products and product candidates on acceptable prices, terms and conditions. Any growth through development will depend upon our identifying and obtaining product candidates, our ability to develop those product candidates and the availability of funding to complete the development of, obtain regulatory approval for and commercialize these product candidates. As a result of the EUSA Acquisition, we added several new projects and product candidates to our development pipeline, including the product candidate Asparec, which was licensed by EUSA Pharma from Alizé Pharma II, or Alizé, in 2009. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities.

We cannot assure you that we will be able to successfully manage these risks or other anticipated and unanticipated problems in connection with integrating any products and product candidates we may acquire or develop in the future, 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.

The commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.*

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

- the clinical indications for which a product is approved, including any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;

perceived advantages over alternative treatments;

relative convenience and ease of administration;

the cost of treatment in relation to alternative treatments, including generic products;

the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and

the availability of adequate reimbursement by third parties.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, from time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use,

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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.

Negative publicity resulting from our receipt of a Form FDA 483 in May 2012 and warning letter from the FDA in October 2011, or other related regulatory actions, could adversely affect sales of Xyrem.

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

The network through which we sell some of 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 27% of our total revenue during the quarter ended June 30, 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, including larger sales organizations and more experience working with large and diverse product portfolios, than we have.*

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

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

As a result of the EUSA Acquisition, we recently added Erwinaze, as well as other smaller products in the oncology supportive care market. We compete with other pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in the oncology and oncology supportive care markets, and our failure to compete effectively in this area could negatively affect our sales of Erwinaze and other products.

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

As a result of the EUSA Acquisition, we added several new projects and product candidates to our development pipeline, including clinical testing of the intravenous administration of Erwinaze for approval in the United States and of the product candidates Asparec and Leukotac. In addition, we are continuing to pursue development of Clozapine OS, an oral suspension formulation of clozapine. We intend to pursue clinical development of other product candidates in the future. Significant clinical, development and financial resources will be required to progress these product candidates to obtain necessary regulatory approvals and to develop them into commercially viable products. If a product candidate fails at any stage of development, it will not receive regulatory approval, we will not be able to commercialize it, or potentially even to continue to receive modest revenue being generated as a result of sales under a named patient program, such as in the case of Leukotac, and we will not

receive any return on our investment from that product candidate.

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

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

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

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

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

We are conducting and may in the future conduct additional clinical studies of our products in different diseases or conditions or with additional or different doses or dosage forms of our products, such as our efforts to obtain approval for the intravenous administration of Erwinaze, which is intended to provide more convenient dosing for patients. These development efforts may not be successful, and any adverse events or other information generated during the course of our studies related to existing products could result in action by the FDA or any foreign regulatory agency, which may restrict our ability to sell, or sales of, currently marketed products, or such events or other information could otherwise have a material adverse effect on a commercial product related to a product candidate we are developing. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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 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

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requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and foreign regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its foreign counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or foreign regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA s cGMP regulations and similar regulations outside of the United States. Our failure, or the failure of our 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 the members of our executive management team or our board of directors, our operations, the success of our integration activities following the Azur Merger and the EUSA Acquisition and our future growth may be adversely affected.*

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team and other critical personnel, all of whom work on many complex matters that are essential to our success. We do not carry key person insurance. The loss of services of one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities. In particular, our success in integrating the historical businesses of Jazz Pharmaceuticals, Inc., Azur Pharma and EUSA Pharma will depend, in part, on retaining key employees, including those with important institutional knowledge, from those entities. Such employees might experience uncertainty about their future roles in the combined enterprise which may adversely affect our ability to retain them. Any employee may terminate his or her employment at any time without notice or with only a few months notice and without cause or good reason.

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

We also depend on the unique abilities, industry experience and institutional knowledge of the members of our board of directors to efficiently set company strategy and effectively guide our executive management team. Since the Azur Merger, we have experienced and continue to experience board turnover. We cannot be certain that these changes or future board turnover will not negatively affect our business in the future.

Risks Related to Our Intellectual Property

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

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

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions 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. Although Xyrem is covered by patents covering its formulation, distribution system and method of use, a third party is seeking to introduce a generic equivalent of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem. Once orphan drug exclusivity in the United States for Xyrem for the treatment of excessive daytime sleepiness in patients

with narcolepsy expires in November 2012, other companies could possibly introduce generic versions of Xyrem if they do not infringe our patents or if they can demonstrate that our patents are invalid or unenforceable, and they receive FDA approval.

On October 18, 2010, we received notice that Roxane filed an ANDA with the 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

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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 decrease. We have sued Roxane to prevent Roxane from introducing a generic version of Xyrem in violation of our patents, 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.

On May 18, 2012, we submitted a Citizen Petition to the FDA requesting that the FDA include in the Orange Book bioequivalence requirements specifying whether *in vitro* bioequivalence studies, or *in vivo* bioequivalence studies, or both, are required for ANDAs referencing Xyrem. In this Citizen Petition, we also asked the FDA not to accept for review, review or approve any ANDA referencing Xyrem until such requirements are published in the Orange Book, and to require *in vivo* bioequivalence studies for any sodium oxybate drug product seeking approval under an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On July 10, 2012, we submitted a second Citizen Petition to the FDA, asking the FDA to rescind acceptance of any previously filed ANDA referencing Xyrem, and not to accept any future ANDA referencing Xyrem, unless such ANDA contains, at the time of acceptance for review, a proposed risk management system demonstrating that the proposed generic product would have the same labeling and condition of use of Xyrem. We cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, either of our Citizen Petitions, or the effect of any such response or action on the timing of the potential introduction of a generic version of Xyrem or the ongoing litigation between us and Roxane.

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 for FazaClo LD commenced in July 2012; the sublicense for FazaClo HD will commence in May 2015 or earlier upon the occurrence of certain events. In August 2011, Azur Pharma received a Paragraph IV certification notice from Teva advising that Teva had filed an ANDA with the FDA seeking approval to market a generic version of FazaClo HD. As noted above, FazaClo HD was covered under the July 2011 settlement agreement with Teva. In the July 2011 settlement agreement, Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma s rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. Teva has exercised its option for supply of an authorized generic product for FazaClo LD, and we are addressing the FDA requirements to permit a launch of the authorized generic product. Introduction of an authorized generic product for FazaClo LD in the market, which we expect could occur this year, would have a negative impact on our sales of FazaClo LD.

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.

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, financial condition, results of operations and growth prospects.

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

others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;

we or our licensors or partners might not have been the first to 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;

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

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

our pending patent applications may not result in issued patents;

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

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

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

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

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

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. For example, Erwinaze has no patent protection, and we therefore must rely on trade secrets and other unpatented proprietary information in order to obtain a competitive advantage. Erwinaze, as a biologic product approved under a BLA, is subject to the U.S. Biologics Price Competition and Innovation Act, or BPCIA. The BPCIA establishes a period of 12 years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a 12-year period. While Erwinaze has orphan drug marketing exclusivity for a seven-year period from its FDA approval in the United States through 2018, and data exclusivity in the United States through 2023 under the BPCIA, it is possible that a potential competitor might obtain earlier approval from the FDA based upon an approval application that does not rely on or refer to data in our BLA for Erwinaze. If a biosimilar product to Erwinaze is approved in the future in the United States or in other countries where it is sold, a significant percentage of the prescriptions written for Erwinaze may be filled with the biosimilar version, resulting in a loss in sales of Erwinaze, and there may be decrease in the price at which Erwinaze can be sold. Competition from a biosimilar product to Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, our product candidate Asparec is not covered by any issued patents, although there is one patent application pending before the United States Patent Office. We therefore must rely on trade secrets and other unpatented proprietary information in order to obtain a competitive advantage. Asparec was granted orphan drug designation by the FDA subject to certain conditions. If we fail to meet those conditions, Asparec may not obtain orphan drug marketing exclusivity and/or data exclusivity, and if we also fail to successfully execute on other strategies to protect our intellectual property with respect to Asparec, including protection by one or more issued patents, Asparec would be subject to competition from a biosimilar product which could have a material adverse effect on our ability to recognize any return on our investment in the development of this product as well as on our future growth prospects.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do

not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our research and development collaborators over the ownership of rights to jointly developed intellectual property. Such disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

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

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and 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.

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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.

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

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

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many 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.

We own patents and trade secrets that cover the Xyrem Success Program. In 2008, following the implementation of the FDAAA, we filed a supplement conforming the elements of the Xyrem Success Program to the new REMS formatting requirements and seeking approval of the document. We have had communications with the FDA with respect to our submitted REMS document, but we cannot assure you that the FDA will agree with the updated REMS document we submitted, and we cannot predict the timing of their response. The FDA may impose new and onerous requirements under the new REMS structure that could make it more difficult or expensive for us to distribute Xyrem, make competition easier and/or negatively affect the commercial success of Xyrem. In addition, the regulatory scheme that governs REMS programs is complex, and includes provisions that favor operation of a single shared REMS for the holder of the NDA and a generic product, and that encourages generic companies to seek a license if the NDA holder s REMS program is protected by intellectual property. The FDAAA further specifies that a REMS should not prevent generic drugs from entering the market and includes provisions that provide considerable relief for generic drug makers. Accordingly, we may face pressure to license or share the Xyrem Success Program with generic competitors in the future. We cannot predict the impact that any changes to the Xyrem Success Program would have on our business.

Risks Related to Our Industry

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

The research, testing, manufacturing, labeling, advertising and promotion, distributing and exporting of pharmaceutical products are subject to extensive regulation 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

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candidates. We are not permitted to market our product candidates in the United States or countries in the EU until we receive approval from the FDA or the applicable European authorities, respectively, of an application for approval in the form and containing the data and information required in the relevant jurisdiction. The application must contain all of the information on the drug or biological candidate gathered to that date, including data from the pre-clinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability. Submission of an application does not assure approval for marketing in any jurisdiction. Obtaining the FDA s or, to the extent applicable, the applicable European authorities approval of an NDA or a BLA can be a lengthy, expensive and uncertain process, and we may encounter significant difficulties or costs in our efforts to obtain approvals or approvals to market products in other jurisdictions as well. The FDA and the comparable authorities in jurisdictions outside of the United States have substantial discretion in the approval process and may disagree with an applicant s interpretation of the data submitted in the application. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

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

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

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, 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. The Healthcare Reform Act also makes changes to the Medicaid Drug Rebate Program, discussed further herein, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for innovator products and from 11% to 13% for non-innovator products.

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

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

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. Likewise, in the countries in the EU, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to health care cost containment and other austerity

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measures in the EU. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third-party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem voucher program and coupon programs for certain products. Within the past few months, the coupon programs of other pharmaceutical manufacturers have become the subject of ongoing lawsuits, and our coupon programs could become the target of similar lawsuits. In addition, coupon programs, including our program for Xyrem, have received some negative publicity. It is possible that the outcome of the pending litigation against other manufacturers and/or the introduction and enactment of new legislation could restrict or otherwise negatively affect these programs, which could result in fewer patients using affected products and therefore could have a material adverse effect on our sales, business and financial condition.

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

Oversight by FDA and Equivalent Foreign Regulatory Authorities

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, and recordkeeping for our products are, and any of our product candidates that may be approved by the FDA or EU and other foreign regulatory authorities will be, subject to extensive and ongoing regulatory requirements. Failure by us or any of our partners, including suppliers, manufacturers and distributors and our central pharmacy for Xyrem, to comply with applicable requirements could result in, among other things, one or more of the following actions: withdrawal of product approval, notices of violation, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution.

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

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

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

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

Some of our 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

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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.

We have not obtained marketing authorizations and/or may not have always sufficiently updated the marketing authorization approval dossiers for Erwinase and several other medicinal products or drugs in all of the countries in the EU in which we sell those products. For example, in some EU countries where we do not have a marketing authorization, Erwinase is being provided to patients on the basis of named patient programs or temporary use authorizations. In addition, we may not be able to maintain our marketing authorizations in all countries in which we currently have marketing authorizations. If any country s regulatory authorities determine that we are promoting Erwinase without a marketing authorization in place, we could be found to be in violation of pharmaceutical advertising law or the regulations permitting sales under named patient programs or temporary use authorizations, in which case we may be subject to financial or other penalties.

The FDA requires advertising and promotional labeling to be truthful and not misleading, and that products be marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA routinely provides its interpretations of that authority in informal communications and also in more formal communications such as untitled letters or warning letters, and although such communications are not final agency decisions, companies may decide not to contest the agency s interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful. If the FDA or other regulatory authorities were to challenge our promotional materials or activities, they may bring enforcement action, which may have a negative impact on our sales and/or may subject us to financial or other penalties.

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

Other Regulatory Authorities

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

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition, pursuant to the Export Administration Regulations, we are required to obtain a license from the U.S. Department of Commerce prior to the exportation of certain materials and technical information related to Prialt, a synthesized conotoxin, which is a designated controlled biological toxin.

The U.S. federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors

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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. Foreign governments often have similar regulations which we will also be subject to in those countries where we market and sell products.

Our business activities outside of the United States are subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act of 2010, which in some respects is more restrictive than the FCPA. The FCPA generally prohibits companies, either directly or through intermediaries, from giving payments or other inducements to public officials (broadly interpreted by U.S. enforcement authorities) for the purpose of obtaining or retaining business or securing any other improper advantage. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of foreign governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by the government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies.

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 the Physician Payment Sunshine provisions. The Physician Payment Sunshine provisions will require 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, either or both of which may be postponed to a later date. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Compliance with 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, in some cases, the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. For example, the FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular whether REMs may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMs or other practices are being used in an anticompetitive manner. Such a challenge or any challenge that we our are partners have failed to comply with laws and regulations could have a material adverse effect on our business, financial condition, results of operations and growth prospects. If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our ability to commercialize our products

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

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

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid supplemental rebate programs, and we have obligations to report average sales price for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the Centers for Medicare and Medicare Services, or CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug. Such data previously have not been submitted for our two radiopharmaceutical products, ProstaScint (capromab pendetide) and Quadramet (samarium 5m 153 Lexidronam Injection). We expect to begin reporting Medicaid pricing data and paying Medicaid rebates on these products effective later this year. Any additional rebate liability resulting from this reporting will negatively impact our revenues.

The PPACA made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organizations. With regard to the amount of the rebates owed, the PPACA increased the minimum Medicaid rebate for all drugs; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the 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 issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under PPACA and subsequent legislation but has not yet issued final regulations. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

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

These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 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. 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.

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

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average sales price, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the submission is late beyond the due date. 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 these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. 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 various legislation that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting by certain covered entity hospitals, where those drugs are used for the covered entity s uninsured inpatients.

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

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing to an agreed tracking customer is reduced. Further, in addition to the Big Four agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies negotiated pricing for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor s commercial most favored customer pricing. We offer one single FCP-based FSS contract price to all FSS purchasers for some products, while our other products have an FCP-capped price for the Big Four purchasers and a negotiated price for other FSS purchasers. Pursuant to regulations issued by the DoD TRICARE Management Activity, or TMA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, we have entered into a Section 703 Agreement with TMA under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the Annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

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

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

In both U.S. and foreign markets, our ability to commercialize our products successfully 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

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they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because some of our products compete in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only 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. Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has stated its intention to begin making pharmacy National Average Drug Acquisition Cost data publicly available on at least a monthly basis in 2012. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover products appropriately under our DoD pricing agreements, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the Federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressures in the United States 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. In the various EU countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. We have periodically increased the price of Xyrem, most recently in August 2012, and we have made and may in the future make similar price increases on our other products. We cannot assure you that such price adjustments will not negatively affect our ability to secure and maintain reimbursement coverage for our products, which could negatively impact our sales volumes.

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. Some of our products, including Xyrem, 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. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions,

limitations on the indications for which they may be used, or suspension or withdrawal of approval.

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Risks Relating to Our Financial Condition

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

As of June 30, 2012, we had approximately $475.0 million in secured debt outstanding, all of which was incurred under our new credit agreement entered into in connection with the EUSA Acquisition. Our debt may:

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

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

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

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

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;

make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;

enter into agreements that restrict distributions from our subsidiaries;

sell assets and capital stock of our subsidiaries;

enter into certain transactions with affiliates; and

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

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

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

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

the revenues from our commercial products, which may be affected by many factors, including the extent of generic competition for our products;

the costs of our commercial operations;

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- the costs of integration activities related to the Azur Merger and the EUSA Acquisition;
- the cost of acquiring and/or licensing any new products and product candidates;
- the scope, rate of progress, results and costs of our development and clinical activities;
- the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost of investigations, litigation and/or settlements related to regulatory oversight and third-party claims; and
- changes in laws and regulations, including, for example, healthcare reform legislation.

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

We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.*

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

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

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

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

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

For us to be treated as a foreign corporation for U.S. federal tax purposes under Section 7874 of the Code, either (1) the former stockholders of Jazz Pharmaceuticals, Inc. must have owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Jazz Pharmaceuticals, Inc., or (2) we must have substantial

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business activities in Ireland after the Azur Merger (taking into account the activities of our expanded affiliated group). The Jazz Pharmaceuticals, Inc. stockholders owned less than 80% of our share capital immediately after the Azur Merger by reason of their ownership of shares of Jazz Pharmaceuticals, Inc. common stock. As a result, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes.

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

Section 7874 of the Code 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. s 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 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.

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

As of June 30, 2012, we had recorded $1.4 billion of intangible assets and goodwill related to our past acquisitions. Intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

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

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

With the EUSA Acquisition, we now have significant operations in Europe as well as in the United States, but we report revenues, costs and earnings in U.S. dollars. Our primary currency translation exposures relate to our subsidiaries that have functional currencies denominated in the Euro and the British Pound Sterling, or GBP. Exchange rates between the U.S. dollar and each of the Euro and GBP are likely to fluctuate from period to period. Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the local currency financial statements of foreign subsidiaries are translated to U.S. dollars for reporting purposes. If we continue to expand our international operations, we will conduct

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more transactions in currencies other than the U.S. dollar. To the extent that foreign revenue and expense transactions are not denominated in the local currency, we are also subject to the risk of transaction losses. Given the volatility of exchange rates, there is no assurance that we will be able to effectively manage currency transaction and/or conversion risks. We have not entered into derivative instruments to offset the impact of foreign exchange fluctuations. Fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations and financial condition.

Risks Relating to Our Ordinary Shares

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

Investors who hold our ordinary shares may not be able to sell their shares at or above the price at which they purchased their ordinary shares (or the price at which they purchased their shares of Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger). The price of our ordinary shares has fluctuated significantly from time to time since the completion of the Azur Merger in January 2012, and the price of Jazz Pharmaceuticals, Inc. s common stock fluctuated significantly from time to time and increased substantially during 2011 and the first half of 2012. The risk factors described above relating to our business and products could cause the price of our ordinary shares to continue to fluctuate significantly. In addition, the stock market in general, including the market for life sciences companies, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our ordinary shares, regardless of our operating performance.

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

In addition, the market price of our ordinary shares may decline if the integration of the acquired Azur Pharma and EUSA Pharma 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 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 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 July 31, 2012, we had 57,536,632 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 July 31, 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 at the closing of the Azur Merger. 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 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, 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 we entered into with the holders of Azur Pharma s outstanding ordinary shares in January 2012, we filed a shelf registration statement with the SEC covering the resale of ordinary shares held by these holders following the closing of the Azur Merger to permit these holders to immediately resell their ordinary shares.

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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 July 31, 2012, our executive officers and directors, together with the shareholders with which our executive officers and directors were affiliated or associated as of such date, beneficially owned approximately 26% 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;
- 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.

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

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who holds our ordinary shares directly in his, her or its own name could be subject to this stamp duty. We, in our absolute discretion and insofar as the Irish Companies Acts or any other applicable law permit, may, or may provide that a subsidiary of ours will, pay Irish stamp duty arising on a transfer of our ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of our ordinary shares which would otherwise be payable by the transferee is paid by us or any of our subsidiaries on behalf of the transferee, then in those circumstances, we will, on our behalf or on behalf of our subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

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

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

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

On June 22, 2012, we issued 550,010 of our ordinary shares pursuant to the cash exercise of a warrant originally issued by Jazz Pharmaceuticals, Inc. in 2005, which warrant we assumed upon the closing of the Azur Merger. This warrant had an exercise price of $9.34 per share, resulting in gross proceeds to us upon exercise of $5,137,093. In issuing the above-mentioned shares, we relied on the exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering.

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Item 6. Exhibits.

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Public Limited Company (formerly Azur Limited Company), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan as Indemnitors Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc. s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.4 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

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4.5	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.6 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6A	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).
4.6B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.7	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	Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc, the Lenders and Barclays Bank PLC, as Administrative Agent, Collateral Agent, Swing Line Lender and L/C Issuer (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 June 12, 2012).
10.2	Lease, dated May 8, 2012, by and between John Ronan and Castle Cove Property Developments Limited and Jazz Pharmaceuticals plc.
10.3	Jazz Pharmaceuticals plc 2012 Executive Officer Compensation Arrangements.
10.4+	Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc.
10.5+	Noncompetition Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc.
10.6+	Amendment to Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc.
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10.10+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Ireland) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (updated as of July 27, 2012).
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS++	XBRL Instance Document
101.SCH++	XBRL Taxonomy Extension Schema Document
101.CAL++	XBRL Taxonomy Extension Calculation Linkbase Document

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

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

\+ Indicates management contract or compensatory plan.

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

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SIGNATURES

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

Dated: August 7, 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)

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