

Jazz Pharmaceuticals plc  
Form 10-K  
February 28, 2012  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
December 31, 2011 For the fiscal year ended December 31, 2011

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)

Filed on behalf of and as successor to Jazz Pharmaceuticals, Inc.

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

**Ireland**  
(State or other jurisdiction of incorporation or organization)  
**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)

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

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

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

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

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

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

This Annual Report on Form 10-K is being filed by the registrant on behalf of and as successor to Jazz Pharmaceuticals, Inc. The aggregate market value of the voting and non-voting stock held by non-affiliates of Jazz Pharmaceuticals, Inc. as of June 30, 2011, based upon the last sale price reported for such date on the NASDAQ Global Market, was \$769,138,777. The calculation of the aggregate market value of voting and non-voting stock excludes 18,625,735 shares of Jazz Pharmaceuticals, Inc. s common stock held by executive officers, directors, and stockholders that Jazz Pharmaceuticals, Inc. concluded were affiliates of Jazz Pharmaceuticals, Inc. on that date.

On January 18, 2012, all of the issued and outstanding shares of the Jazz Pharmaceuticals, Inc. s common stock, par value \$0.0001 per share, were canceled and automatically converted into and became the right to receive ordinary shares, nominal value \$0.0001 per share, of the registrant. As of February 21, 2012, a total of 56,243,783 ordinary shares, nominal value \$0.0001 per share, of Jazz Pharmaceuticals plc were outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement for the 2012 Annual General Meeting of Shareholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

**Table of Contents**

**EXPLANATORY NOTE**

This Annual Report on Form 10-K is being filed by the registrant on behalf of and as successor to Jazz Pharmaceuticals, Inc. The registrant is 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. In accordance with Rule 12g-3(g) under the Exchange Act, this Annual Report on Form 10-K covers the last full fiscal year of Jazz Pharmaceuticals, Inc. and contains information that would be required if filed by Jazz Pharmaceuticals, Inc., in addition to information regarding the registrant, as successor to Jazz Pharmaceuticals Inc., following the merger described below.

The registrant is an Irish public limited company that was formerly named Azur Pharma Public Limited Company. Pursuant to an Agreement and Plan of Merger and Reorganization, or Merger Agreement, dated as of September 19, 2011, as amended, a wholly-owned subsidiary of the registrant merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the merger and becoming a wholly-owned subsidiary of the registrant. The merger was consummated on January 18, 2012. Pursuant to the Merger Agreement, the registrant changed its name to Jazz Pharmaceuticals Public Limited Company (referred to herein as Jazz Pharmaceuticals plc), and each share of the common stock of Jazz Pharmaceuticals, Inc. issued and outstanding immediately prior to the effective time of the merger was canceled and automatically converted into and became the right to receive one ordinary share of the registrant. The registrant's 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 merger.

Jazz Pharmaceuticals, Inc. is treated as the acquiring company in the merger for accounting purposes and the transaction is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the historical financial statements of Jazz Pharmaceuticals, Inc. for the periods through the effective time on January 18, 2012 became the registrant's historical financial statements. The consolidated financial statements of Jazz Pharmaceuticals, Inc. included in this Annual Report on Form 10-K do not include any operations of Azur Pharma prior to the merger because the merger was consummated after the periods covered by the financial statements included in this Annual Report on Form 10-K. Although the historical financial statements of Jazz Pharmaceuticals, Inc. became the registrant's historical financial statements, because the merger was consummated after December 31, 2011, the registrant is also filing a separate Annual Report on Form 10-K that covers the last full fiscal year of Azur Pharma that include the historical financial statements of Azur Pharma, which will be filed under Azur Pharma's initial Commission File Number (333-177528). Accordingly, investors should review such separate Annual Report for information related to the historical results of operations and financial condition of Azur Pharma.

Unless otherwise indicated or the context otherwise requires, references to Jazz Pharmaceuticals, the registrant, we, us, and our refer to Jazz Pharmaceuticals plc, 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 merger on January 18, 2012. The historical financial information set forth in this Annual Report on Form 10-K, unless otherwise indicated or the context otherwise requires, reflects the consolidated results of operations and financial position of Jazz Pharmaceuticals, Inc. prior to the merger.

**Table of Contents**

**JAZZ PHARMACEUTICALS PLC**

**2011 ANNUAL REPORT ON FORM 10-K**

(filed on behalf of and as successor to Jazz Pharmaceuticals, Inc.)

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
Item 1. <u>Business</u>	4
Item 1A. <u>Risk Factors</u>	22
Item 1B. <u>Unresolved Staff Comments</u>	48
Item 2. <u>Properties</u>	48
Item 3. <u>Legal Proceedings</u>	48
Item 4. <u>Mine Safety Disclosures</u>	50
<b>PART II</b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	51
Item 6. <u>Selected Financial Data</u>	55
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	57
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	68
Item 8. <u>Financial Statements and Supplementary Data</u>	69
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	70
Item 9A. <u>Controls and Procedures</u>	70
Item 9B. <u>Other Information</u>	72
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	72
Item 11. <u>Executive Compensation</u>	73
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	73
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	73
Item 14. <u>Principal Accounting Fees and Services</u>	73
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	73
<u>Signatures</u>	81

In this report, unless otherwise indicated or the context otherwise requires, Jazz Pharmaceuticals, the registrant, we, us, and our refer to Jazz Pharmaceuticals plc, a public limited company formed under the laws of Ireland, 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



**Table of Contents**

Company) and its consolidated subsidiaries prior to the effective time of the merger referred to in the Explanatory Note above. The historical financial information set forth in this Annual Report on Form 10-K, unless otherwise indicated or the context otherwise requires, reflects the consolidated results of operations and financial position of Jazz Pharmaceuticals, Inc. prior to the merger.

We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, FazaClo® (clozapine, USP), Luvox CR® (fluvoxamine maleate) Extended-Release Capsules, Luvox® (fluvoxamine maleate), Prial® (ziconotide intrathecal infusion), Elestrin® (estradiol gel 0.06%), Urelle® (urinary antiseptic), Gesticare® (prenatal vitamin), Natelle® (prenatal vitamin), Gastrocrom® (cromolyn sodium oral concentrate), Niravam® (alprazolam), Parcopa® (carbidopa/levodopa), and AVC Cream (sulfanilamide). This report also includes trademarks, service marks, and trade names of other companies.

---

## **Table of Contents**

*This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, intend, potential and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading 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 Annual Report on Form 10-K 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.*

*Unless otherwise indicated or the context otherwise requires, all references herein to Jazz Pharmaceuticals, we, us, and our refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, including its predecessor Jazz Pharmaceuticals, Inc. All references to Azur Pharma are references to Jazz Pharmaceuticals plc (f/k/a Azur Pharma Public Limited Company) and its consolidated subsidiaries prior to the effective time of the merger described below.*

## **PART I**

### **Item 1. Business Overview**

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

Key elements of our strategy include:

*Growing and protecting our existing product franchises;*

*Acquiring or in-licensing additional marketed or close to approval products; and*

*Pursuing development of additional specialty products.*

### **The Merger; Historic Businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma**

On January 18, 2012, Azur Pharma and Jazz Pharmaceuticals, Inc. completed a merger transaction pursuant to which we were re-named Jazz Pharmaceuticals plc and became the parent company of and successor to Jazz



---

## **Table of Contents**

Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. becoming our wholly-owned subsidiary. In the merger, all outstanding shares of Jazz Pharmaceuticals, Inc. s common stock were canceled and converted into the right to receive, on a one-for-one basis, our ordinary shares. Our ordinary shares trade on the same exchange, The NASDAQ Global Select Market, and under the same trading symbol, JAZZ, that the shares of Jazz Pharmaceuticals, Inc. s common stock traded on and under prior to the merger. Jazz Pharmaceuticals, Inc., a Delaware corporation, was incorporated in California in March 2003 and reincorporated in Delaware in January 2004. Prior to the merger, Jazz Pharmaceuticals, Inc. marketed its two products, Xyrem and Luvox CR, through its experienced specialty sales force targeting sleep specialists, neurologists, pulmonologists and psychiatrists. Prior to the merger, Azur Pharma was a specialty pharmaceutical company engaged in the acquisition, development and commercialization of therapeutic products for the central nervous system and women s health areas. Azur Pharma s lead marketed products were FazaClo LD and FazaClo HD, and Prialt. Azur Pharma also marketed several women s health products, including Elestrin and the prescription prenatal vitamin brands Natelle and Gesticare. Azur Pharma also sold a portfolio of non-promoted products including Gastrocrom (cromolyn sodium), Niravam (orally disintegrating tablet presentation of alprazolam), Urelle (urinary antiseptic), Parcopa (orally disintegrating tablet presentation of carbidopa/levodopa) and AVC (sulfanilamide) cream.

Jazz Pharmaceuticals, Inc. is treated as the acquiring company in the merger for accounting purposes, and the merger is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the consolidated financial statements of Jazz Pharmaceuticals, Inc. became our consolidated financial statements. The consolidated financial statements included in this Annual Report on Form 10-K do not cover any operations of Azur Pharma prior to the merger because the merger was consummated after the periods covered by the financial statements included in this Annual Report on Form 10-K. Accordingly, the historical financial information included in this Annual Report on Form 10-K, unless otherwise indicated or the context otherwise requires, is that of Jazz Pharmaceuticals, Inc. prior to the merger.

### **Marketed Products**

#### ***Xyrem (sodium oxybate) oral solution***

Xyrem is the only treatment approved by the FDA for both excessive daytime sleepiness and cataplexy in patients with narcolepsy. Sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a formulation of the sodium salt of g-hydroxybutyrate, an endogenous neurotransmitter and metabolite of g-aminobutyric acid. Xyrem was approved for the treatment of cataplexy in patients with narcolepsy in 2002, and was approved for its second indication, the treatment of excessive daytime sleepiness in patients with narcolepsy, in 2005. The American Academy of Sleep Medicine recommends Xyrem as a standard of care for the treatment of both excessive daytime sleepiness and cataplexy associated with narcolepsy.

Narcolepsy is a chronic neurologic disorder caused by targeted loss of neurons that use the neurotransmitter hypocretin (also known as orexin), which is hypothesized to stabilize sleep-wake states. The primary symptoms of narcolepsy include excessive daytime sleepiness, cataplexy, sleep paralysis, sleep-onset and sleep-offset hallucinations and fragmented nighttime sleep. These symptoms can lead to a variety of complications for the patient, such as limitations on education and employment opportunities, driving or machinery accidents, difficulties at work resulting in disability, forced retirement or job dismissal. Several significant medical comorbidities are also common in narcolepsy, including obstructive sleep apnea, obesity, bipolar disorder and depression. Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. Excessive daytime sleepiness is characterized by chronic, pervasive sleepiness as well as sudden irresistible and overwhelming urges to sleep (inadvertent naps and sleep attacks). Cataplexy, the sudden loss of muscle tone, can be one of the most debilitating symptoms of narcolepsy. Cataplexy is present in approximately 70% of patients with narcolepsy. Cataplexy can range from slight weakness or a drooping of the face to the complete loss of muscle tone resulting in collapse. Cataplexy is often triggered by strong emotions such as laughter, anger or surprise. Cataplexy can severely impair a patient s quality of life and ability to function.

According to the American Sleep Association, about 150,000 to 200,000 people in the United States are affected by narcolepsy and only approximately 25% of those people have been definitively diagnosed with

## **Table of Contents**

narcolepsy. Xyrem is currently being used to treat over 9,000 patients in the United States, and we believe there are significantly more patients with narcolepsy and cataplexy and/or excessive daytime sleepiness who might benefit from treatment with Xyrem.

In 2011, net product sales of Xyrem were \$233.3 million.

### *Commercialization and Distribution*

We promote Xyrem in the United States through a specialty sales force. Our marketing, sales and distribution of Xyrem are subject to a risk management plan which was required in conjunction with Xyrem's approval by the FDA.

Under the Xyrem risk management plan, the Xyrem Success Program<sup>®</sup>, Xyrem is distributed through a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or ESSDS, with which we have an exclusive relationship. The central pharmacy maintains physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient receives materials concerning the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and obtains additional information by contacting the patient's insurance company. The central pharmacy also speaks with the patient before it ships Xyrem to the patient. The central pharmacy ships the product directly to the patient by a courier service, and the patient or his/her designee signs for the package. The initial shipment may only be for a one-month supply and physicians may only prescribe up to six months of supply of Xyrem at one time.

Pursuant to our exclusive agreement, ESSDS distributes Xyrem and provides customer support services related to the sales and marketing of Xyrem in the United States. Our agreement, which has been in effect since July 2002, expires on June 30, 2015, subject to automatic two-year extensions unless either party provides notice to the other of its intent to terminate the agreement. Under the agreement, we own all of the standard operating procedures, business rules and intellectual property, and the agreement provides for ESSDS to assist in the orderly transfer of the services ESSDS provides to us and the related intellectual property, including that of the patient database, to any new pharmacy we engage.

Outside the United States, we have licensed to UCB Pharma Limited, or UCB, the exclusive right to market Xyrem for the treatment of narcolepsy in 54 countries in exchange for milestone and royalty payments to us. UCB currently markets the product in 15 countries in Europe. We have licensed to Valeant Canada Limited, or Valeant, the Canadian marketing rights to Xyrem for the treatment of narcolepsy. We supply Xyrem to UCB and Valeant.

Xyrem is a controlled substance in the United States and therefore its manufacturing and distribution are highly restricted. Quotas from the United States Drug Enforcement Administration, or DEA, are required in order to manufacture and package sodium oxybate. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for the request, obtaining a DEA quota has been a difficult and time consuming process. The final product and active pharmaceutical ingredient are manufactured for us by single source contract manufacturers. We have patents covering Xyrem, the last to expire of which expires in 2024. We are currently involved in litigation with a third party that filed an abbreviated new drug application, or ANDA, seeking FDA approval to market a generic version of Xyrem.

### *Psychiatry Products*

#### **FazaClo LD (clozapine, USP) Orally Disintegrating Tablet and FazaClo HD (clozapine, USP) Orally Disintegrating Tablet**

We market FazaClo LD and FazaClo HD, which are orally disintegrating tablet formulations of clozapine, indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard

---

## **Table of Contents**

drug treatment for schizophrenia and for reduction in the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state. FazaClo LD, comprising the original three lower strength presentations, was approved by the FDA in February 2004 with respect to the 25mg and 100mg tablet strengths and in May 2007 for the 12.5mg tablet strength. Azur Pharma initiated development of FazaClo HD, 150 mg and 200 mg dosage strengths, in late 2008. FazaClo HD received FDA approval in July 2010 and was launched in September 2010. Azur Pharma acquired the rights to FazaClo LD from Avanir Pharmaceuticals, Inc., or Avanir, in August 2007.

According to IMS Health Inc., or IMS, the U.S. clozapine market is dominated by generics which accounted for approximately 88% of clozapine prescription volumes in 2011. FazaClo products accounted for approximately 9% of clozapine prescription volumes in 2011. The generics are referenced to Clozaril, a standard immediate release tablet formulation of clozapine from Novartis. FazaClo LD and FazaClo HD incorporate the DuraSolv® orally disintegrating tablet technology we license from CIMA Labs Inc., or CIMA, now a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, which enables the products to dissolve without the need to chew or to swallow with water. FazaClo LD and FazaClo HD are currently the only orally disintegrating tablet formulations of clozapine available in the United States.

We promote FazaClo LD and FazaClo HD in the United States through a specialty sales force, with the support of our in-house registry team located in our Philadelphia office. Patients being prescribed any clozapine product must be enrolled in an FDA-approved patient registry. The FazaClo patient registry, an element of the FDA's mandated risk management plan, is a database monitoring patients' white blood cell counts, or WBC, and absolute neutrophil counts, or ANC, to permit early detection of clozapine-induced leucopenia or agranulocytosis. The registry team maintains a continuing record of total WBC and ANC and related information in the database for all patients who receive FazaClo therapy. All clozapine patients must have frequent monitoring for acceptable WBC and ANC levels which the pharmacist must verify prior to dispensing a clozapine prescription. Weekly blood samples are monitored for the first six months of treatment, and bi-weekly testing is required for the second six months with monthly monitoring for patients who have 12 months of acceptable blood test results.

We have a team of compliance liaisons, located throughout the country, who provide FazaClo patient registry support services for FazaClo.

Three generic manufacturers have filed ANDAs requesting permission to market generic versions of FazaClo LD, and one of them, Teva, has also filed an ANDA requesting permission to market a generic version of FazaClo HD. Azur Pharma brought lawsuits against all of them, and settled the suit with Teva in 2011. Under the settlement, Teva was granted a sublicense of our rights to have manufactured, market and sell a generic version of FazaClo LD and FazaClo HD, commencing in July 2012 and May 2015, respectively, or earlier upon the occurrence of certain events.

### **Luvox CR (fluvoxamine maleate) Extended-Release Capsules**

We market Luvox CR for the treatment of obsessive compulsive disorder. Luvox CR received FDA approval in 2008. Luvox CR incorporates the SODAS® drug delivery technology, developed by Elan Pharma International Limited, or Elan, which subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes. The product is designed to minimize peak-to-trough plasma fluctuations over a 24-hour period and enable once-a-day dosing.

Obsessive compulsive disorder is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health, obsessive compulsive disorder affects approximately 2.2 million adults in the United States. According to

---

## **Table of Contents**

an article published in the *International Journal of Clinical Practice*, it is estimated that 60% of patients with obsessive compulsive disorder worldwide receive no treatment for their disorder. Patients with obsessive compulsive disorder use rituals to help control anxiety related to their obsessive thoughts, and these rituals become disruptive to their daily life.

We acquired the rights to market Luvox CR in the United States from Solvay Pharmaceuticals, Inc., or Solvay, which was subsequently acquired by Abbott Laboratories, or Abbott. Solvay assigned to us its rights and obligations under its license and supply agreement with Alkermes, and we sublicensed back to Solvay the rights under that agreement outside of the United States. Luvox CR is not currently marketed outside the United States.

Three companies have filed ANDAs requesting FDA approval to market a generic version for Luvox CR, and we sued all three companies. We have settled the suit against one of the companies, Anchen Pharmaceuticals, Inc. (now owned by Par Pharmaceutical Companies, Inc.), as a result of which a generic version of Luvox CR could be introduced as early as February 2013, if it receives FDA approval.

### ***Prialt (ziconotide) intrathecal infusion***

Prialt is 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. Intrathecal therapy is the delivery of the drug into the intrathecal space in the spine through an infusion system comprised of a programmable infusion pump and catheter. Ziconotide is a synthetic neuroactive peptide known as conotoxin and is the synthetic equivalent of a naturally-occurring conopeptide found in the piscivorous marine snail, *Conus Magus*. Ziconotide is thought to inhibit pain signals transmitted via N-type calcium channels, most densely located in the dorsal horn of the spinal cord, although the precise mechanism of action in humans is unknown. For most patients who achieve good pain relief and tolerability, pain relief can be maintained over time without dose increases or cumulative toxicity. Prialt is the only FDA-approved non-opioid intrathecal analgesic. Prialt is approved for use with Medtronic Inc.'s SynchroMed EL and SynchroMed II programmable implantable pumps.

Azur Pharma acquired the rights to Prialt from Elan in May 2010. Pursuant to an asset purchase agreement executed between Azur Pharma and Elan in April 2010, Azur Pharma acquired worldwide rights to Prialt excluding those territories licensed by Elan to Eisai Co. Limited, which consist of 34 countries outside of the United States, mainly in Europe. Azur Pharma paid Elan \$5 million on the closing of the transaction, with an additional \$12 million in deferred payments due to Elan from us in 2012. We are also obligated to pay up to a maximum aggregate amount of \$120 million in contingent payments if certain net sales milestones are achieved and a tiered royalty payment on net sales.

We promote Prialt through a specialty sales force. We provide reimbursement support through our Express Pain Information Center, a dedicated Prialt call center outsourced to a third party reimbursement specialist vendor. Our internal reimbursement team provides additional reimbursement support, dealing specifically with the more complex needs of physicians and payors.

### ***Women's Health and Other Products***

We also sell a portfolio of women's health and other products, including:

Elestrin (estradiol gel 0.06%), indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes and night sweats) associated with menopause;

Natelle and Gesticare prescription prenatal vitamins franchises, used to support the nutritional status of women through pregnancy and in the postnatal period;

Urelle, indicated for the treatment of symptoms of irritative voiding and for the relief of local signs and symptoms, such as inflammation, hypermotility and pain that accompany lower urinary tract infections;

## **Table of Contents**

Gastrocrom (cromolyn sodium) oral concentrate, indicated for the management of patients with mastocytosis, providing relief of associated symptoms such as diarrhea, flushing, headaches, vomiting, urticaria, abdominal pain, nausea and itching;

Niravam (orally disintegrating tablet presentation of alprazolam), indicated for the management of anxiety disorder or the short-term relief of symptoms of anxiety and also indicated for the treatment of panic disorder, with or without agoraphobia;

Parcopa (orally disintegrating tablet presentation of carbidopa/levodopa), indicated for the treatment of symptoms associated with idiopathic Parkinson's disease; and

AVC (sulfanilamide) cream, indicated for the treatment of vulvovaginitis caused by *Candida albicans*.

We promote Elestrin and our prenatal vitamin brands, Natelle and Gesticare, in the United States through a specialty sales force.

## **Clinical Development Pipeline**

Our current product candidates are Clozapine OS and Clozapine QD, development of which was initiated by Azur Pharma. Clozapine OS is an oral suspension formulation of clozapine currently approved and marketed by other companies in Europe and in other territories outside of the U.S. Azur Pharma licensed U.S. rights for the product candidate from Douglas Pharmaceuticals America Limited in February 2010. Clozapine OS successfully completed its pivotal bioequivalence study in October 2011 and a new drug application, or NDA, was submitted to the FDA in December 2011. Clozapine QD is being developed to provide the benefits of once-daily dosing of clozapine and has been evaluated in four Phase I studies.

## **Sales and Marketing**

As of February 21, 2012, our commercial activities were divided among our marketed products as follows: Xyrem, psychiatry products (FazaClo LD and HD and Luvox CR), Prialt, and women's health and other products (Elestrin and prenatal vitamin brands Natelle and Gesticare). We have approximately 195 carefully-trained, experienced sales professionals who detail our products to physicians in specialties appropriate for each product. Our commercial activities also include marketing and related services and commercial support services such as commercial operations, managed markets, and commercial analytics.

We also employ third party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support related services to assist with our commercial activities.

## **Competition**

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies as well as specialty pharmaceutical companies that market psychiatry, neurology, pain and women's health products. Many of these companies have financial resources and marketing capabilities substantially greater than ours. Our ability to continue to grow over the long-term also requires that we compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. Some of these competitors include Valeant, Shire Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., Forest Laboratories, Inc., and Teva. These established companies may have a competitive advantage over us due to their size and financial resources.

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

*Xyrem*. Xyrem is the only product approved for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. No products other than Xyrem are approved for the treatment of



---

## Table of Contents

cataplexy. The only other products approved by the FDA for the treatment of excessive daytime sleepiness in patients with narcolepsy are Provigil® (modafinil) and Nuvigil® (armodafinil), which are marketed by Cephalon, Inc, now part of Teva. Provigil and Nuvigil are also approved for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder. Xyrem is often used in conjunction with stimulants and wakefulness promoting drugs, which are administered during the day. During the pivotal Phase III trials of Xyrem for use in patients with narcolepsy, approximately 80% of patients maintained concomitant stimulant use.

As alternatives to Xyrem, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, or SSRIs, or selective norepinephrine reuptake inhibitors, or SNRIs, although these products are not approved by the FDA for the treatment of cataplexy. Tricyclic antidepressants are a class of antidepressant drugs first used in the 1950s. The use of these drugs can often result in somnolence, which exacerbates the excessive daytime sleepiness already experienced by all patients with narcolepsy. SSRIs and SNRIs are compounds typically used for the treatment of clinical depression. Somnolence and insomnia are commonly reported side effects with SSRIs while loss of sleep is a commonly reported side effect with SNRIs. These side effects may be problematic for patients with narcolepsy.

*FazaClo LD and FazaClo HD.* FazaClo LD and FazaClo HD are the only orally disintegrating tablet formulations of clozapine available. While FazaClo is a branded product currently with no direct generic competition, the bulk of prescriptions for clozapine are generic tablets. These products also compete with larger branded products, including Seroquel®, marketed by AstraZeneca, Risperdal®, marketed by Janssen, and Zyprexa®, marketed by Eli Lilly.

*Luvox CR.* The market for drugs to treat obsessive compulsive disorder is very fragmented. We believe that, in addition to Luvox CR, a large number of branded and generic drugs are used for the treatment of this disorder. Seven branded products, including Luvox CR, and generic equivalents of many of these, have been approved by the FDA for the treatment of obsessive compulsive disorder, and we believe that other products are regularly used to treat this disorder. We believe that none of these products has a significant percentage of the market. The presence in a particular patient of more than one psychiatric condition is an important consideration by physicians in the selection of drugs to treat obsessive compulsive disorder. Certain drugs are approved for one or more well recognized psychiatric disorders such as major depressive disorder, which may give them broader recognition and use by physicians and patients than Luvox CR.

*Prialt.* Prialt is the only FDA-approved non-opioid intrathecal analgesic. It competes with intrathecal morphine, which is the only other product approved by the FDA for the intrathecal treatment of severe chronic pain. Other drugs are also used intrathecally by physicians, including: hydromorphone, clonidine, baclofen and sufentanil.

*Women's Health and Other Products.* Our women's health and other products face competition from both generic entrants and existing branded products. Some of our women's health and other products have limited or no patent protection and potential competitors face fewer barriers in introducing competing products or generic products. On October 27, 2011, an ANDA from Pack Pharmaceuticals LLC, seeking to manufacture and sell a generic version of Gastrocrom, was approved by the FDA, and a generic version of Gastrocrom has since been launched. There may also be other companies developing products competitive to our products.

*Product Candidates.* With respect to our current and potential future product candidates, we believe that our ability to successfully compete will depend on, among other things:

- efficacy, safety and reliability of our product candidates;
- product acceptance by physicians, other health care providers and patients;

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

- protection of our proprietary rights and the level of generic competition;
- obtaining reimbursement for product use in approved indications;



## **Table of Contents**

- our ability to complete clinical development and obtain regulatory approvals for our product candidates;
- the timing and scope of regulatory approvals;
- our ability to supply commercial quantities of a product to the market; and
- our ability to recruit and retain skilled employees.

## **Customers and Financial Information about Geographic Areas**

In the United States, Xyrem is sold to one specialty pharmacy which ships Xyrem directly to patients. During 2011, the specialty pharmacy for Xyrem was ESSDS. Outside the United States, UCB Pharma is our European commercial partner for Xyrem.

Our other products are sold primarily to distributors who distribute the product to pharmacies in the United States. In 2011, the principal distributors for our products in the United States were Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Corporation and its subsidiary Integrated Commercialization Solutions Inc. We have standard industry agreements made in the ordinary course of business with these distributors which include prompt payment discounts, and various standard fee or rebate arrangements. Purchases are made on a purchase order basis. With the exception of Prialt where we have rights in some non-U.S. territories, we generally do not have rights to these products outside the United States.

Information on total revenues of Jazz Pharmaceuticals, Inc. attributed to domestic and foreign sources and customers who represent at least 10% of total revenues is included in Note 14 to the consolidated financial statements.

## **Manufacturing**

We do not have our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. We have engaged third parties to manufacture our products. For each of our marketed and approved products, we utilize a single supplier for the active pharmaceutical ingredient and a separate finished product manufacturer.

In April 2010, we entered into an agreement with Siegfried (USA) Inc., or Siegfried, for the supply of sodium oxybate. Siegfried was approved by the FDA as our supplier in November 2011. We have the right to purchase a portion of our worldwide requirements of sodium oxybate from other suppliers. The agreement with Siegfried expires in April 2015, subject to automatic three-year extensions until either party provides notice to the other of its intent to terminate the agreement at least 18 months before the end of the then current term. During the term of the agreement and, under certain circumstances for 18 months after the agreement terminates, Siegfried is not permitted to manufacture sodium oxybate for any other company.

We have an exclusive agreement with Patheon Pharmaceuticals, or Patheon, which became effective in 2008, under which we have agreed to purchase, and Patheon has agreed to supply, our worldwide supply of Xyrem. The current term of the agreement with Patheon extends until July 2014 and may be extended, at our option, for additional two-year terms.

Quotas from the DEA are required in order to manufacture and package sodium oxybate and Xyrem. Siegfried and Patheon each require quota from the DEA to supply us with sodium oxybate and Xyrem. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for the request, obtaining a sufficient DEA quota can be a difficult and time consuming process. In the past, the need for quota has prevented us from building significant inventories, although we have never run out of product.

For FazaClo LD and HD, and Luvox CR, we have single sources of supply, and changing suppliers can take two years or longer. We are in the process of changing suppliers for Prialt finished product and for ziconotide,

## **Table of Contents**

the active ingredient in Prialat. We have identified and commenced the transfer of Prialat finished product manufacturing as well as the transfer of ziconotide to a new manufacturer, respectively. We believe that we have sufficient supply of ziconotide to meet our commercial requirements until supply becomes available from a new manufacturer. Final batches of Prialat finished product are scheduled for manufacture at the current manufacturer with supply expected to be sufficient to meet commercial requirements before the time we expect a new manufacturer to be approved as a supplier by the FDA.

Manufacturers and suppliers of our products and product candidates are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and other rules and regulations prescribed by foreign regulatory authorities. We depend on our third party suppliers and manufacturers for continued compliance with cGMP requirements and applicable foreign standards.

## **Government Regulation**

The testing, manufacturing, labeling, advertising, promotion, distribution, export and marketing of our products are subject to extensive regulation by governmental authorities in the United States and in other countries. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, regulates pharmaceutical products. Several of our products and product candidates are regulated as controlled substances and are subject to additional regulation by the DEA under the Controlled Substances Act. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, withdrawal of approval of approved products, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, suspension of licenses, civil penalties and/or criminal prosecution.

### ***Drug Approval Process***

To obtain FDA approval of a product candidate, we must, among other things, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product candidate and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our product candidates.

The steps required before a drug may be approved for marketing in the United States generally include: preclinical laboratory tests and animal tests; submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials commence; adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication; the submission to the FDA of an NDA; satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made, analyzed and stored to assess compliance with cGMP; potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and FDA review and approval of the NDA.

An applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than, or before, accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

## **Table of Contents**

After the FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA may also refer an application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval (Subpart H), that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints or restricted distribution. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our product candidates will qualify for any of these programs, or that, if a product candidate does qualify, that the review time will be shorter than a standard review.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approval for new indications for any product will be approved on a timely basis, or at all.

Often, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to: report certain adverse reactions to the FDA; comply with certain requirements concerning advertising and promotional labeling for their products; submit drug safety or adverse event reports and continue to have quality control and manufacturing procedures conform to cGMP after approval.

We monitor adverse events resulting from the use of our commercial products, as does the FDA, and we file periodic reports with the FDA concerning adverse events. The FDA reviews these events and reports, and if it determines that any events and/or reports indicate a trend or signal, the FDA can require a change in a product label, restrict sales and marketing and/or require or conduct other actions. The FDA also periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

The FDA and other governmental authorities also actively enforce regulations prohibiting off-label promotion, and the government has levied large civil and criminal fines against companies for alleged improper promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that can impose significant reporting and other burdens on the affected companies.

The approval process described above is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a "full" or "stand-alone" NDA, is governed by Section 505(b)(1) of the FDCA. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information. As an alternate path to FDA approval of, for example, new indications or improved formulations of previously-approved products, a company

---

**Table of Contents**

may submit a Section 505(b)(2) NDA, instead of a stand-alone or full NDA filing under Section 505(b)(1). Section 505(b)(2) of the FDCA was enacted as part of the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug product for all or some of the label indications for which the referenced product has been approved, or for a new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify that there are no patents listed for that product in the FDA's approved drug products with therapeutic equivalence evaluation document, or Orange Book, or that for each Orange Book-listed patent the listed patent has expired, or will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

A certification that the new product will not infringe the already approved product's Orange Book-listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired, as well as any additional period of exclusivity that might be obtained for completing pediatric studies pursuant to the FDA's written request. The Section 505(b)(2) application may also not be approved until any applicable non-patent exclusivity, such as exclusivity that results from obtaining approval of a new chemical entity, and until any patent listed in the Orange Book covering the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the holder of the NDA and the relevant patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the NDA with the five-year exclusivity period. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's 505(b)(2) NDA will not be subject to the 30-month stay.

***The Hatch-Waxman Act***

Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits having an effective approval date for an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another full NDA; however, the applicant would

---

## **Table of Contents**

be required to conduct its own preclinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the FDCA to require each NDA sponsor to submit with its application information on any patent that claims the active pharmaceutical ingredient, drug product (formulation and composition), and method-of-use for which the applicant submitted the NDA and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our products and product candidates, and to vigorously defend any Orange Book-listed patents for our approved products. In November 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV certification relating to Xyrem. For a description of this matter, please see Item 3. Legal Proceedings.

The Hatch-Waxman Act also permits a patent term extension of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years after the FDA approves a marketing application. The patent term extension period is generally equal to the sum of one-half the time between the effective date of an IND and the submission date of an NDA, and all of the time between the submission date of an NDA and the approval of that application, up to a total of five years. Only one patent applicable to a regulatory review period, that represents the first commercial marketing of that drug, is eligible for the extension, and it must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We will consider applying for a patent term extension for some of our patents to add patent life beyond the expiration date, if we meet the legal requirements permitting an extension and depending on the expected length of clinical trials and other factors involved in the submission of an NDA.

### ***Food and Drug Administration Amendments Act of 2007***

On September 27, 2007, the Food and Drug Administration Amendments Act, or the FDAAA, was enacted into law, amending both the FDCA and the Public Health Service Act. The FDAAA makes a number of substantive and incremental changes to the review and approval processes in ways that could make it more difficult or costly to obtain approval for new pharmaceutical products, or to produce, market and distribute existing pharmaceutical products. Most significantly, the law changes the FDA's handling of postmarketing drug product safety issues by giving the FDA authority to require post approval studies or clinical trials, to request that safety information be provided in labeling, or to require an NDA applicant to submit and execute a REMS. Xyrem is subject to REMS requirements. Xyrem was approved before 2007 with a risk mitigation program which is a deemed REMS in the view of the FDA, and we are working with the FDA to develop an amended REMS for Xyrem under FDAAA. The risk management plan for FazaClo, which was adopted prior to 2008, is not in the same form as required under the newer REMS structure under the FDA. We are working with the FDA to develop an amended REMS for FazaClo under the FDAAA and have submitted a supplement for a FazaClo REMS to the FDA. The submission is not yet approved. We will work with the FDA if the agency determines that REMS are necessary for our other products or our product candidates.

### ***Orphan Drug Designation and Exclusivity***

Some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in

---

## **Table of Contents**

the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.

The FDA designated and approved Xyrem as an orphan drug for each of excessive daytime sleepiness and cataplexy in patients with narcolepsy. The period of orphan drug exclusivity for cataplexy in patients with narcolepsy expired in July 2009 and the period of orphan drug exclusivity for excessive daytime sleepiness in patients with narcolepsy will expire in November 2012.

### ***Unapproved Drugs***

In the United States, legally marketed prescription drugs include those drugs marketed in accordance with an approved NDA or ANDA and drugs that are otherwise exempt from the NDA or ANDA approval requirement. This latter category includes pre-1938 and pre-1962 grandfathered drugs and drugs marketed pursuant to the FDA's Over-The-Counter monograph process. In addition, FDA policy has generally been that products subject to an ongoing Drug Efficacy Study Implementation, or DESI, proceeding may remain on the market during the pendency of that proceeding and any additional period specifically provided in the proceeding. FDA policy has been that DESI products may continue to be marketed while the DESI review is ongoing. However, once the relevant DESI proceeding is completed and any additional grace period specifically provided in the proceeding has expired, the FDA has stated that all products that are not in compliance with the conditions for marketing determined in that proceeding are subject to enforcement action at any time without further notice. The FDA has generally used enforcement discretion to prioritize action against products that the FDA considers to present a potential safety risk, lack evidence of effectiveness, or be deceptively promoted, among other enforcement priority reasons. In a September 19, 2011 Compliance Policy Guide, the FDA announced a change to the FDA's enforcement policy for marketed unapproved drugs. In this guidance, the FDA informed marketers of unapproved drugs that, notwithstanding the FDA's enforcement priorities for unapproved drugs on the market as of that date, 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 potentially subject the manufacturer to immediate FDA enforcement action to remove such product from the market. Some of our women's health and other products, such as Urelle, Natelle and Gesticare, have not been approved by the FDA, and the FDA may view them as unapproved new drugs. These products would have historically been afforded FDA enforcement discretion, consistent with the FDA's Compliance Policy Guidelines; however, the FDA may not continue to permit marketing of these products in their existing formulations, or at all, without submission and approval of an NDA. Moreover, under the September 19, 2011 guidance, any formulation or labeling changes to these products may also subject them to FDA enforcement action to remove them from the market. Net sales of these products by Azur Pharma in 2011 totaled approximately \$12.4 million.

### ***Other Regulatory Requirements***

In addition to regulation by the FDA and certain state regulatory agencies, the DEA imposes various registration, recordkeeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the Controlled Substances Act. The states also impose similar requirements for handling controlled substances. A principal factor in determining the particular requirements, if any, applicable to a

## **Table of Contents**

product is the actual or potential abuse profile. Sodium oxybate, in the form of an active pharmaceutical ingredient, is regulated by the DEA as a Schedule I controlled substance, a category reserved for products believed to present the highest risk of substance abuse and with no approved medicinal use. When contained in Xyrem, sodium oxybate is regulated as a Schedule III controlled substance. Controlled substances are subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of the scheduled substance that would be available for clinical trials and commercial distribution. Sodium oxybate, as a Schedule I substance, is subject to additional controls, including quotas that limit the amount of product that can be manufactured each year. As a Schedule III drug, Xyrem is subject to limitations on prescription refills. The third parties who perform our clinical and commercial manufacturing, distribution, dispensing and clinical studies for Xyrem are required to maintain necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA or relevant state authorities could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, and could have an adverse effect on our business and financial condition.

We are also subject to a variety of regulations in countries outside the United States governing clinical trials and the marketing of other products. Outside of the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above. A World Health Organization (WHO) subcommittee plans to further evaluate the scheduling of sodium oxybate under the international drug control treaties, which could result in a recommendation to the U.N. Commission on Narcotic Drugs to place Xyrem in a more restrictive schedule, thereby causing a more restrictive scheduling of this product in Europe and certain other countries than its current Schedule IV controlled substance status, and in a more restrictive schedule in the United States than its current Schedule III controlled substance status. The WHO review process is long and complicated and the timing and outcome of the review process is uncertain.

Prialt is a synthesized conotoxin, a designated controlled biological toxin. 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.

## **Pharmaceutical Pricing and Reimbursement**

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. 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 product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. We anticipate that

---

## **Table of Contents**

the United States Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include: controls on government funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs, controls on healthcare providers; challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; changes in drug importation laws; expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and public funding for cost effectiveness research, which may be used by government and private third party payors to make coverage and payment decisions.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted, could have a material adverse effect on our ability to operate profitably.

### **Patents and Proprietary Rights**

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products, inventions and improvements that we consider important to the development of our business. We own a portfolio of U.S. and foreign patents and patent applications and have licensed rights to a number of U.S. issued patents and patent applications. Our owned and licensed patents and patent applications cover formulations of our products and product candidates, uses of our products and product candidates to treat particular conditions, drug delivery technologies and delivery profiles relating to our products and product candidates and methods for producing our products and product candidates. However, patent protection is not available for the active pharmaceutical ingredients in our commercial products, including Xyrem. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. The patents and patent applications that relate to our products and product candidates include the following:

*Xyrem.* Xyrem is covered by nine patents, of which seven are listed in the FDA's approved drug products with therapeutic equivalence evaluation document, or Orange Book. Of the patents listed in the Orange Book, two are formulation patents expiring in 2020 and four are method of use patents covering the distribution of Xyrem, three of which expire in 2024 and one of which expires in 2022; and one is a method of use patent covering Xyrem's use in narcolepsy which expires in 2019. A process patent and a distribution system patent not listed in the Orange Book also cover the product and expire in 2019 and 2024, respectively. In addition to our issued patents, we have a number of patent applications covering Xyrem pending.

*FazaClo.* FazaClo LD and FazaClo HD are covered by three formulation patents. All are licensed by us, one from Ethypharm, expiring in December 2017, and the other two from CIMA, expiring April 2018. The three patents are listed in the Orange Book. The two patents licensed from CIMA are subject to ongoing re-examination proceedings at the U.S. Patent and Trademark Office, as further described below.

*Luvox CR.* Luvox CR is covered by a U.S. patent owned by Alkermes with claims covering the orally administered formulation of extended-release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours. This patent is listed in the Orange Book, and will expire in 2020. A continuation application is pending in the United States.

*Prialt.* Prialt is covered by a portfolio of 11 issued U.S. patents with expirations ranging from June 2012 to October 2024, two of which are listed in the FDA's Orange Book. Of the patents listed in the Orange Book, one is a method of use patent, expiring in December 2016, and the other is a formulation



---

**Table of Contents**

patent expiring in June 2015. There is also a method of use patent application pending in the United States. In addition, Prialt is covered by eight foreign patents and three foreign patent applications with expirations ranging from December 2012 to October 2024.

*Elestrin.* There are two formulation patents licensed by us that are listed in the FDA's Orange Book for Elestrin. One expires in August 2021 and the other in June 2022.

*Product candidates.* For Clozapine OS, we have rights to a U.S. patent and a pending U.S. patent application from Douglas Pharmaceuticals under a license and supply agreement. The Clozapine OS patent was issued in November 2011 and will expire in February 2027. In relation to Clozapine QD, Azur Pharma has filed a U.S. and European patent application and also licensed rights to patents and patent applications from Alkermes under a development and license agreement.

We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents. Changes in patent laws could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, because the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any additional patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. We cannot assure you that our patents will not be challenged by third parties or that we will be successful in any defense we undertake. Failure to successfully defend a patent challenge could materially and adversely affect our business.

Generic manufacturers have challenged our patents covering Xyrem, FazaClo LD and HD and Luvox CR. Azur Pharma settled a suit against Teva relating to FazaClo, and we settled one against Anchen relating to Luvox CR. As a result of these settlements, generic products are likely to be introduced long before the expiration of our patents covering the products. Other suits are ongoing. See Item 3. Legal Proceedings.

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. Decisions which contain new grounds of rejection have been issued with respect to both patents. In response to these decisions, CIMA has requested to re-open prosecution at the examiner level. Once a final decision is reached by the U.S. Patent and Trademark Office, further appeal to the U.S. Court of Appeals for the Federal Circuit is possible. 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 and, if so, whether any appeal will be successful.

We cannot ensure that others will not be issued patents that may prevent the sale of our products or require licensing and the payment of significant fees or royalties. Furthermore, to the extent that any of our future products or methods is not patentable or infringe the patents of third parties, or in the event that our patents or future patents fail to give us an exclusive position in the subject matter claimed by those patents, our business could be adversely affected. We may be unable to avoid infringement of third party patents and may have to obtain a license, defend an infringement action, or challenge the validity of the patents in court. A license may be unavailable on terms and conditions acceptable to us, if at all. Patent litigation is costly and time consuming, and we may be unable to prevail in any such patent litigation or devote sufficient resources to even pursue such litigation. If we do not obtain a license under necessary patents, are found liable for infringement, or are not able to have such patents declared invalid, we may be liable for significant money damages, encounter significant delays in bringing products to market, or be precluded from participating in the manufacture, use or sale of products or methods of treatment requiring such licenses.

We have also applied for a number of trademarks and service marks to further protect the proprietary position of our products. We own 80 registered trademarks and service marks in the United States and 37

## **Table of Contents**

registered trademarks and service marks in other jurisdictions. We also have three pending trademark and service mark applications in the United States. We also rely on our trade secrets and those of our licensors, as well as other unpatented proprietary information, to protect our products. To the extent that our products have a competitive edge as a result of our reliance on trade secrets and unpatented know-how, our competitive position may be compromised if others independently develop products using the same or similar technologies or trade secrets.

We seek to protect our trade secrets and proprietary knowledge in part through confidentiality agreements with our employees, consultants, advisors and collaboration partners. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of our confidential information. In addition, if our employees, consultants, advisors or collaboration 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. Such inventions and processes will not necessarily become our property, but may remain the property of those third parties or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on our business.

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

## **Employees**

As of February 21, 2012, we had 431 regular employees. None of our employees is represented by a labor union, and we consider our employee relations to be good.

## **About Jazz Pharmaceuticals plc**

We are a public limited company originally formed under the laws of Ireland (registered number 399192) in March 2005. We were originally formed as a private limited liability company under the name Azur Pharma Limited. Effective October 20, 2011, Azur Pharma was re-registered as a public limited company under the name Azur Pharma Public Limited Company. On September 19, 2011, Azur Pharma entered into an Agreement and Plan of Merger and Reorganization, or Merger Agreement, with Jazz Pharmaceuticals, Inc. and certain other parties. The related merger was consummated on January 18, 2012. Pursuant to the Merger Agreement, the name of Azur Pharma was changed to Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc. became a wholly-owned subsidiary of Jazz Pharmaceuticals plc and Jazz Pharmaceuticals plc issued ordinary shares to the former Jazz Pharmaceuticals, Inc. stockholders. Immediately after giving effect to the issuance of our ordinary shares in the merger, approximately 78% of our ordinary shares were held by the former Jazz Pharmaceuticals, Inc. stockholders and approximately 22% were held by the persons who acquired our ordinary shares prior to the merger. Jazz Pharmaceuticals, Inc. was incorporated in California in March 2003 and reincorporated in Delaware in January 2004. Jazz Pharmaceuticals, Inc. is treated as the acquiring company for accounting purposes and the transaction is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the historical financial statements of Jazz Pharmaceuticals, Inc. became our historical financial statements. We are also considered to be the successor to Jazz Pharmaceuticals, Inc. for certain purposes under both the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended.

Our principal offices are located at 45 Fitzwilliam Square, Dublin, Ireland, and our telephone number is 353-1-634-4183. Our U.S. operations are located in Palo Alto, California and Philadelphia, Pennsylvania. Our

**Table of Contents**

website address is [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com). Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K. Service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

**Available Information**

We file electronically with the U.S. Securities and Exchange Commission our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com), free of charge, copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to the SEC. Further copies of these reports are located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at [www.sec.gov](http://www.sec.gov).

---

## **Table of Contents**

### **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.*

#### **Risks Relating to Our Business**

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

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

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

the potential introduction of a generic version of Xyrem;

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

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

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

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

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

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

These and the other risks described in these risk factors related to Xyrem product sales could have a material adverse effect on our ability to maintain or increase sales of Xyrem.

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

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

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

Although Xyrem is covered by patents covering its formulation, distribution system and method, and certain of our other products are covered by patents covering their respective formulations, distributions systems or methods of use, we cannot assure you that third parties will not attempt to invalidate or design around the

---

**Table of Contents**

patents, or assert that they are invalid or otherwise unenforceable, and introduce generic equivalents of Xyrem or any other products. Once orphan drug exclusivity for Xyrem in the United States for the treatment of excessive daytime sleepiness in patients with narcolepsy expires in November 2012 and exclusivity has expired for the other products, other companies could possibly introduce generic equivalents of these products if they do not infringe our patents or can demonstrate that our patents are invalid or unenforceable.

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

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

We received Paragraph IV certification notices relating to three generic versions of Luvox CR, two in 2009 and one in 2011. We filed lawsuits against all of these companies after receipt of their certifications. We and Elan Pharma International Limited, which has subsequently transferred its rights to Alkermes Pharma Ireland Limited, or Alkermes, entered into settlement agreements with one of the companies, granting to such company a sublicense of its rights to have manufactured, market and sell a generic version of Luvox CR commencing in February 2013, or earlier upon the occurrence of certain events. The lawsuits against the other two companies are pending. We cannot assure you that these lawsuits, or any others we may bring, will prevent the introduction of generic versions of Luvox CR for any particular length of time, or at all.

Azur Pharma received Paragraph IV certifications from three generic manufacturers, two in 2008 and one in 2010, relating to generic versions of FazaClo LD. Azur Pharma and CIMA Labs Inc., a subsidiary of Teva, or CIMA, our licensor and whose drug-delivery technology is incorporated into FazaClo LD, filed lawsuits in response to each certification. In July 2011, Azur Pharma, CIMA, Barr Laboratories (one of the three generic manufacturers) and Teva, which had acquired Barr Laboratories, entered into an agreement settling the patent litigation and granting a license of our rights to have manufactured, market and sell a generic version of FazaClo LD and FazaClo HD. The sublicenses will commence in July 2012 and May 2015 for FazaClo LD and FazaClo HD, respectively, or earlier upon the occurrence of certain events. We cannot assure you that the lawsuits against the other generic manufacturers, or any other lawsuit we may bring, will prevent the introduction of generic versions of FazaClo LD and FazaClo HD for any particular length of time, or at all. 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.

---

## **Table of Contents**

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

After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product generally may be filled with the generic version, resulting in a loss in sales of the branded product, including for indications for which the generic version has not been approved for marketing by the FDA. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic equivalent is available. Generic competition for Xyrem and our other products could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

***The combination of the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma creates numerous risks and uncertainties, which could adversely affect our operating results or prevent us from realizing the expected benefits of the merger.***

The merger transaction between Jazz Pharmaceuticals, Inc. and Azur Pharma has created numerous uncertainties and risks, and has required, and will continue to require, significant efforts and expenditures. Jazz Pharmaceuticals, Inc. transitioned from a standalone public Delaware corporation to being part of a combined company organized in Ireland. This combination entails many changes, including the integration of Azur Pharma and its personnel with those of Jazz Pharmaceuticals, Inc. and changes in systems. These transition activities are complex, and we may encounter unexpected difficulties or incur unexpected costs, including:

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

difficulties in achieving anticipated business opportunities and growth prospects from combining the business of Azur Pharma with that of Jazz Pharmaceuticals, Inc.;

difficulties in the integration of operations and systems;

difficulties in the assimilation of employees and corporate cultures;

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

challenges in keeping existing customers and obtaining new customers; and

challenges in attracting and retaining key personnel.

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

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

expectations of financial analysts or investors.



---

**Table of Contents**

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

The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem, sodium oxybate, is a Schedule I controlled substance, our current and any potential new suppliers of sodium oxybate, as well as our product manufacturer, must each obtain separate DEA quotas in order to supply us with sodium oxybate and Xyrem. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate or Xyrem exceed our suppliers' and product manufacturer's DEA quotas, our suppliers and product manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. We cannot assure you that our suppliers will receive sufficient quota from the DEA to meet our needs, and if we and our suppliers cannot obtain as much quota as is needed, on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem. The risk management plan includes unique features that provide information about adverse events, including deaths, that is generally not available for other products that are not subject to a similar risk management plan. Information concerning adverse events that may not be related to the use of Xyrem is likely to be collected under the risk management plan. This information, which we are required to report regularly to the FDA, could result in the FDA requiring changes to the Xyrem label or taking or requiring us to take other actions that could have an adverse effect on Xyrem's commercial success.

Under the risk management plan, all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under the Xyrem risk management program is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or ESSDS, through June 2015, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem and our sales would be adversely affected. If we change our central pharmacy, new contracts might be required 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 the risk management plan approved by the FDA. Transitioning to a new central pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the United States, result in additional costs and expenses for us, and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In late April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA as required. Promptly after learning of them, we reported to the FDA all of the previously unreported cases that we and ESSDS had identified. We also began immediately taking specific steps to strengthen our own procedures, and those between us and ESSDS, to ensure that all adverse events are reported to us, and to the FDA, in an appropriate and timely manner.

In early May 2011, we received a Form 483 as a result of an FDA inspection, which included the inspector's observations concerning our adverse event reporting system. That document discussed the failure to report serious adverse events, including certain cases of deaths as described above, and also noted deficiencies in certain of our drug safety procedures. After receipt of the Form 483, we continued our efforts to improve our systems, and those used by us and ESSDS, to ensure that we correct the deficiencies noted in the Form 483, and

---

## **Table of Contents**

those efforts are continuing. In October 2011, we received a warning letter from the FDA relating to the matters covered by the Form 483. We have responded to the warning letter, advising the FDA of the efforts we have taken to date and are continuing to take, and we are continuing to strengthen our procedures and take appropriate corrective actions to address all of the matters covered in the warning letter. While we have responded to the warning letter in a timely manner and we intend to demonstrate our compliance to the FDA's satisfaction, we cannot assure you that we will be able to adequately address the FDA's requirements pursuant to the warning letter, and the failure to do so could have a material and adverse effect on our business, financial condition and results of operations.

The information we initially received concerning the cases discussed above does not specify the cause of death in most cases, and as a result we cannot be certain whether any, or how many, of the cases are related to Xyrem. We are gathering additional information under a plan we have discussed with the FDA, and we plan to provide the FDA with this information in the next several months. As a result of our review to date, we believe that the adjusted annual all-cause mortality rate has been consistent since the product's launch and that it does not constitute a new safety signal for Xyrem. 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 open an evaluation based on the FDA's Adverse Event Reporting System database, require changes to Xyrem's label or take or require us to take other actions that could be costly or time-consuming and/or negatively affect the commercial success of Xyrem. We cannot assure you that regulatory authorities in other countries where Xyrem is sold will not take similar actions.

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

The FDA has required that Xyrem's label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, ads which mention the pharmaceutical brand name but not the indication or medical condition it treats. In addition, Xyrem's FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use.

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

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

---

## **Table of Contents**

The risk management plan for FazaClo, which was adopted in 2004, is not in the same form as required under the newer REMS structure under the Food and Drug Administration Amendments Act of 2007. The FDA has required that the existing risk management program for FazaClo LD and FazaClo HD be converted to its current REMS structure. Azur Pharma submitted a supplement for a new REMS plan, which, once approved, will replace the current risk management plan for FazaClo LD and FazaClo HD. We cannot assure you that the FDA will not impose new and onerous requirements under the new REMS structure that could make it more difficult or expensive for us to distribute FazaClo or could adversely affect our sales or make competition easier.

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

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

We do not have, and do not intend to establish in the near term, our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. In part due to the limited market size for our approved products, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. If our suppliers and contract manufacturers, including any new suppliers without a track record of meeting our supply needs, do not manufacture our products or product candidates without interruption or do not comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates.

The availability of our products for commercial sale depends upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a prior approval supplement and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take up to two years, or longer in certain cases, to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer. For Xyrem or sodium oxybate, any new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. Our new supplier of sodium oxybate, Siegfried (USA) Inc., or Siegfried, was approved by the FDA in late 2011 and became our sole commercial supplier in 2012.

## **Table of Contents**

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

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

We are in the process of changing suppliers for Prialt finished product and for ziconotide, the active ingredient in Prialt. We have identified and commenced the transfer of ziconotide to a new manufacturer. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for a number of years, by which time we expect supply to be available from a new manufacturer. We have also identified and begun the transfer of Prialt finished product manufacturing to a new manufacturer. Final batches are scheduled for manufacture at the current manufacturer with supply expected to be sufficient to meet commercial requirements through the end of 2013, by which time we expect a new manufacturer to be approved as a supplier by the FDA. However, there can be no assurance that such new manufacturers of ziconotide and Prialt finished product or any other manufacturer will be approved by the FDA, or that our supplies of ziconotide and Prialt will be sufficient until such manufacturers or other manufacturers have been approved, and any failure to obtain sufficient commercial supplies of Prialt would have a material adverse effect on our business, financial condition and results of operations.

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

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

Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products in the United States and our partners' needs outside the United States, or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

## **Table of Contents**

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

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

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

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

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

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

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

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

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

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

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

prevalence of the disease or condition for which the product is approved and the severity of side effects;

acceptance by physicians and patients of each product as a safe and effective treatment;

perceived advantages over alternative treatments;

relative convenience and ease of administration;

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

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

the availability of adequate reimbursement by third parties.

From time to time, there is negative publicity about illicit gamma-hydroxybutyrate, or GHB, and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the active

---

**Table of Contents**

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

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

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

The network through which we sell our products has undergone significant consolidation through mergers and acquisitions among wholesale distributors. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drugstore chains has decreased. Three large wholesale distributors and one of their subsidiaries accounted for an aggregate of 90% of Azur Pharma's total sales during the year ended December 31, 2011, and the same three large wholesale distributors accounted for an aggregate of 11% of Jazz Pharmaceuticals, Inc.'s total sales during the year ended December 31, 2011. If any of our major distributors reduces its inventory levels or otherwise reduces purchases of our products, it could lead to periodic and unanticipated future reductions in revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug companies, including us.

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

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

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

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

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

We have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales

## **Table of Contents**

representatives is responsible for a territory of significant size. Future commercial products may require expansion of our sales force and sales support organization, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization before the commercial launch of those product candidates. 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.

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

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

We and our partners have conducted, and we may in the future conduct, additional clinical trials for our product candidates including: an oral suspension formulation of clozapine, Clozapine OS, and a once-daily formulation of clozapine, Clozapine QD. Clinical testing can take many years to complete, especially for product candidates that are in Phase II, or earlier, clinical trials, and failure can occur any time during the clinical trial process. In addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials. Our product candidates are subject to competition for clinical study sites and patients from other therapies under development that may delay the enrollment in or initiation of our clinical trials. Many of these companies have far greater financial and human resources than we do.

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

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

We rely on our licensors, contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out clinical trials for our product candidates, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as FDA's and foreign regulatory agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA enforces good clinical practices through periodic inspections of trial sponsors,



## **Table of Contents**

principal investigators and trial sites. If we, our licensors, contract research organizations or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations. Our failure, or the failure of our contract manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates.

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

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. Our current and prospective employees might experience uncertainty about their roles with us during the integration phase of the businesses of Jazz pharmaceuticals, Inc. and Azur Pharma, which might adversely affect our ability to retain key managers and other employees. We are highly dependent upon our executive management team and other key personnel, all of whom work on many complex matters that are critical to our success. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry key person insurance. Any employee may terminate his or her employment at any time without notice (or, in the case of certain employees who entered into employment agreements with Azur Pharma, with up to three months notice) and without cause or good reason.

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

### **Risks Related to Our Intellectual Property**

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

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

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. For example, even though we have patents covering

## **Table of Contents**

Xyrem, an ANDA was filed requesting permission from the FDA to market a generic form of Xyrem, and we have received notices from the company that filed the ANDA stating that the ANDA included Paragraph IV certifications with respect to our Xyrem patents listed in the FDA's Orange Book. In the case of Luvox CR, we have received three Paragraph IV certifications which allege that the Alkermes patent listed in the Orange Book for Luvox CR is invalid. Similarly, three ANDAs were filed requesting approval from the FDA to market a generic form of FazaClo LD and one ANDA has been filed requesting approval from the FDA to market a generic form of FazaClo HD. Azur Pharma has received notices from the companies that filed the ANDAs stating that such ANDAs included Paragraph IV certifications with respect to the patents listed in the FDA's Orange Book.

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

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent Office is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;

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

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;

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

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

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

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

## **Table of Contents**

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

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

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

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

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

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents, our licensed patents or our partners' patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity. We are prosecuting lawsuits against the generic manufacturers who delivered Paragraph IV certifications to Jazz Pharmaceuticals, Inc. or Azur Pharma with respect to Xyrem, FazaClo LD and Luvox CR. See Item 3. Legal Proceedings. We

## **Table of Contents**

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.

## **Risks Related to Our Industry**

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

The research, testing, manufacturing, labeling, advertising and promotion, distributing and exporting of pharmaceutical products are subject to extensive regulation by FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, generally of a new drug application, or an NDA. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process, and the FDA has substantial discretion in the approval process. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs.

---

**Table of Contents**

***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, or the Healthcare Reform Act. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. In addition, under the Healthcare Reform Act, the minimum Medicaid rebate has been increased from 15.1% to 23.1% of the average manufacturer price for our products. We expect that the Healthcare Reform Act and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales or successfully commercialize our product candidates or could limit or eliminate our future spending on development projects.

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

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

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

We are subject to significant ongoing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products are, and any of our product candidates that may be approved by the FDA will be, subject to extensive and ongoing regulatory requirements. If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the commercial potential of the product. If we become aware of previously unknown problems with any of our products in the United States or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions

---

**Table of Contents**

on our products, our contract manufacturers or on us. In such an instance, we could experience a significant drop in the sales of the affected products, our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits.

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

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

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

In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to other administrative or judicially imposed sanctions, including warning letters, untitled letters, other civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production, withdrawal of the products from the market and refusal to approve pending NDAs or supplements to approved NDAs. We are also subject to regulation by regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, the U.S. Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we commercialize our products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our manufacturing partners are subject to many of the same requirements, which include obtaining sufficient quota

## **Table of Contents**

from the DEA each year to manufacture sodium oxybate and Xyrem. Pursuant to the Export Administration Regulations, we are required to obtain a license from the U.S. Department of Commerce prior to the exportation of certain materials and technical information related to Prialt.

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

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

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals.

Compliance with various federal and state laws is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim



---

**Table of Contents**

violations and, as required by the Physician Payment Sunset provisions, extensive tracking and maintenance of database starting in 2012 and public reporting beginning in March 2013 of payments by pharmaceutical manufacturers to physicians and teaching hospitals nationwide. 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.

If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our or our partners' ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

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

We participate in the federal Medicaid rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under a fee-for-service arrangement, as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the Centers for Medicare and Medicare Services, or CMS, the federal agency that administers the Medicaid rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 and subsequent legislation, or PPACA, made significant changes to the Medicaid rebate program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organizations. With regard to the amount of the rebates owed, the PPACA increased the minimum Medicaid rebate for innovator drugs; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and caps the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the PPACA and subsequent legislation changed the definition of average manufacturer price. Finally, the PPACA requires pharmaceutical manufacturers of branded prescription drugs to pay a new branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of \$2.5 billion in 2011 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

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

---

**Table of Contents**

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

These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The PPACA expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the PPACA. Except for children's hospitals, the PPACA exempts orphan drugs those designated under section 526 of the Federal Food Drug and Cosmetic Act from the ceiling price requirements for these newly-eligible entities.

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

In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Our failure to submit monthly/quarterly average manufacturer price and best price data on a timely basis could result in a civil monetary penalty of \$10,000 per day for each day the submission is late beyond the due date. In the event that the CMS terminates our rebate agreement, no Federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

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

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

## **Table of Contents**

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

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

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. For example, a final rule published by the U.S. Department of Defense, or DoD, in March 2009 (and reissued in October 2010), implementing the terms of Section 703 of the National Defense Authorization Act for Fiscal Year 2008, established a program under which the DoD expects rebates from pharmaceutical manufacturers on all prescriptions of covered drugs (including innovator drugs and biologics) filled under the TRICARE retail pharmacy program from January 28, 2008 forward, unless the DoD agrees to a waiver or compromise of amounts due. Additionally, under the final rule, to remain eligible for inclusion on the DoD Uniform Formulary, a pharmaceutical manufacturer must enter into a pricing agreement under which it agrees to pay rebates to the DoD on TRICARE retail pharmacy utilization on a prospective basis. These rebates are meant to enable the DoD to access pricing that is either close to or equal to Federal Ceiling Prices, as defined under the Veterans Health Care Act of 1992. Pursuant to the final rule, Jazz Pharmaceuticals, Inc. and Azur Pharma entered into separate pricing agreements with the DoD in July 2009 and June 2009, respectively. These legislative and regulatory changes, including our DoD pricing agreements, could impact our ability to maximize revenues in the Federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

***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

## **Table of Contents**

result in product liability claims and/or recalls of one or more of our products. Xyrem, FazaClo, Luvox CR, Prialt, and Elestrin have boxed warnings in their labels.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. The risk of product liability claims may also increase when a company receives a warning letter. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. Partly as a result of product liability lawsuits related to pharmaceutical products, product liability and other types of insurance have become more difficult and costly for pharmaceutical companies to obtain. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

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

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims.

## **Risks Relating to Our Financial Condition**

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

To grow our business over the longer-term, we will need to commit substantial resources to in-licensing and/or acquiring new products and product candidates, and to costly and time-consuming product development and clinical trials of our product candidates. We will also need to continue to invest in our commercial operations. Our future capital requirements will depend on many factors, including many of those discussed above, such as:

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

the extent of generic competition for our products;

the cost of acquiring and/or licensing any new products and product candidates;

the scope, rate of progress, results and costs of our development and clinical activities;

the cost and timing of obtaining regulatory approvals and of compliance with laws and regulations;

the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

the cost of investigations, litigation and/or settlements related to regulatory activities and third-party claims; and

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

---

## **Table of Contents**

One of our corporate goals is to expand our business through the licensing, acquisition and/or development of additional products and product candidates. We cannot assure you that our funds will be sufficient to fund these activities if opportunities arise, and we may be unable to expand our business if we do not have sufficient capital or cannot borrow or raise additional capital on attractive terms. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

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

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

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

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because Azur Pharma was, and we continue to be after the merger, 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 merger at the closing, we could be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874.

For us to be treated as a foreign corporation for U.S. federal tax purposes under Section 7874 of the Code, either (1) the former stockholders of Jazz Pharmaceuticals, Inc. must have owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Jazz Pharmaceuticals, Inc., or (2) we must have substantial business activities in Ireland after the 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 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 merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. Moreover, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be

**Table of Contents**

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 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 merger for a period of time following the 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 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 328 of the Code, and, therefore, we have not established whether the IRS agrees with our analysis regarding the application of Section 382 of the Code.

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

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

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

We have and will continue to incur additional costs and expenses in connection with and as a result of the merger. These costs and expenses include professional fees to comply with Irish corporate and tax laws and

---

## **Table of Contents**

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

### **Risks Relating to Our Ordinary Shares**

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

Investors who hold our ordinary shares may not be able to sell their shares at or above the price at which they purchased their ordinary shares (or the price at which they purchased their shares Jazz Pharmaceuticals, Inc. common stock prior to the merger). The price of Jazz Pharmaceuticals, Inc.'s common stock has fluctuated significantly from time to time and increased substantially during the past year, and we cannot predict if the price of our ordinary shares will continue to do so. The risk factors described above relating to our business and products could cause the price of our ordinary shares to fluctuate significantly. In addition, the stock market in general, including the market for life sciences companies, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our ordinary shares, regardless of our operating performance. In addition, our stock price may be dependent upon the valuations and recommendations of the analysts who cover our business, and if our results do not meet our analysts' forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In addition, the market price of our ordinary shares may decline if the integration of the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma is unsuccessful, takes longer than expected or fails to achieve financial benefits to the extent anticipated by financial analysts or investors, or the effect of the business combination on the financial results of the 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 stock price to fall.*

Sales of a substantial number of shares of our ordinary shares in the public market or the perception that these sales might occur, could depress the market price of our ordinary shares, and could impair our ability to raise capital through the sale of additional equity securities. As of February 21, 2012, we had 56,243,783 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 February 21, 2012, the holders of up to approximately 12,601,202 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 merger. Certain of our executive officers are entitled to rights under the amended and restated investor rights agreement with respect to registration of the ordinary shares acquired on exercise of their stock options. If such holders, by exercising their registration rights or otherwise, sell a large number of shares, the sale could adversely affect the market price of our ordinary shares. If in the future we file a registration statement and include shares held by 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.



## **Table of Contents**

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 merger, we agreed to file a registration statement under the Securities Act registering the resale of 1,895,734 ordinary shares held by the investors in the July 2009 private placement, as well as the 947,867 ordinary shares now underlying the warrants held by such investors. In addition, if we propose to register any of our securities under the Securities Act after February 14, 2012, either for our own account or for the account of others, the investors in the private placement are entitled to notice of the registration and are entitled to include, at our expense, their ordinary shares in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration.

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

In addition, we expect that generally, U.S. holders of Jazz Pharmaceuticals, Inc. should be taxable on gain recognized, if any, on the receipt of our ordinary shares in exchange for Jazz Pharmaceuticals, Inc. common stock in the merger. Since the historic stockholders of Jazz Pharmaceuticals Inc. received did not receive any cash in exchange for their shares of Jazz Pharmaceuticals, Inc. common stock in the merger, these holders may choose to sell the ordinary shares they received in the merger to generate cash to satisfy their tax obligations, which could increase the number of our ordinary shares being sold in the public market and the volatility of the price of our ordinary shares.

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

As of February 21, 2012, our executive officers and directors, together with the shareholders with which our executive officers and directors are affiliated or associated, beneficially owned approximately 43.3% of our ordinary shares. Accordingly, our executive officers and directors, together with their respective affiliates or associates, are likely able to significantly influence the composition of our board of directors, retain the voting power to approve all matters requiring shareholder approval, including mergers and other business combinations and 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 differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies

---

## **Table of Contents**

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.***

Neither Jazz Pharmaceuticals, Inc. nor Azur Pharma has ever declared or paid any cash dividends. We do not expect to pay dividends in the foreseeable future. We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs. Even if we propose to pay dividends in the future, we may be unable to do so under Irish law. Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, distributable reserves. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant. Holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future.

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

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

---

## **Table of Contents**

(i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those ordinary shares and (iii) claim a first and permanent lien on the ordinary shares on which stamp duty has been paid by us or our subsidiary for the amount of stamp duty paid. Our lien shall extend to all dividends paid on those ordinary shares.

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

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

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

Our corporate headquarters are located in Dublin, Ireland and our U.S. operations are located in Palo Alto, California and Philadelphia, Pennsylvania. We lease approximately 4,000 square feet of office space in Dublin, Ireland under a lease which expires in October 2029. In Palo Alto, California, we occupy approximately 44,000 square feet of office space under a lease which expires in August 2017. We have the right to extend the term for up to an additional two years. We also occupy approximately 10,000 square feet of office space in Philadelphia, Pennsylvania, under a lease which expires in February 2013.

We believe that our existing properties are in good condition and suitable for the conduct of our business. As we continue to expand our operations, we may need to lease additional or alternative facilities.

### **Item 3. Legal Proceedings**

On October 18, 2010, Jazz Pharmaceuticals, Inc. received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleges that all five patents listed for Xyrem in the FDA's approved drug products with therapeutic equivalence evaluation documents, or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, Jazz Pharmaceuticals, Inc. 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. Jazz Pharmaceuticals, Inc. is seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) 30 months from the 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 Jazz Pharmaceuticals, Inc. amended the lawsuit against Roxane on February 4, 2011 to include the additional patent in the litigation in response to Roxane's Paragraph IV Certification against this patent. An additional method of use patent covering the distribution system for Xyrem issued in February 2011 and is listed in the Orange Book, and Jazz Pharmaceuticals, Inc. amended the lawsuit on May 2, 2011 to include this additional patent in response to Roxane's Paragraph IV Certification against it. We cannot predict the outcome of this matter.

---

**Table of Contents**

In August 2009, Jazz Pharmaceuticals, Inc. 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. In September 2009, Jazz Pharmaceuticals, Inc. received a Paragraph IV Certification notice from Anchen Pharmaceuticals, Inc., now owned by Par Pharmaceutical Companies, Inc., or Anchen, advising that Anchen 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 Jazz Pharmaceuticals, Inc., is invalid on the basis that the inventions claimed therein were obvious. Anchen's Paragraph IV Certification alleged that the Alkermes patent will not be infringed by Anchen's manufacture, use or sale of the generic product for which the ANDA was submitted and that the Alkermes patent is invalid on the basis that the inventions claimed therein were obvious. On October 6, 2009, Jazz Pharmaceuticals, Inc. and Elan, as plaintiffs, filed a lawsuit against Actavis, Anchen, and Anchen Incorporated, the parent of Anchen, in the United States District Court for the District of Delaware claiming infringement of the Alkermes patent by the defendants in response to the Paragraph IV Certifications filed by Actavis and Anchen. On October 14, 2009, Jazz Pharmaceuticals, Inc. and Elan, as plaintiffs, also filed a lawsuit in the United States District Court for the Central District of California against Anchen claiming infringement of the Alkermes patent based upon Anchen's Paragraph IV Certification. In both cases, the plaintiffs were seeking a permanent injunction that prevented Actavis and Anchen from introducing a generic version of Luvox CR prior to the expiration of the Alkermes patent. On August 25, 2010, Jazz Pharmaceuticals, Inc. and Elan entered into settlement agreements with Anchen. Under the agreements, we, Elan and Anchen agreed to dismiss all of the claims brought in the litigation without prejudice, Anchen agreed not to contest the validity or enforceability of the Alkermes patent in the United States, and Jazz Pharmaceuticals, Inc., Elan and Anchen agreed to release each other from all claims arising in the litigation or relating to the product Anchen intends to market under its ANDA. In addition, Jazz Pharmaceuticals, Inc. granted a sublicense to Anchen of its rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicense is non-transferable, non-sublicensable and royalty-free and is exclusive even as to us and Alkermes (except with respect to Luvox CR) for a period of time. The sublicense will commence on February 15, 2013 or earlier upon the occurrence of certain events. On October 5, 2010, the United States District Court for the Central District of California dismissed the case against Elan without prejudice. On the same date, the United States District Court for the District of Delaware also dismissed the case against Anchen without prejudice. The lawsuit against Actavis is pending in the United States District Court for the District of Delaware. The court has scheduled a Markman hearing for July 24, 2012 and a pretrial conference for March 5, 2013. We cannot predict or determine the outcome of this matter. On September 10, 2011, Jazz Pharmaceuticals, Inc. received a Paragraph IV Certification from Torrent Pharma Limited, or Torrent, advising that it had filed an ANDA with the FDA requesting approval to market a generic version of Luvox CR. Torrent's Paragraph IV Certification alleges that the Alkermes patent will not be infringed by the manufacture, use, sale or offer for sale of the generic product for which the ANDA was submitted and that the Alkermes patent is invalid. On October 21, 2011, Jazz Pharmaceuticals, Inc. 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 by Torrent in response to Torrent's Paragraph IV Certification. Jazz Pharmaceuticals, Inc. is seeking a permanent injunction that prevents Torrent from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. We cannot predict the outcome of this litigation.

Azur Pharma received Paragraph IV Certifications from three generics manufacturers indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD: Barr Laboratories, Inc.'s notice, dated July 11, 2008; Novel Laboratories, Inc.'s notice, dated October 16, 2008; and Mylan Pharmaceuticals, Inc.'s notice, dated June 17, 2010. Each alleged that all of Azur Pharma's licensed patents listed for FazaClo LD in the Orange Book on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by the proposed generic product. Azur Pharma and CIMA filed a lawsuit in response to each certification claiming infringement based on such certification: against Barr Laboratories, Inc. on August 21, 2008; against Novel Laboratories, Inc. on November 25, 2008, and against Mylan Pharmaceuticals, Inc. on July 23, 2010. Each case was filed in the U.S. District Court for the District of

**Table of Contents**

Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr Laboratories, entered into an agreement settling the patent litigation and granted a sublicense of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD. The sublicenses will commence in July 2012 and May 2015 for FazaClo LD and FazaClo HD, respectively, or earlier upon the occurrence of certain events. In August 2011, Azur Pharma received a Paragraph IV Certification from Teva advising that Teva has filed an ANDA with the FDA seeking approval to market a generic version of FazaClo HD. As noted above, FazaClo HD was covered in the July 2011 settlement agreement with Teva. We cannot predict the outcome of the matters with Novel Laboratories, Inc. and Mylan Pharmaceuticals, Inc.

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, in California Superior Court in the County of Los Angeles. The complaint, among other things, alleges that Azur Pharma and its subsidiary breached certain contractual obligations relating to contingent payments in respect of FazaClo. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations owing to Dr. Cutler and certain other persons in relation to FazaClo. The complaint further alleges that certain contingent payments are due because sales thresholds have been achieved, entitling him to either \$10.5 million or \$25.0 million, plus unspecified punitive damages and attorneys' fees. Azur Pharma denied the allegations in the complaint, moved to quash the summons for lack of jurisdiction by the California state court, and requested that the court send the dispute to arbitration under the contract under which Azur Pharma was sued. The litigation is in the early stages. We intend to vigorously defend ourselves in connection with this litigation; however, this, like all litigation, carries certain risks and there can be no assurance of the outcome.

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

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**  
**Market Information**

As a result of the merger, all of the shares of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the merger were canceled and automatically converted into and became the right to receive our ordinary shares on a one-for-one basis, and Jazz Pharmaceuticals, Inc. became a wholly-owned subsidiary of Jazz Pharmaceuticals plc.

Prior to January 18, 2012, the common stock of Jazz Pharmaceuticals, Inc. was traded on The NASDAQ Global Select Market (or The NASDAQ Global Market prior to January 3, 2012) under the trading symbol **JAZZ**. The following table sets forth the high and low intraday sales prices of Jazz Pharmaceuticals, Inc. common stock on The NASDAQ Global Market from January 1, 2010 through December 31, 2011 for the periods indicated.

	<b>High</b>	<b>Low</b>
<b>Calendar Quarter 2010</b>		
First Quarter	\$ 13.95	\$ 8.01
Second Quarter	\$ 12.19	\$ 6.38
Third Quarter	\$ 11.90	\$ 7.51
Fourth Quarter	\$ 20.28	\$ 9.61
<b>Calendar Quarter 2011</b>		
First Quarter	\$ 33.83	\$ 18.85
Second Quarter	\$ 34.97	\$ 23.50
Third Quarter	\$ 47.88	\$ 31.87
Fourth Quarter	\$ 45.81	\$ 34.02

Our ordinary shares began trading on The NASDAQ Global Select Market under the trading symbol **JAZZ** on January 18, 2012. On February 21, 2012, the last reported sales price per share of our ordinary shares was \$46.91 per share.

**Holders of Ordinary Shares**

As a result of the merger, Jazz Pharmaceuticals, Inc. became our wholly-owned subsidiary. As of February 21, 2012, there were five holders of record of our ordinary shares. Because many of our ordinary shares are held by brokers, nominees and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

**Dividends**

Neither Jazz Pharmaceuticals, Inc. nor Azur Pharma has ever declared or paid any cash dividends and we do not presently plan to pay cash dividends in the foreseeable future. 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.

**Unregistered Sales of Equity Securities**

Except as previously reported in Jazz Pharmaceuticals, Inc.'s quarterly reports on Form 10-Q filed with the SEC during the year ended December 31, 2011, there were no unregistered sales of equity securities by Jazz Pharmaceuticals, Inc. during the year ended December 31, 2011.

**Irish Law Matters**

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

As a result of the merger, the outstanding shares of the common stock of Jazz Pharmaceuticals, Inc. were canceled and automatically converted into the right to receive our ordinary shares. As we are an Irish incorporated company, the following matters of Irish law are relevant to the holders of our ordinary shares.

---

**Table of Contents**

*Irish Restrictions on Import and Export of Capital*

Except as indicated below, there are no restrictions on non-residents of Ireland dealing in Irish domestic securities, which includes ordinary shares of Irish companies. Dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. The Financial Transfers Act, 1992 gives power to the Minister for Finance of Ireland to restrict financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union. The acquisition or disposal of interests in shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Burma (Myanmar), Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaida, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People's Republic of Korea (North Korea), Iran, Iraq, Côte d'Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbor certain terrorist groups, without the prior permission of the Central Bank of Ireland.

Any transfer of, or payment in respect of, a share or interest in a share involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law.

*Irish Taxes Applicable to U.S. Holders*

*Withholding and Income Tax on Dividends.* While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish dividend withholding tax, or DWT, at the standard rate of income tax (currently 20%), unless an exemption applies. Dividends on our ordinary shares that are owned by residents of the United States and held beneficially through the Depositary Trust Company, or DTC, will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the United States.

Dividends on our ordinary shares that are owned by residents of the United States and held directly would be paid on or before one year after the relevant date (defined below) without any DWT if the shareholder held shares of Jazz Pharmaceuticals, Inc. common stock on December 12, 2011, the date on which it was publicly announced that the last Jazz Pharmaceuticals, Inc. stockholder vote approving the merger had passed, which is referred to as the relevant date, and has provided a valid Form W-9 showing a U.S. address or a valid U.S. taxpayer identification number to our transfer agent or if the shareholder did not hold shares of Jazz Pharmaceuticals, Inc. common stock on the relevant date and has provided the appropriate Irish dividend withholding tax forms to our transfer agent, in either case, by the due date to be determined by us before the record date for the first dividend to which the shareholder is entitled.

In addition, all shareholders who hold their ordinary shares directly and who are residents of the United States (regardless of when such shareholders acquired their ordinary shares) must complete the appropriate Irish DWT forms in order to receive dividends paid later than one year after the relevant date without DWT. Such shareholders must provide the appropriate Irish forms to their brokers (so that such brokers can further transmit the relevant information to our qualifying intermediary) before the record date for the first dividend paid later than one year after the relevant date (in the case of ordinary shares held beneficially), or to our transfer agent by the due date to be determined by us before such record date (in the case of ordinary shares held directly).

If any shareholder who is resident in the United States receives a dividend subject to DWT, he or she should generally be able to make an application for a refund from the Irish Revenue Commissioners on the prescribed form.



## **Table of Contents**

Irish income tax (if any) may arise in respect of dividends paid by us. However, a shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT, generally has no liability for Irish income tax or to the universal social charge on a dividend from us unless he or she holds his or her ordinary shares through a branch or agency in Ireland which carries out a trade on his or her behalf.

While the U.S./Ireland Double Tax Treaty contains provisions regarding withholding, due to the wide scope of the exemptions from DWT available under Irish domestic law, it would generally be unnecessary for a U.S. resident shareholder to rely on the treaty provisions.

*Capital Acquisitions Tax.* Irish capital acquisitions tax, or CAT, is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 30% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the donee and (ii) the aggregation of the values of previous gifts and inheritances received by the donee from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Our shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

*Stamp Duty.* Irish stamp duty (if any) may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC will not be subject to Irish stamp duty. A transfer of our ordinary shares (i) by a seller who holds ordinary shares outside of DTC to any buyer, or (ii) by a seller who holds the ordinary shares through DTC to a buyer who holds the acquired ordinary shares outside of DTC, may be subject to Irish stamp duty (currently at the rate of 1% of the price paid or the market value of the ordinary shares acquired, if greater). The person accountable for payment of stamp duty is the buyer or, in the case of a transfer by way of a gift or for less than market value, all parties to the transfer.

A shareholder who holds ordinary shares outside of DTC may transfer those ordinary shares into DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) as a result of the transfer and at the time of the transfer into DTC there is no sale of those book-entry interests to a third party being contemplated by the shareholder. Similarly, a shareholder who holds ordinary shares through DTC may transfer those ordinary shares out of DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the ordinary shares (and in exactly the same proportions) as a result of the transfer, and at the time of the transfer out of DTC there is no sale of those ordinary shares to a third party being contemplated by the shareholder. In order for the share registrar to be satisfied as to the application of this Irish stamp duty treatment where relevant, the shareholder must confirm to us that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) (or vice-versa) as a result of the transfer and there is no agreement for the sale of the related book-entry interest or the ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party being contemplated.

**Table of Contents**

**Performance Measurement Comparison(1)**

The following graph shows the total stockholder return on the last day of each month of an investment of \$100 in cash on June 1, 2007, the date of Jazz Pharmaceuticals, Inc.'s initial public offering, for (i) Jazz Pharmaceuticals, Inc. common stock; (ii) the NASDAQ Composite Index; and (iii) the NASDAQ Biotechnology Index through December 31, 2011. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of the full amount of all dividends; however no dividends have been declared on our common stock to date. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

**COMPARISON OF 55 MONTH CUMULATIVE TOTAL RETURN(2)**

Among Jazz Pharmaceuticals Inc., the NASDAQ Composite Index,  
and the NASDAQ Biotechnology Index

\*\$100 invested on 6/1/07 in stock or 5/31/07 in index, including reinvestment of dividends.

Fiscal year ending December 31.

- (1) This section is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Jazz Pharmaceuticals plc, under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.
- (2) Information used in the graph was obtained from Research Data Group, Inc.

**Table of Contents**

**Item 6. Selected Financial Data**

The following selected consolidated financial data reflects the consolidated results of operations and financial position of Jazz Pharmaceuticals, Inc. as of and for the years presented herein. Jazz Pharmaceuticals, Inc. is treated as the acquiring company in the merger for accounting purposes and the merger transaction is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the historical financial statements of Jazz Pharmaceuticals, Inc. prior to the effective time of the merger on January 18, 2012 became our historical financial statements. The consolidated financial statements of Jazz Pharmaceuticals, Inc. included in this Annual Report on Form 10-K do not include any operations of Azur Pharma prior to the merger because the merger was consummated after the periods covered by the financial statements included in this Annual Report on Form 10-K.

The following selected consolidated financial data should be read together with our consolidated financial statements and accompanying notes and Management's Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this Annual Report on Form 10-K. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and the accompanying notes. Jazz Pharmaceuticals, Inc.'s historical results are not necessarily indicative of our future results.

We derived the consolidated statements of operations data for the years ended December 31, 2011, 2010 and 2009 and the consolidated balance sheet data as of December 31, 2011 and 2010 from Jazz Pharmaceuticals, Inc.'s audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2008 and 2007, and the selected consolidated balance sheet data as of December 31, 2009, 2008, and 2007 are derived from Jazz Pharmaceuticals, Inc.'s audited consolidated financial statements not included in this Annual Report on Form 10-K.

**Table of Contents**

	2011	Year Ended December 31,			2007
		2010	2009	2008	
(In thousands, except per share amounts)					
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales, net	\$ 266,518	\$ 170,006	\$ 115,108	\$ 64,637	\$ 53,536
Royalties and contract revenues	5,759	3,775	13,341	2,877	11,767
<b>Total revenues</b>	<b>272,277</b>	<b>173,781</b>	<b>128,449</b>	<b>67,514</b>	<b>65,303</b>
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technology and intangible asset impairment)	13,942	13,559	9,638	13,924	8,903
Selling, general and administrative	108,936	68,996	58,652	111,401	78,540
Research and development	14,120	25,612	36,561	69,963	69,792
Intangible asset amortization	7,448	7,825	7,668	12,828	9,217
Intangible asset impairment				29,763	20,160
Provision for government settlement					17,469
<b>Total operating expenses</b>	<b>144,446</b>	<b>115,992</b>	<b>112,519</b>	<b>237,879</b>	<b>204,081</b>
Income (loss) from operations	127,831	57,789	15,930	(170,365)	(138,778)
Interest income and other, net	75	4	30	1,850	7,739
Interest expense (including \$570, \$1,183, \$1,179 and \$4,104 for the years ended December 31, 2010, 2009, 2008 and 2007, respectively, pertaining to a related party)	(1,675)	(12,728)	(22,796)	(19,742)	(13,647)
Gain on sale of product rights				3,918	5,860
Loss on extinguishment of debt (including \$701 for the year ended December 31, 2010 pertaining to a related party)	(1,247)	(12,287)			
<b>Net income (loss)</b>	<b>\$ 124,984</b>	<b>\$ 32,778</b>	<b>\$ (6,836)</b>	<b>\$ (184,339)</b>	<b>\$ (138,826)</b>
Net income (loss) per share:					
Basic	\$ 3.01	\$ 0.90	\$ (0.23)	\$ (7.19)	\$ (10.04)
Diluted	\$ 2.67	\$ 0.83	\$ (0.23)	\$ (7.19)	\$ (10.04)
Weighted-average common shares used in computing net income (loss) per share :					
Basic	41,499	36,343	30,018	25,646	13,829
Diluted	46,798	39,411	30,018	25,646	13,829
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities	\$ 157,898	\$ 44,794	\$ 15,595	\$ 25,907	\$ 102,945
Working capital (deficit)	146,261	14,522	(22,287)	(129,492)	79,235
Total assets	253,573	135,729	107,396	117,498	207,554
Long-term debt, current and non-current (including \$6,552, \$6,747 and \$23,474 as of December 31, 2009, 2008 and 2007, respectively, held by a related party)		40,693	114,866	118,534	75,116
Accumulated deficit	(349,882)	(474,866)	(507,644)	(500,808)	(316,469)

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

Total stockholders equity (deficit)	192,788	30,551	(72,830)	(92,878)	54,992
-------------------------------------	---------	--------	----------	----------	--------

---

## **Table of Contents**

### **Item 7. 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 consolidated financial statements and notes to consolidated financial statements included elsewhere in this Annual Report on Form 10-K. 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 I 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.*

### **The Merger**

On January 18, 2012, pursuant to an Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, as amended, or the merger agreement, a wholly-owned subsidiary of Jazz Pharmaceuticals plc (formerly known as Azur Pharma Public Limited Company) merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the merger and becoming a wholly-owned subsidiary of Jazz Pharmaceuticals plc, which merger is referred to herein as the merger.

Pursuant to the merger agreement, Azur Pharma changed its name to Jazz Pharmaceuticals plc and each share of the common stock, par value \$0.0001 per share, of Jazz Pharmaceuticals, Inc. issued and outstanding immediately prior to the effective time of the merger was canceled and automatically converted into and became the right to receive one ordinary share, nominal value \$0.0001 per share, of Jazz Pharmaceuticals plc. Immediately after giving effect to the issuance of our ordinary shares to the former stockholders of Jazz Pharmaceuticals, Inc. in the merger, approximately 78% of our ordinary shares were held by the former stockholders of Jazz Pharmaceuticals, Inc. and the remaining 22% of our ordinary shares outstanding immediately after giving effect to the merger were held by persons and entities who acquired our ordinary shares prior to the merger. The ordinary shares of Jazz Pharmaceuticals plc trade on the same exchange, The NASDAQ Global Select Market, and under the trading symbol JAZZ, as the Jazz Pharmaceuticals, Inc. common stock prior to the merger. We are considered to be the successor to Jazz Pharmaceuticals, Inc. for certain purposes under both the Securities Exchange Act of 1934, as amended and the Securities Act of 1933, as amended.

Jazz Pharmaceuticals, Inc. is treated as the acquiring company in the merger for accounting purposes, and the merger is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the consolidated financial statements of Jazz Pharmaceuticals, Inc. became our consolidated financial statements. The consolidated financial statements included in this Annual Report on Form 10-K do not cover any operations of Azur Pharma prior to the merger because the merger was consummated after the periods covered by the financial statements included in this Annual Report on Form 10-K. Accordingly, the historical financial information included in this Annual Report on Form 10-K, unless otherwise indicated or as the context otherwise requires, is that of Jazz Pharmaceuticals, Inc. prior to the merger. For information regarding the historical results of the operations and financial condition of Azur Pharma, please refer to the separate Annual Report on Form 10-K for the year ended December 31, 2011 that we filed with the Securities and Exchange Commission covering the last full fiscal year of Azur Pharma (Commission File No. 333-177528).

Unless otherwise indicated or the context otherwise requires, all references herein 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 to the effective time of the 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 merger on January 18, 2012. The historical financial information included in this Management's Discussion and Analysis of Financial Condition and Results of Operations is that of Jazz Pharmaceuticals, Inc. prior to the merger.

## Table of Contents

### Overview

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

In 2011 we achieved our second successive year of profitability, with significant increases in net income and operating cash flows, driven by increases in product sales, in particular an increase in sales of Xyrem. In 2011, net income and operating cash flows were \$125.0 million and \$151.6 million, respectively, representing increases of 281% and 158% over 2010, respectively. In July 2011, with cash generated from operations, we repaid in full the \$33.3 million principal amount of our term loan and as of December 31, 2011 we had \$157.9 million of cash, cash equivalents and marketable securities and no debt.

While we have a more diversified product portfolio as a result of the merger, Xyrem continues to be our largest selling product. As a result, we continue to place a high priority on growing sales of Xyrem in its approved indications and enforcing our intellectual property rights. Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, as set forth in Part I Item 1A of this Annual Report on Form 10-K. We plan to leverage the commercial, medical and scientific experience of the combined enterprise resulting from the merger in maximizing the potential of our other products and product candidates.

### Results of Operations

The following table presents revenues and expenses for the years ended December 31, 2011, 2010 and 2009 (amounts in thousands):

	2011	Change	2010	Change	2009
Product sales, net	\$ 266,518	57%	\$ 170,006	48%	\$ 115,108
Xyrem	233,348	64%	142,630	47%	96,763
Luvox CR	33,170	21%	27,376	49%	18,345
Royalties and contract revenues	5,759	53%	3,775	(72%)	13,341
Cost of product sales (excluding amortization of acquired developed technology)	13,942	3%	13,559	41%	9,638
Selling, general and administrative	108,936	58%	68,996	18%	58,652
Research and development	14,120	(45%)	25,612	(30%)	36,561
Intangible asset amortization	7,448	(5%)	7,825	2%	7,668
Interest income and other, net	75	1775%	4	(87%)	30
Interest expense	1,675	(87%)	12,728	(44%)	22,796
Loss on extinguishment of debt	1,247	(90%)	12,287	N/A(1)	

(1) Comparison to prior period is not meaningful.

#### *Product Sales, Net*

Xyrem product sales increased in 2011 and 2010 compared to the immediately preceding years, primarily due to price increases and to a lesser extent increases in sales volume of 11% in 2011 and 7% in 2010. Luvox CR product sales increased in 2011 compared to 2010, primarily due to price increases and to a lesser extent

## **Table of Contents**

increases in sales volume. Luvox CR product sales increased in 2010 compared to 2009, primarily due to increases in sales volumes and to a lesser extent price increases. We expect total product sales will increase in 2012 over 2011 due to growth in sales of Xyrem and due to the inclusion of product sales from our expanded product portfolio resulting from the merger, which will be included in our revenue from the effective time of the merger on January 18, 2012.

### *Royalties and Contract Revenues*

Royalties and contract revenues increased in 2011 compared to 2010, primarily due to the recognition of a \$1.5 million milestone payment related to sales of Xyrem in Europe by UCB Pharma Limited, or UCB, under a license agreement. Royalties and contract revenues decreased in 2010 as compared to 2009 due to the recognition of a \$10.0 million milestone payment in 2009 which was received from UCB in 2008. We expect royalty and contract revenue to decrease slightly in 2012 as compared to 2011.

### *Cost of Product Sales*

Cost of product sales increased in 2011 and 2010 compared to the immediately preceding years primarily due to increased sales volumes in both years. As a percentage of product sales, costs were 5.2%, 8.0% and 8.4% in 2011, 2010 and 2009, respectively. The decrease in cost of product sales as a percentage of product sales in 2011 was primarily due to increases in average selling prices. We expect cost of product sales as a percentage of sales to increase in 2012 compared to 2011 because the cost of product sales as a percentage of revenue on the products added to our portfolio as a result of the merger is higher than that of our existing products. In addition, we expect to record expense related to the fair value adjustment to Azur Pharma's inventory held at the effective time of the merger.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses were higher in 2011 compared to 2010, primarily due to increases in employee-related expenses as a result of an increase in commercial activities, higher stock-based compensation expense including \$6.9 million resulting from the modification of certain stock options in connection with the merger and higher legal and professional expenses of \$11.2 million associated with the merger. Selling, general and administrative expenses were higher in 2010 compared to 2009, primarily due to increases in employee-related expenses and, to a lesser extent, expenses related to our previously planned launch of a product candidate. We expect that selling, general and administrative expenses will be higher in 2012 than in 2011 due to the inclusion of expenses of the former Azur Pharma business subsequent to the effective time of the merger on January 18, 2012.

### *Research and Development Expenses*

Research and development expenses were lower in 2011 and 2010 compared to the immediately preceding years. Direct project costs decreased to \$1.6 million in 2011 from \$11.4 million in 2010 and \$24.3 million in 2009, primarily due to the completion in 2010 of a clinical development program. Our direct development project costs consist primarily of out-sourced study costs, including investigator payments and consulting fees. Headcount-related expenses incurred in the research and development organization were \$12.5 million, \$14.3 million and \$12.3 million in 2011, 2010 and 2009, respectively. We expect research and development expenses to be higher in 2012 than in 2011 due to the inclusion of expenses of the former Azur Pharma business subsequent to the effective time of the merger on January 18, 2012.

### *Intangible Asset Amortization*

During 2011, 2010 and 2009 our intangible assets consisted primarily of developed technology related to Xyrem and Luvox CR, which are amortized on a straight-line basis over their estimated useful lives. As a result



## **Table of Contents**

of the merger we expect to record a significant amount of intangible assets and accordingly we expect intangible asset amortization to increase significantly in 2012.

### *Interest Income and Other, Net*

Interest income was higher in 2011 compared to 2010 because of higher cash, cash equivalents and marketable securities. Interest income was lower in 2010 compared to 2009 due to lower average interest rates.

### *Interest Expense*

Interest expense decreased in 2011 and 2010 compared to the immediately preceding years due to lower average borrowings and lower interest rates.

### *Loss on Extinguishment of Debt*

In 2011, as a result of the repayment of a term loan and the termination of a credit agreement, we recorded a loss on extinguishment of debt of \$1.2 million, which consisted of a \$0.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount with the remainder related to a prepayment penalty and a termination fee. The loss on extinguishment of debt in 2010 was due to the repayment of long-term debt and consisted of \$8.5 million of prepayment premiums and fees, and a \$3.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount.

## **Non-GAAP Financial Measures**

To supplement our financial results presented on a GAAP basis, we use the non-GAAP measures adjusted net income (loss) and adjusted net income (loss) 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 (loss) and adjusted net income (loss) 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: contract revenues related to previously deferred upfront and milestone payments, the gross margin impact of a change in the timing of when Luvox CR revenue is recognized, amortization of intangible assets, stock-based compensation, non-cash interest expense associated with a debt discount and debt issuance costs, loss on extinguishment of debt and costs related to the merger with Azur Pharma.

**Table of Contents**

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

	Year Ended December 31,		
	2011	2010	2009
	(In thousands, except per share amounts)		
GAAP net income (loss)	\$ 124,984	\$ 32,778	\$ (6,836)
Add:			
Intangible asset amortization	7,448	7,825	7,668
Stock-based compensation expense	20,704	8,219	5,957
Non-cash interest expense	394	2,406	2,810
Loss on extinguishment of debt	1,247	12,287	
Transaction and integration costs	11,245		
Deduct:			
Contract revenues	(1,138)	(1,138)	(11,138)
Luvox CR revenue recognition timing change		(1,345)	
Adjusted net income (loss)	\$ 164,884	\$ 61,032	\$ (1,539)
GAAP net income (loss) per diluted share	\$ 2.67	\$ 0.83	\$ (0.23)
Adjusted net income (loss) per diluted share	\$ 3.52	\$ 1.55	\$ (0.05)
Shares used in computing GAAP and adjusted net income (loss) per diluted share amounts	46,798	39,411	30,018

**Liquidity and Capital Resources**

We generated cash flows from operations of \$151.6 million and \$58.9 million in 2011 and 2010, respectively, and have taken a number of measures in the past two years designed to strengthen our balance sheet and improve our liquidity and financial condition. Most recently, in July 2011, we repaid in full the \$33.3 million principal amount of a term loan and repaid all borrowings under a revolving credit facility and in December 2011 we terminated the credit agreement under which we made these borrowings.

As of December 31, 2011, we had cash, cash equivalents and marketable securities of \$157.9 million. On a combined pro forma basis, we would have added an additional \$80.3 million in cash held by Azur Pharma as of December 31, 2011, and our combined business is expected to generate significant operating cash flows. We believe that our existing cash balances and cash we expect to generate from operations will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses as well as the other factors set forth in Part I Item 1A of this Annual Report on Form 10-K under the headings Xyrem is our largest selling product, and, if we are not able to maintain or increase sales of Xyrem, it would have a material adverse effect on our business, financial condition, results of operations and growth prospects and To grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To grow our business over the longer-term, we will need to commit substantial resources to product acquisition and in-licensing costs, to expensive and time-consuming product development and clinical trials of our product candidates, and to expanding our commercial operations. We may need to raise additional funds to license or acquire additional products, product candidates or companies or seek to raise additional funds for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our stockholders.

**Table of Contents**

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

	2011	Year Ended December 31,	
		2010	2009
(In thousands)			
Net cash provided by (used in) operating activities	\$ 151,596	\$ 58,868	\$ (15,878)
Net cash used in investing activities	(81,232)	(2,143)	(6,124)
Net cash (used in) provided by financing activities	(33,082)	(27,526)	12,694
Net increase (decrease) in cash and cash equivalents	\$ 37,282	\$ 29,199	\$ (9,308)

Net cash from operating activities increased by \$92.7 million in 2011 primarily due to an increase in net income of \$92.2 million. Net cash from operating activities increased by \$74.7 million in 2010 primarily due to an increase in net income of \$39.6 million, a net increase in working capital of \$21.1 million and an increase in non-cash adjustments of \$14.0 million which related primarily to the loss on extinguishment of long-term debt.

Net cash used in investing activities in 2011 primarily related to purchases of marketable securities, scheduled payments under our agreement for the rights to market Luvox CR and to a lesser extent purchases of property and equipment, partially offset by proceeds from maturities of marketable securities and releases of restricted cash. Net cash used in investing activities in 2010 included scheduled payments under our agreement for the rights to market Luvox CR, partially offset by a decrease in restricted cash. Net cash used in investing activities in 2009 included scheduled payments under our agreement for the rights to market Luvox CR and an increase in restricted cash, offset by the maturity of an investment in a marketable security.

Net cash used in financing activities in 2011 included a repayment of \$41.7 million for the full principal amount outstanding under a term loan and \$7.4 million for net repayments of a revolving credit facility, partially offset by proceeds from employee stock option exercises and warrant exercises. Net cash used in financing activities in 2010 included the principal repayment of other long-term debt of \$119.5 million offset by proceeds from a common stock offering of \$56.8 million and net cash inflows from a term loan of \$40.1 million. Net cash provided by financing activities in 2009 included net proceeds of \$6.8 million from a private placement of common stock and warrants and \$5.5 million in net borrowings under a prior revolving bank line of credit.

**Contractual Obligations**

The table below presents a summary of our contractual obligations as of December 31, 2011.

Contractual Obligations(1)(2)	Total	Payments due by period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
(In thousands)					
Liability under government settlement	\$ 7,336	\$ 7,336	\$	\$	\$
Purchased product rights liability(3)	4,500	4,500			
Operating lease obligations(4)	3,434	1,898	1,535	1	
Purchase obligations(5)	5,725	5,725			
Total	\$ 20,995	\$ 19,459	\$ 1,535	\$ 1	\$

- (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. The table does not include a fee of \$1.5 million we were required to pay our investment banker contingent upon the successful completion of the merger with Azur Pharma.

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

- (2) We have not included any of the contractual obligations of Azur Pharma as of December 31, 2011. Contractual obligations of Azur Pharma as of December 31, 2011 (excluding milestone or royalty payments)

**Table of Contents**

where the amount and timing of such obligations are unknown or uncertain) principally related to an obligation to make payments totaling \$12.0 million related to the acquisition of rights to Prialt due in 2012, the obligation to make payments totaling \$5.3 million under operating leases and a fee of \$11.5 million payable to an investment banker contingent upon the successful completion of the merger, which fee was subsequently paid.

- (3) This represents payments due to Abbott under a product license agreement. These amounts exclude \$5.0 million we would pay Abbott if net sales of Luvox CR have reached 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.
- (4) Includes the minimum lease payments for our office building in Palo Alto and automobile lease payments for our sales force. In February 2012, we renewed the operating lease for our Palo Alto office building and as a result, we are obligated to make additional payments of \$0.5 million, \$2.1 million, \$2.2 million, \$2.2 million, \$2.3 million and \$1.6 million in 2012, 2013, 2014, 2015, 2016 and 2017. In addition to the minimal lease payments on our office building we are obligated to pay for operating expenses for the lease property, which are not included in the table above.
- (5) Consists of non-cancelable commitments to third party manufacturers of Xyrem and Luvox CR.

**Critical Accounting Policies and Significant Estimates**

The above discussion and analysis of our operating results and financial condition is based upon Jazz Pharmaceuticals, Inc.'s consolidated financial statements, which were prepared in accordance with accounting principles generally accepted in the United States of America. Accordingly, the following discussion of critical accounting policies and significant estimates pertains to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries prior to the merger. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 1 of the Notes to the Consolidated Financial Statements included in this Annual Report, we believe the following accounting estimates and policies to be critical.

**Revenue Recognition**

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured.

*Product Sales, Net*

*Xyrem Domestic.* We sell Xyrem in the United States to a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or Express Scripts. In 2011, sales of Xyrem to Express Scripts accounted for 85% of our net product sales. We recognize revenues from sales of Xyrem within the United States upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment directly to a patient.

We accept returns from and provide Express Scripts with a credit for any product returned by patients to Express Scripts with defects that were not reasonably discoverable upon receipt of the consigned product by Express Scripts. Based on our experience over the past six years, product returns to Express Scripts from patients are rare; during 2011, we issued credits totaling \$0.2 million to Express Scripts for returned product.

*Xyrem International.* We sell limited quantities of Xyrem to UCB for sale in territories outside of North America, and to Valeant, for sale in Canada, under license and distribution agreements. We recognized revenue of \$0.8 million, \$0.7 million and \$1.0 million from international sales of Xyrem during 2011, 2010 and 2009, respectively.

**Table of Contents**

*Luvox CR.* We grant rights to our wholesaler customers to return product six months prior to and up to twelve months after product expiration and issue credits which may be applied against existing or future invoices. We recognize revenue on sales of Luvox CR when the product is delivered to our wholesaler customers and record an estimated amount of product returns.

*Items Deducted from Gross Sales.* Revenues from sales of products within the United States are recorded net of estimated allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and channel inventory data. Because we derive most of our revenues from sales of Xyrem in the United States to one specialty pharmacy customer, Express Scripts, we have a much higher level of knowledge about each prescription than if we sold the product through the normal pharmaceutical wholesaler channel as we do with Luvox CR. As a result, we do not exercise a high degree of judgment in estimating most of the items that are deducted from gross sales. The two most significant items deducted from gross revenue where we exercise judgment are government rebates, which include Medicaid and TRICARE rebates, and estimated returns of Luvox CR.

The following table shows activity related to government rebates for Xyrem and Luvox CR and estimated returns of Luvox CR:

	<b>Government Rebates Payable</b>	<b>Sales Returns Reserve</b>
	(In thousands)	
Balance at December 31, 2008	\$ 171	\$
Provision related to sales in current year	3,158	
Provision adjustment related to sales in prior year	619	
Payments/credits	(1,678)	
Balance at December 31, 2009	2,270	
Provision related to sales in current year	11,083	3,921
Provision adjustment related to sales in prior year	(100)	
Payments/credits	(6,665)	(382)
Balance at December 31, 2010	6,588	3,539
Provision related to sales in current year	21,400	3,055
Provision adjustment related to sales in prior year	82	(805)
Payments/credits	(17,439)	(1,487)
Balance at December 31, 2011	\$ 10,631	\$ 4,302

*Contract Revenues*

Nonrefundable fees where we have no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. In situations where we have continuing performance obligations, nonrefundable fees are deferred and recognized ratably over our estimated performance period. We recognize at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when our performance obligations are completed.

We have an agreement with UCB under which UCB has the right to market Xyrem for certain indications in various countries outside the United States. In 2011, we recognized revenue of \$1.5 million when UCB recorded product sales exceeding an amount specified in our contract with them. In 2008, we received a \$10.0 million

---

## **Table of Contents**

nonrefundable milestone payment which we recognized as revenue in 2009 upon achievement of the milestone. We recognized contract revenues of \$1.1 million during each of 2011, 2010, and 2009 related to two upfront payments from UCB totaling \$15.0 million. As of December 31, 2011, \$9.1 million was recorded as deferred revenues related to these upfront payments and is being recognized ratably through 2019, the end of the expected performance period under the agreement. There has been no change in the expected performance period under our agreement with UCB since its establishment in 2006 at the time of the initial upfront payments. A change in our estimate of the performance period would result in a change in contract revenues.

### ***Inventory Valuation***

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for the product. If our estimate of future demand is too high we may have to write down the carrying value of inventory and record additional charges to cost of product sales. Charges related to inventory reserves during 2011, 2010 and 2009 were insignificant.

### ***Goodwill and Intangible Assets***

#### ***Goodwill***

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products therefore the goodwill impairment test is done by comparing our market capitalization, as determined by our traded share price, to the book value of net assets. 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.

#### ***Intangible Assets***

Intangible assets consist of purchased developed technology and trademarks. The method of amortization reflects the pattern in which the economic benefits of the intangible asset are consumed. If that pattern cannot be reliably determined, we use a straight-line amortization method. Our intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from three to ten years. The estimated useful lives associated with intangible assets are consistent with the estimated lives of the products and may be modified when circumstances warrant. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. We evaluate purchased intangibles and other long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

Our two most significant intangible assets are related to Xyrem for the treatment of cataplexy in patients with narcolepsy and the Xyrem trade name, collectively the Xyrem intangibles, which were recorded as part of an acquisition in 2005. As of December 31, 2011, those two assets had a carrying value of \$13.3 million, or 91% of our total intangible asset carrying amount of \$14.6 million. At the time of the acquisition we estimated the life

**Table of Contents**

of the Xyrem intangibles to be 9.5 years, or through December 31, 2014, which corresponded to the time period during which we expected the assets to generate cash flows in our valuation analysis.

As of December 31, 2011, the gross carrying amount of goodwill was \$38.2 million and the gross carrying amounts and net book values of intangible assets were as follows:

		<b>Gross Carrying Amount</b>	<b>Accumulated Amortization (In thousands)</b>	<b>Net Book Value</b>	<b>Weighted Average Remaining Useful Life (In years)</b>
Developed technology	Xyrem	\$ 39,700	\$ 27,185	\$ 12,515	3.0
Developed technology	Luvox CR	9,700	8,449	1,251	0.4
Trademarks		2,600	1,781	819	3.0
Total		\$ 52,000	\$ 37,415	\$ 14,585	

**Stock-Based Compensation**

We have elected to use the Black-Scholes option pricing model to calculate the fair value of stock option grants under our equity incentive plans and grants under our employee stock purchase plan, or ESPP, and we are using the straight-line method to allocate compensation cost to reporting periods. The fair value of stock options was estimated using the following assumptions:

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Volatility	72%	85%	91%
Expected term (years)	5.2	6.0	6.1
Range of risk-free rates	0.0-2.7%	1.5-3.1%	1.8-3.1%
Expected dividend yield	0.0%	0.0%	0.0%

The two inputs which require the greatest judgment and have a large impact on fair values are expected term and volatility.

The expected term of stock options grants represents the weighted-average period the awards are expected to remain outstanding. For stock options granted in 2011, we estimated the weighted-average expected term based on historical exercise and expiration data related to our stock options as well as the contractual term and vesting terms of the grants. Prior to 2011, the expected term was estimated by assuming stock options would be exercised at the mid-point between the vest date and the contractual term due, at that time, to limited historical exercise data.

We use a weighting of the historic volatility of a peer group, the historic volatility of our own common stock and the implied volatility of our own common stock to estimate future volatility for stock option grants and we used the implied volatility of our own common stock to estimate the volatility for grants under our ESPP.

**Accrued Liabilities**

As part of the process of preparing financial statements, we are required to estimate accrued liabilities. This process involves identifying goods received and services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued liabilities include the cost of marketing and promotional materials, contract service fees, such as amounts paid to clinical monitors, data management organizations, clinical research organizations and fees paid to contract manufacturers in conjunction with the production of clinical materials, and professional service fees, such as fees to lawyers and accountants. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. To the extent that we do not





## **Table of Contents**

identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to our judgment. We make these judgments in accordance with the facts and circumstances known to us through our internal processes. Our internal processes require substantially all of our spending for services to be under contracts with our service providers and to be documented and tracked under internally-generated purchase orders based on designated spending authorizations. As of each balance sheet date, employees who are responsible for managing the contracts, and who are in contact with the outside service providers as to progress or stage of completion of the services and the agreed upon fee to be paid for such services, review current contracts and the related open purchase orders. We adjust for spending not already reflected in our accounting records in accordance with generally accepted accounting principles. To date, there have been no material differences between the amounts of expenses accrued at our balance sheet dates and the amount at which such expenses were subsequently invoiced. Although we do not expect our current estimates to be materially different when invoiced, our understanding of the status and timing of services provided relative to the actual timing and levels of service provided may vary and may result in adjustments in future periods.

### ***Income Taxes***

We utilize the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Based on available objective evidence, management believes it more likely than not that our deferred tax assets are not recognizable and will not be recognizable until we have sufficient taxable income. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. In the future, we may conclude that it is more likely than not that all or a portion of our deferred tax assets are realizable, and we will reverse the valuation allowance and recognize a related tax benefit at such time. This determination depends on a variety of factors, some of which are subjective. We have also provided for uncertain tax positions that we believe are not more likely than not to be sustained upon examination by tax authorities.

### **Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board, or the FASB, issued guidance which changes certain fair value measurement principles and increases disclosure requirements, particularly for fair value measurements subject to significant judgment and is effective for fiscal years beginning after December 15, 2011. The adoption of this amendment will not have a material impact on our results of operations or financial position.

In June and December 2011, the FASB issued amended guidance on the presentation of comprehensive income in financial statements. The amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. The amendment eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this amendment will not have a material impact on our results of operations or financial position.

In September 2011, the FASB issued amended guidance related to the goodwill impairment test which allows companies to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The amendment is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this amendment will not have a material impact on our results of operations or financial position.

---

## **Table of Contents**

### **Off-Balance Sheet Arrangements**

Since Jazz Pharmaceuticals, Inc.'s inception, except for standard operating leases, Jazz Pharmaceuticals, Inc. has not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

### **Related Parties**

*Senior Secured Notes.* In 2010, we repaid in full all of our then outstanding senior secured notes, of which \$6.8 million principal amount was paid to an entity affiliated with Kohlberg, Kravis & Roberts & Co. L.P., or KKR, a significant stockholder. In addition, in 2010 we paid prepayment penalties and a fee to the holders of the senior secured notes totaling \$8.5 million, of which \$0.5 million was paid to the KKR affiliate. Cash paid for interest with respect to then outstanding senior secured notes held by the KKR affiliate was \$0.5 million and \$1.3 million in 2010 and 2009, respectively. All payments to KKR were in proportion to its ownership of the senior secured notes.

In 2009, the exercise price of all warrants to purchase common stock issued to the holders of the then outstanding senior secured notes was reduced to \$9.34 per share as a result of an amendment to the agreement governing the senior secured notes. This included warrants to purchase 70,156 shares of our common stock held by the KKR affiliate the exercise price of which was reduced from \$20.36 to \$9.34 per share.

*2009 and 2010 Common Stock Offerings.* In a private placement we completed in 2009, 1,858,486 shares of common stock and a warrant to purchase 929,243 shares of common stock were acquired by Longitude Venture Partners, L.P. and 37,248 shares of common stock and a warrant to purchase 18,624 shares of common stock were acquired by Longitude Capital Associates, L.P. In July 2009, Patrick G. Enright was elected to our board of directors in connection with the closing of the private placement. Mr. Enright is a managing member of Longitude Capital Partners, LLC, the sole general partner of Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P. In addition, in 2010 we issued 7,000,000 shares of our common stock in an underwritten public offering of which 821,851 shares and 16,472 shares were purchased from the underwriter by Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P., respectively. The remaining shares were purchased from the underwriter by third party investors on the same terms and conditions.

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Except as the context otherwise requires, the following discussion of quantitative and qualitative disclosures about market risk pertains to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries as of December 31, 2011. As of December 31, 2011, our exposure to market risk was confined to our cash equivalents and marketable securities, all of which have maturities of less than one year and bear interest rates at variable rates and are denominated in, and pay interest in, U.S. dollars. The fair value of items exposed to market risk was \$124.6 million as of December 31, 2011. The goals of our investment policy are liquidity and capital preservation. We limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including U.S. government agencies, corporate bonds, commercial paper and money market funds. Our cash equivalents and marketable securities as of December 31, 2011 consisted primarily of corporate debt securities, money market funds, obligations of U.S. government agencies and certificates of deposit. The effect of a 50 basis point change in the average yield earned on our cash equivalents and short-term investments would have the effect of increasing our interest income by less than \$0.6 million and, due to the nature of the investments, would not have had an impact on their fair value. For additional information see Note 3 of the Notes to the Financial Statements included elsewhere in this Annual Report on Form 10-K.

As of December 31, 2011, operating expenses and capital expenditures denominated in currencies other than U.S. dollars were insignificant. We receive royalties on certain net product sales that are denominated in other currencies, primarily in Euros, but these royalties comprise a small portion of our revenues. As a result of the

**Table of Contents**

merger, we will face exposure to changes in the exchange rate of the U.S. dollar and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. However, we do not expect our exposure to such exchange rate changes will have a material impact on our reported expenses.

**Item 8. Financial Statements and Supplementary Data**

On January 18, 2012, the merger contemplated by an Agreement and Plan of Merger and Reorganization dated as of September 19, 2011, as amended, was consummated in connection with which a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the merger and becoming a wholly-owned subsidiary of Jazz Pharmaceuticals plc. In connection with the merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc and became the successor to Jazz Pharmaceuticals, Inc. under the Exchange Act. In the merger, each share of the common stock, par value \$0.0001 per share, of Jazz Pharmaceuticals, Inc. issued and outstanding immediately prior to the effective time of the merger was canceled and automatically converted into and became the right to receive one ordinary share, nominal value \$0.0001 per share, of Jazz Pharmaceuticals plc. Immediately after giving effect to the issuance of our ordinary shares to the former stockholders of Jazz Pharmaceuticals, Inc. in the merger, approximately 78% of our ordinary shares were held by the former stockholders of Jazz Pharmaceuticals, Inc. and the remaining 22% of our ordinary shares outstanding immediately after giving effect to the merger were held by persons and entities who acquired our ordinary shares prior to the merger. Jazz Pharmaceuticals, Inc. is treated as the acquiring company for accounting purposes and the merger is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. As a result, the consolidated financial statements of Jazz Pharmaceuticals, Inc. for the periods through January 18, 2012 became our consolidated financial statements for the same respective periods. The consolidated financial statements included in this Annual Report on Form 10-K do not include any operations of Azur Pharma prior to the merger because the merger was consummated after the periods covered by the financial statements included in this Annual Report on Form 10-K. Accordingly, the historical financial information included in this Annual Report on Form 10-K, unless otherwise indicated or the context otherwise requires, is that of Jazz Pharmaceuticals, Inc. prior to the merger.

Jazz Pharmaceuticals, Inc.'s consolidated financial statements as listed below are included in this Annual Report on Form 10-K as pages F-1 through F-28.

	<b>Page</b>
<b>Jazz Pharmaceuticals, Inc.</b>	
<u>Reports of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets</u>	F-2
<u>Consolidated Statements of Operations</u>	F-3
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	F-4
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

---

**Table of Contents**

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

**Item 9A. 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 Jazz Pharmaceuticals, Inc.'s 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 Annual Report on Form 10-K. Based on their evaluation, our principal executive officer and principal financial officer concluded that Jazz Pharmaceuticals, Inc.'s disclosure controls and procedures were effective as of December 31, 2011.

*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 Jazz Pharmaceuticals, Inc.'s 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**

No changes in Jazz Pharmaceuticals, Inc.'s internal control over financial reporting occurred during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Upon completion of the merger transaction on January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined. As a result of the completion of the merger, we are evaluating our internal control policies and procedures and may make modifications to the design of our internal control policies and procedures.

**Management's Report on Internal Control over Financial Reporting**

The following report is provided by management in respect of Jazz Pharmaceuticals, Inc.'s internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act):

1. Management is responsible for establishing and maintaining adequate internal control over financial reporting.
2. Management has used the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO framework, to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of Jazz Pharmaceuticals, Inc.'s internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of Jazz Pharmaceuticals, Inc.'s internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.
3. Management has assessed the effectiveness of Jazz Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011 and has concluded that such internal control over financial reporting was effective. There were no material weaknesses in internal control over financial reporting identified by management.
4. Ernst & Young LLP, Jazz Pharmaceuticals, Inc.'s independent registered public accounting firm has audited the consolidated financial statements of Jazz Pharmaceuticals, Inc. included herein and has issued an audit report on Jazz Pharmaceuticals, Inc.'s internal control over financial reporting which is included below.

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholder of

Jazz Pharmaceuticals, Inc., a wholly-owned subsidiary of Jazz Pharmaceuticals plc

We have audited Jazz Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Jazz Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Jazz Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Jazz Pharmaceuticals, Inc. as of December 31, 2011 and 2010 and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2011 of Jazz Pharmaceuticals, Inc. and our report dated February 28, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

February 28, 2012

---

## **Table of Contents**

### **Item 9B. Other Information**

On February 28, 2012, Jazz Pharmaceuticals, Inc. entered into a Second Amendment of Lease, or Second Amendment, to the Commercial Lease, or Lease, dated as of June 2, 2004, as amended, with Wheatley-Fields, LLC, successor in interest to The Board of Trustees of the Leland Stanford Junior University. Under the Second Amendment, the term of the Lease has been extended by five years, or the Extended Term, at new rental rates beginning September 1, 2012. September 1, 2012 is also the effective date of the Second Amendment.

Under the terms of the Second Amendment the monthly base rent will change from its current rate of \$78,926.40 per month to the following: \$36,000 for the month of September 2012; \$171,007.20 per month from October 1, 2012 through August 31, 2013; \$177,874.49 per month from September 1, 2013 through August 31, 2014; \$184,961.39 per month from September 1, 2014 through August 31, 2015; \$192,360.84 per month from September 1, 2015 through August 31, 2016; and \$200,054.24 per month from September 1, 2016 through August 31, 2017.

Jazz Pharmaceuticals, Inc. has one renewal option to extend the term of the Lease for a period of two years beyond the Extended Term. If an option is exercised, the renewal term will be upon the same terms and conditions as the original term, except that the base rent will be: \$208,056.41 per month from September 1, 2017 through August 31, 2018, and \$216,378.66 per month from September 1, 2018 through August 31, 2019.

The foregoing description of the material terms of the Second Amendment does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the Second Amendment that is attached to and filed as Exhibit 10.31 to this Annual Report on Form 10-K.

## **PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K and incorporated by reference to our definitive proxy statement for our 2012 annual general meeting of shareholders to be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended. If such definitive proxy statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

### **Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item relating to our directors and nominees for director is to be found under the section entitled "Proposal 1 Election of Directors" in the proxy statement for our 2012 annual general meeting of shareholders. Such information is incorporated herein by reference. The information required by this item relating to our executive officers is to be found under the section entitled "Executive Officers" in the proxy statement for our 2012 annual general meeting of shareholders. Such information is incorporated herein by reference. The information required by this item relating to our audit committee, audit committee financial expert and procedures by which shareholders may recommend nominees to our board of directors, may be found under the section entitled "Corporate Governance and Board Matters" appearing in the proxy statement for our 2012 annual general meeting of shareholders. Such information is incorporated herein by reference. Information regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, is to be found under the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in our proxy statement for our 2012 annual general meeting of shareholders. Such information is incorporated herein by reference.

Our Code of Conduct applies to all of our employees, directors and officers, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and those of our subsidiaries, including Jazz Pharmaceutical, Inc. The Code of Conduct is available on our website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) under the section entitled "About Us" at "Corporate Responsibility". Shareholders may request a free copy of the Code of Conduct by submitting a written request to Jazz Pharmaceuticals plc, Attention: Investor Relations, c/o Jazz Pharmaceuticals, Inc., 3180 Porter Drive, Palo

## **Table of Contents**

Alto, California 94304. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

### **Item 11. Executive Compensation**

The information required by this item is to be included in our proxy statement for our 2012 annual general meeting of shareholders under the sections entitled Executive Compensation, Director Compensation, Corporate Governance and Board Matters Compensation Committee Interlocks and Insider Participation and Corporate Governance and Board Matters Compensation Committee Report and is incorporated herein by reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item with respect to equity compensation plans is to be included in our proxy statement for our 2012 annual general meeting of shareholders under the section entitled Equity Compensation Plan Information and is incorporated herein by reference. As a consequence of the merger, Jazz Pharmaceuticals, Inc. became our wholly-owned subsidiary on January 18, 2012. Information concerning the ownership of our ordinary shares is to be included in our proxy statement for our 2012 annual general meeting of shareholders.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item is to be included in our proxy statement for our 2012 annual general meeting of shareholders under the sections entitled Certain Relationships and Related Transactions and Corporate Governance and Board Matters Independence of Jazz Pharmaceuticals Board of Directors and is incorporated herein by reference.

### **Item 14. Principal Accounting Fees and Services**

The information required by this item is to be included in our proxy statement for our 2012 annual general meeting of shareholders under the section entitled Proposal 2 Approval of the Appointment of Independent Auditors and Auditors Remuneration and is incorporated herein by reference.

## **PART IV**

### **Item 15. Exhibits and Financial Statement Schedules**

*(a) The following documents are filed as part of this Annual Report on Form 10-K*

*1. Index to Financial Statements:*

See Index to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K.

*2. Financial Statement Schedules:*

The following financial statement schedule of Jazz Pharmaceuticals, Inc. is filed as part of this Annual Report on Form 10-K on page F-29 and should be read in conjunction with the consolidated financial statements of Jazz Pharmaceuticals, Inc.

Schedule II: Valuation and Qualifying Accounts



## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

All other schedules are omitted because they are not applicable, not required under the instructions, or the requested information is shown in the consolidated financial statements or related notes thereto.

*(b) Exhibits The following exhibits are included herein or incorporated herein by reference. The exhibits listed below and in the Exhibit Index hereto include exhibits that would be required if this report were filed by Jazz Pharmaceuticals, Inc. and also includes requisite exhibits of the registrant.*

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500) filed with the Commission 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).
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).
3.2A	Fifth Amended and Restated Certificate of Incorporation of Jazz Pharmaceuticals, Inc.
3.2B	Amended and Restated Bylaws of Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.4 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
4.1A	Reference is made to Exhibit 3.1 with respect to Jazz Pharmaceuticals plc.
4.1B	Reference is made to Exhibits 3.2A and 3.2B with respect to Jazz Pharmaceuticals, Inc.
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.
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Series BB Preferred Stock Warrants originally issued by Jazz Pharmaceuticals, Inc.
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc.
4.5	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc.

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
4.6	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. on July 7, 2009.
4.7A*	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.7B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein.
4.8	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1A+*	Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.21 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.1B+	Jazz Pharmaceuticals plc 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.5 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.2+*	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.22 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.3A+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.3 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.3B+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland.
10.3C+*	Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.23 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.4+*	Form of Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.24 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007).
10.5	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.50 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007).
10.6	Quality Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.51 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).
10.7	Commercial Lease, dated as of June 2, 2004, by and between Jazz Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.52 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.8A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc. and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57A in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.8B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57B in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.8C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57C in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.8D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57D in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.9+*	Form of Letter, amending outstanding options granted under Jazz Pharmaceuticals, Inc. s 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.60 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
10.10+*	Form of Stock Award Grant Notice and Stock Award Agreement under Jazz Pharmaceuticals, Inc. s 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.73 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008).
10.11	Revision of Payment Terms of the Plea Agreement dated as of July 17, 2007 between the U.S. Attorney for the Eastern District of New York and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.82 in Jazz Pharmaceuticals, Inc. s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009).
10.12	Amendment to Settlement Agreement, signed by the Company on February 6, 2009, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc. and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.83 in Jazz Pharmaceuticals, Inc. s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009).
10.13	First Amendment of Lease, dated June 1, 2009, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.86 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 4, 2009).
10.14	Form of Indemnification Agreement between Jazz Pharmaceuticals, Inc. and its officers and directors (incorporated herein by reference to Exhibit 10.89 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
10.15+	Offer Letter from Jazz Pharmaceuticals, Inc. to Kathryn Falberg (incorporated herein by reference to Exhibit 10.92 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on December 3, 2009).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.16	Supply Agreement, dated as of April 1, 2010, by and between Jazz Pharmaceuticals, Inc. and Siegfried (USA) Inc. (incorporated herein by reference to Exhibit 10.54 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2010, as filed with the SEC on May 6, 2010).
10.17A+*	Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.25 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.17B+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.26 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.17C+*	Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.17D+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.17E+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 99.4 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.18A+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.18B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 99.2 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.18C+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan Offering Document, as amended and restated (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.19+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document.
10.20A+*	Jazz Pharmaceuticals, Inc. Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.20B+	Jazz Pharmaceuticals plc Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 99.6 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.21+	Separation Agreement, dated January 6, 2011, by and between Jazz Pharmaceuticals, Inc. and Robert Myers (incorporated herein by reference to Exhibit 10.53 in Jazz Pharmaceuticals, Inc. s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
10.22	Master Services Agreement, dated April 15, 2011, by and between Jazz Pharmaceuticals, Inc., CuraScript, Inc. and Express Scripts Specialty Distribution Services, Inc. (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2011, as filed with the SEC on May 9, 2011).
10.23+	Offer Letter from Jazz Pharmaceuticals, Inc. to Jeffrey Tobias, M.D. (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 8, 2011).
10.24+	Form of Notice to Option Holder Re: Outstanding Nonstatutory Stock Options to Purchase Shares of Jazz Pharmaceuticals, Inc. s Common Stock (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 28, 2011).
10.25	Form of Indemnification Agreement between Jazz Pharmaceuticals plc and its officers and directors (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.26	Escrow Agreement made and entered into as of January 18, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., Seamus Mulligan, solely in his capacity as Indemnitors Representative, and Deutsche Bank National Trust Association, as escrow agent (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.27+	Separation Agreement, dated January 18, 2012, by and between Jazz Pharmaceuticals plc and Carol Gamble.
10.28	Lease Agreement, dated October 20, 2008, between Seamus Mulligan, as lessor, and Jazz Pharmaceuticals plc, as lessee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc s registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.29+	Employment Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc s registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.30	Noncompetition Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc s registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.31	Second Amendment of Lease, dated February 28, 2012, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University.
10.32+	Jazz Pharmaceuticals plc Non-Employee Director Compensation Arrangements.
10.33+	Jazz Pharmaceuticals plc Cash Bonus Plan.
10.34+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan.
10.35+	Form of Option Grant Notice and Form of Stock Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.
10.36+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.37+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.
10.38+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.
10.39A+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.1 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.39B+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland.
10.40+	Form of Option Grant Notice and Form of Stock Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.41+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.42+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.43+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.44+	Jazz Pharmaceuticals, Inc. 2011 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2011, as filed with the SEC on May 9, 2011).
10.45+	Jazz Pharmaceuticals, Inc. Non-Employee Director Compensation Arrangements, as amended and restated (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.46+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan, as amended as of February 8, 2011 (incorporated herein by reference to Exhibit 10.54 in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
10.47+	Jazz Pharmaceuticals, Inc. Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.81 in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009).
21.1	Subsidiaries of Jazz Pharmaceuticals, Inc.
21.2	Subsidiaries of Jazz Pharmaceuticals Public Limited Company.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereto).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
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
101.DEF++	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB++	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE++	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

\* Indicates an instrument, agreement or compensatory arrangement or plan assumed by Jazz Pharmaceuticals plc in the merger and no longer binding on Jazz Pharmaceuticals, Inc.

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

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

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



**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 28, 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**

**Senior Vice President and Chief Financial Officer**

**(Principal Financial Officer)**

/s/ KAREN J. WILSON  
**Karen J. Wilson**

**Vice President, Finance**

**(Principal Accounting Officer)**

**Table of Contents****POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bruce C. Cozadd, Kathryn E. Falberg, and Karen J. Wilson, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, the following persons on behalf of the registrant and in the capacities and on the dates indicated have signed this report below:

Signature	Title	Date
/s/ BRUCE C. COZADD  <b>Bruce C. Cozadd</b>	Chairman, Chief Executive Officer and Director  <i>(Principal Executive Officer)</i>	February 28, 2012
/s/ KATHRYN E. FALBERG  <b>Kathryn E. Falberg</b>	Senior Vice President and Chief Financial Officer  <i>(Principal Financial Officer)</i>	February 28, 2012
/s/ KAREN J. WILSON  <b>Karen J. Wilson</b>	Vice President, Finance and Principal Accounting Officer  <i>(Principal Accounting Officer)</i>	February 28, 2012
/s/ PAUL L. BERNIS  <b>Paul L. Bernis</b>	Director	February 28, 2012
/s/ BRYAN C. CRESSEY  <b>Bryan C. Cressey</b>	Director	February 28, 2012
/s/ PATRICK G. ENRIGHT  <b>Patrick G. Enright</b>	Director	February 28, 2012
/s/ JAMES C. MOMTAEZEE  <b>James C. Momtazee</b>	Director	February 28, 2012
/s/ SEAMUS C. MULLIGAN  <b>Seamus C. Mulligan</b>	Director	February 28, 2012
/s/ KENNETH W. O'KEEFE  <b>Kenneth W. O'Keefe</b>	Director	February 28, 2012
/s/ ALAN M. SEBULSKY  <b>Alan M. Sebulsky</b>	Director	February 28, 2012

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

**Alan M. Sebulsky**

/s/ RICK E WINNINGHAM

Director

February 28, 2012

**Rick E Winningham**

82

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholder of

Jazz Pharmaceuticals, Inc., a wholly-owned subsidiary of Jazz Pharmaceuticals plc

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals, Inc. as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2011. Our audits also included the financial statement schedule listed in the Index at Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Jazz Pharmaceuticals, Inc. at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Jazz Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2012, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

February 28, 2012

F-1

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****CONSOLIDATED BALANCE SHEETS****(In thousands, except per share amounts)**

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 82,076	\$ 44,794
Marketable securities	75,822	
Restricted cash		400
Accounts receivable, net of allowances of \$366 and \$482 at December 31, 2011 and 2010, respectively	34,374	22,081
Inventories	3,909	5,046
Prepaid expenses	1,690	1,858
Other current assets	1,260	279
Total current assets	199,131	74,458
Property and equipment, net	1,557	690
Intangible assets, net	14,585	22,033
Goodwill	38,213	38,213
Other long-term assets	87	335
Total assets	\$ 253,573	\$ 135,729
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,129	\$ 3,049
Accrued liabilities	34,783	23,572
Liability under government settlement	7,320	4,128
Purchased product rights liability	4,500	4,500
Revolving credit facility		7,350
Current portion of long-term debt		16,064
Deferred revenue	1,138	1,273
Total current liabilities	52,870	59,936
Purchased product rights liability, non-current		4,500
Liability under government settlement, non-current		6,978
Long-term debt, less current portion		24,629
Deferred rent		82
Deferred revenue, non-current	7,915	9,053
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 20,000 shares authorized; none outstanding		
Common stock, \$0.0001 par value; 150,000 shares authorized; 42,468 and 39,959 shares issued and outstanding at December 31, 2011 and 2010, respectively	4	4
Additional paid-in capital	542,697	505,413
Accumulated other comprehensive loss	(31)	
Accumulated deficit	(349,882)	(474,866)
Total stockholders' equity	192,788	30,551
Total liabilities and stockholders' equity	\$ 253,573	\$ 135,729

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

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

F-2

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts)**

	Year Ended December 31,		
	2011	2010	2009
<b>Revenues:</b>			
Product sales, net	\$ 266,518	\$ 170,006	\$ 115,108
Royalties and contract revenues	5,759	3,775	13,341
<b>Total revenues</b>	<b>272,277</b>	<b>173,781</b>	<b>128,449</b>
<b>Operating expenses:</b>			
Cost of product sales (excluding amortization of acquired developed technology)	13,942	13,559	9,638
Selling, general and administrative	108,936	68,996	58,652
Research and development	14,120	25,612	36,561
Intangible asset amortization	7,448	7,825	7,668
<b>Total operating expenses</b>	<b>144,446</b>	<b>115,992</b>	<b>112,519</b>
<b>Income from operations</b>	<b>127,831</b>	<b>57,789</b>	<b>15,930</b>
Interest income and other, net	75	4	30
Interest expense (including \$570 and \$1,183 for the years ended December 31, 2010 and 2009, respectively, pertaining to a related party)	(1,675)	(12,728)	(22,796)
Loss on extinguishment of debt (including \$701 for the year ended December 31, 2010 pertaining to a related party)	(1,247)	(12,287)	
<b>Net income (loss)</b>	<b>\$ 124,984</b>	<b>\$ 32,778</b>	<b>\$ (6,836)</b>
<b>Net income (loss) per share:</b>			
Basic	\$ 3.01	\$ 0.90	\$ (0.23)
Diluted	\$ 2.67	\$ 0.83	\$ (0.23)
<b>Weighted-average common shares used in computing net income (loss) per share:</b>			
Basic	41,499	36,343	30,018
Diluted	46,798	39,411	30,018

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

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF**  
**STOCKHOLDERS EQUITY (DEFICIT)**

(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount				
<b>Balance at December 31, 2008</b>	28,925	\$ 3	\$ 407,923	\$ 4	\$ (500,808)	\$ (92,878)
Lapse of repurchase rights to shares issued under employment agreements			12,492			12,492
Modification of warrants to purchase common stock issued in conjunction with amended long-term debt			1,254			1,254
Stock issued/issuable under directors deferred compensation plan	4		243			243
Issuance of common stock in conjunction with exercise of stock options for cash and restricted stock units	20		40			40
Issuance of common stock under employee stock purchase plan	410		348			348
Issuance of common stock and warrants in conjunction with private placement offering, net of issuance costs	1,896		6,782			6,782
Stock-based compensation			5,729			5,729
Comprehensive loss:						
Net loss					(6,836)	(6,836)
Unrealized loss on available-for-sale securities				(4)		(4)
Comprehensive loss						(6,840)
<b>Balance at December 31, 2009</b>	31,255	3	434,811		(507,644)	(72,830)
Stock issuable under directors deferred compensation plan			198			198
Issuance of common stock in conjunction with exercise of stock options	955		3,682			3,682
Issuance of common stock in conjunction with vesting of restricted stock units	13					
Issuance of common stock under employee stock purchase plan	520		529			529
Issuance of common stock in conjunction with offering, net of issuance costs	7,000	1	56,816			56,817
Issuance of common stock in conjunction with exercise of warrants	216		1,380			1,380
Stock-based compensation			7,997			7,997
Net income and comprehensive income					32,778	32,778
<b>Balance at December 31, 2010</b>	39,959	4	505,413		(474,866)	30,551





Table of Contents

**JAZZ PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF**  
**STOCKHOLDERS EQUITY (DEFICIT) (Continued)**

(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount				
<b>Balance at December 31, 2010</b>	39,959	4	505,413		(474,866)	30,551
Stock issued/issuable under directors deferred compensation plan	13		368			368
Issuance of common stock in conjunction with exercise of stock options	1,400		12,214			12,214
Issuance of common stock in conjunction with vesting of restricted stock units	13					
Issuance of common stock under employee stock purchase plan	359		1,546			1,546
Issuance of common stock in conjunction with exercise of warrants	724		2,659			2,659
Stock-based compensation			20,497			20,497
Comprehensive income:						
Net income					124,984	124,984
Unrealized loss on available-for-sale securities				(31)		(31)
<b>Comprehensive income</b>						<b>124,953</b>
<b>Balance at December 31, 2011</b>	42,468	\$ 4	\$ 542,697	\$ (31)	\$ (349,882)	\$ 192,788

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

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Year Ended December 31,		
	2011	2010	2009
<b>Operating activities</b>			
Net income (loss)	\$ 124,984	\$ 32,778	\$ (6,836)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	379	886	1,429
Amortization of intangible assets	7,448	7,825	7,668
Loss on disposal of property and equipment	33	279	14
Stock-based compensation expense	20,704	8,219	5,957
Long-term debt, non-cash interest expense	394	2,406	2,810
Loss on extinguishment of debt	1,247	12,287	
Changes in assets and liabilities:			
Accounts receivable	(12,293)	(9,768)	(5,670)
Inventories	1,298	(1,644)	883
Prepaid expenses and other current assets	(934)	426	2,610
Other assets	186		(1,748)
Accounts payable	2,080	891	(3,578)
Accrued liabilities	11,211	9,276	(6,676)
Deferred revenue	(1,273)	(2,540)	(10,786)
Deferred rent	(82)	53	29
Liability under government settlement	(3,786)	(2,506)	(1,984)
Net cash provided by (used in) operating activities	151,596	58,868	(15,878)
<b>Investing activities</b>			
Purchases of property and equipment	(1,279)	(731)	(53)
Purchase of product rights	(4,500)	(4,000)	(6,000)
Decrease (increase) in restricted cash	400	2,588	(1,075)
Purchases of marketable securities	(79,886)		
Proceeds from maturities of marketable securities	4,033		1,004
Net cash used in investing activities	(81,232)	(2,143)	(6,124)
<b>Financing activities</b>			
Repayment of long-term debt (including \$6,816 for the year ended December 31, 2010 paid to a related party)	(41,668)	(127,828)	
Payments of debt extinguishment costs (including \$484 for the year ended December 31, 2010 paid to a related party)	(483)	(8,484)	
Proceeds from offerings of common stock, net of issuance costs		56,817	6,782
Proceeds from issuance of long-term debt, net		48,427	
Proceeds from employee stock purchases, exercise of stock options and warrants	16,419	5,591	388
Net (repayments under) proceeds from revolving credit facilities	(7,350)	(2,049)	5,524
Net cash (used in) provided by financing activities	(33,082)	(27,526)	12,694
Net increase (decrease) in cash and cash equivalents	37,282	29,199	(9,308)
Cash and cash equivalents, at beginning of period	44,794	15,595	24,903
Cash and cash equivalents, at end of period	\$ 82,076	\$ 44,794	\$ 15,595

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

### Supplemental disclosure of cash flow information:

Cash paid for interest (including \$461 and \$1,349 for the years ended December 31, 2010 and 2009, respectively, paid to a related party)	\$ 1,621	\$ 10,234	\$ 24,488
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Liability for purchase of product rights	\$	\$	\$ 5,000
Warrants to purchase common stock	\$	\$	\$ 2,700
Modification to warrants to purchase common stock issued in conjunction with long-term debt	\$	\$	\$ 1,254

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

F-6

---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Description of Business**

Jazz Pharmaceuticals, Inc. was incorporated in California in March 2003 and reincorporated in Delaware in January 2004. On January 18, 2012, the merger contemplated by the Agreement and Plan of Merger and Reorganization dated as of September 19, 2011, as amended, was consummated in connection with which Jazz Pharmaceuticals, Inc. became a wholly-owned subsidiary of Jazz Pharmaceuticals plc (previously known as Azur Pharma Public Limited Company, or Azur Pharma). Jazz Pharmaceuticals, Inc. is treated as the acquiring company in the merger for accounting purposes, and the merger is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. For additional information regarding the merger see Note 15.

Prior to the merger, Jazz Pharmaceuticals, Inc. was a specialty biopharmaceutical company focused on the identification, development and commercialization of pharmaceutical products to meet important unmet medical needs in focused therapeutic areas. Marketed products of Jazz Pharmaceuticals, Inc. consisted of Xyrem (sodium oxybate), which is the only product approved by the United States Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy, and Luvox CR (fluvoxamine maleate) marketed for the treatment of obsessive compulsive disorder.

Except where specifically noted or the context otherwise requires, the use of terms such as Jazz Pharmaceuticals, we, our and us in these Notes to Consolidated Financial Statements refers to Jazz Pharmaceuticals, Inc.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements include the accounts of Jazz Pharmaceuticals, Inc. (a wholly-owned subsidiary of Jazz Pharmaceuticals plc) and its wholly-owned subsidiaries, Orphan Medical, LLC, formerly Orphan Medical, Inc., or Orphan Medical, and JPI Commercial, LLC after elimination of intercompany transactions and balances. Our consolidated financial statements include the operations of an acquired business after the completion of the acquisition; accordingly these consolidated financial statements only include the accounts of Jazz Pharmaceuticals, Inc. for all periods presented because the merger was not effective until January 18, 2012.

***Significant Risks and Uncertainties***

We are subject to risks common to companies in the pharmaceutical industry with development and commercial operations including, but not limited to, risks and uncertainties related to commercial success and acceptance of our products by patients, physicians and payors, competition from branded and generic products, regulatory approvals, regulatory requirements, including those of the United States Food and Drug Administration, or FDA, and the United States Drug Enforcement Administration, dependence on key customers and sole source suppliers and protection of intellectual property rights. In addition, most of our revenues are derived from sales of one product, Xyrem. During 2010, an abbreviated new drug application, or ANDA, was filed with the FDA by a third party seeking to market a generic form of Xyrem. We have sued that third party for infringement of our patents, and the litigation is ongoing. We cannot predict the timing or outcome of this litigation. If an ANDA for Xyrem is approved and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts and disclosures reported in the

---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

***Concentrations of Risk***

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

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company, primarily in the United States, and to international distributors. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced significant credit losses on our accounts receivable. One customer, Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, accounted for 79% of gross accounts receivable as of both December 31, 2011 and December 31, 2010.

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

***Cash Equivalents and Marketable Securities***

We consider all highly liquid investments, readily convertible to cash, that mature within three months or less from date of purchase to be cash equivalents.

Marketable securities are investments in debt securities with maturities of less than one year from the balance sheet date, or securities with maturities of greater than one year that are specifically identified to fund current operations. Collectively, cash equivalents, restricted cash and marketable securities are considered available-for-sale and are recorded at fair value. Unrealized gains and losses, net of tax, are recorded in other comprehensive income and included as a separate component of stockholders' equity. We use the specific-identification method for calculating realized gains and losses on securities sold. Realized gains and losses and declines in value judged to be other than temporary on marketable securities are included in interest income in the statement of operations. Realized gains and losses on sales of marketable securities have not been significant.

***Inventories***

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. If the estimate of future demand is too high, we may have to increase the reserve for excess inventory for that product and record a charge to cost of product sales. For product candidates that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and

---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

development expense. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the clinical trial. Prior to receiving FDA approval costs related to purchases of the active pharmaceutical ingredient and the manufacturing of the product candidate are recorded as research and development expense. All direct manufacturing costs incurred after approval are capitalized into inventory.

***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are three to five years. Leasehold improvements are amortized over the shorter of the noncancelable term of our operating lease or their economic useful lives. Maintenance and repairs are charged to operations as incurred.

***Goodwill and Intangible Assets***

***Goodwill***

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. 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. Management tests goodwill for impairment annually in October and whenever events or changes in circumstances indicate that the carrying value may not be recoverable.

***Intangible Assets***

Intangible assets consist primarily of purchased developed technology and trademarks. Intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from three to ten years. The estimated useful lives associated with intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. We evaluate purchased intangibles and other long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset.

***Revenue Recognition***

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (iii) the buyer's obligation to the seller would not be changed in the event of theft or physical destruction or

---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (v) the seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated.

In evaluating arrangements with multiple elements we consider whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on the relative selling price method under which the selling price for each deliverable is determined using vendor-specific objective evidence of selling price, if it exists; otherwise, third-party evidence of selling price. If vendor-specific objective evidence and third-party evidence of selling price are not available for a deliverable, we will use our best estimate of the selling price for that deliverable when applying the relative selling price method. The applicable revenue recognition criteria are applied to each of the separate units.

Payments received in advance of work performed or milestones achieved are recorded as deferred revenues and recognized when the service is provided or the milestone is achieved, as applicable.

*Product Sales, Net*

We sell Xyrem in the United States to a single central pharmacy, Express Scripts. We recognize revenues from sales of Xyrem within the United States upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment directly to a patient. We accept returns from Express Scripts of any product returned by patients to Express Scripts with defects that were not reasonably discoverable upon receipt of the consigned product by Express Scripts. Based on our experience over the past six years since we acquired the rights to Xyrem, product returns to Express Scripts from patients are rare. We provide Express Scripts with a credit for product returned by patients. During 2011, we issued credits totaling \$0.2 million for returned product.

We sell limited quantities of Xyrem to UCB Pharma Limited, or UCB, for sale in territories outside of North America, and to Valeant Canada Limited, for sale in Canada, under license and distribution agreements. The agreements provide our international licensees with a fixed period of time, typically 30 to 60 days, after delivery to inspect and reject shipments for failure to meet specifications. We do not recognize revenue on the sales to our international licensees until the right of return has lapsed, which occurs when we are notified of their acceptance, or when the time for them to inspect or reject a shipment has lapsed, if earlier.

We grant rights to our wholesaler customers to return product six months prior to and up to twelve months after product expiration and issue credits which may be applied against existing or future invoices. In October 2010, we started recognizing revenue from sales of Luvox CR upon shipment to our wholesaler customers and recorded an estimated amount of product returns. Our liability for estimated future returns as of December 31, 2011 and 2010 was \$4.3 million and \$3.5 million, respectively.

Revenues from sales of products within the United States are recorded net of estimated allowances for returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans. Calculating certain of these items involves estimates and judgments based on sales or invoice data and historical experience. Adjustments to estimates for these allowances have not been material.



---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Royalties and Contract Revenues*

We receive royalties from third parties based on sales of our products under licensing and distribution arrangements. For those arrangements where royalties are reasonably estimable, we recognize revenues based on estimates of royalties earned during the applicable period, and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been significant.

Our contract revenues consist of fees and milestone payments. Nonrefundable fees where we have no continuing performance obligations are recognized as revenues when there is persuasive evidence of an arrangement and collection is reasonably assured. In situations where we have continuing performance obligations, nonrefundable fees are deferred and are recognized ratably over our projected performance period. We recognize at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. Sales-based milestone payments are typically payments made to us that are triggered when aggregate net sales of a product by a collaborator for a specified period (for example, an annual period) reach an agreed upon threshold amount. We recognize sales-based milestone payments from a collaborator when the event which triggers the obligation of payment has occurred, there is no further obligation on our part in connection with the payment, and collection is reasonably assured. Refundable fees are deferred and recognized as revenues upon the later of when they become nonrefundable or when our performance obligations are completed.

*Cost of Product Sales*

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability and cargo insurance, FDA user fees, freight, shipping, handling and storage costs and salaries and related costs of employees involved with production. Excluded from cost of product sales, as shown on the consolidated statements of operations, is amortization of acquired developed technology of \$7.2 million, \$7.2 million and \$6.6 million for 2011, 2010 and 2009, respectively.

*Research and Development*

Research and development expenses consist of expenses incurred in identifying, developing and testing our product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing results from our clinical trials, clinical trial costs paid to sites and investigators fees, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates or drug delivery or formulation technologies that we have licensed, allocated expenses, such as facilities and information technology that support our research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under license agreements. For product candidates that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the trial and therefore is not included in inventory.

*Advertising Expenses*

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses for 2011, 2010 and 2009 were \$1.0 million, \$1.6 million and \$0.4 million, respectively.

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Income Taxes**

We utilize the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

**Comprehensive Income (Loss)**

Comprehensive income (loss) includes net income (loss) and all changes in stockholders' equity (deficit) during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. Comprehensive income (loss) was as follows (in thousands):

	2011	December 31, 2010	2009
Net income (loss)	\$ 124,984	\$ 32,778	\$ (6,836)
Unrealized loss on available-for-sale investments	(31)		(4)
Comprehensive income (loss)	\$ 124,953	\$ 32,778	\$ (6,840)

**Net Income (Loss) Per Common Share**

Basic and diluted net income (loss) per common share is computed using the weighted-average number of shares of common stock outstanding as follows (in thousands, except per share amounts):

	2011	Year Ended December 31, 2010	2009
<b>Numerator:</b>			
Net income (loss)	\$ 124,984	\$ 32,778	\$ (6,836)
<b>Denominator:</b>			
Weighted-average common shares outstanding - basic	41,499	36,343	30,018
Dilutive effect of employee equity incentive and purchase plans	2,715	1,720	
Dilutive effect of warrants	2,584	1,348	
Weighted-average common shares outstanding - diluted	46,798	39,411	30,018
<b>Net income (loss) per share:</b>			
Basic	\$ 3.01	\$ 0.90	\$ (0.23)
Diluted	\$ 2.67	\$ 0.83	\$ (0.23)

Potentially dilutive common shares from employee stock plans and warrants were not included in the diluted net loss per share for 2009 because the inclusion of such shares would have had an anti-dilutive effect.



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	Year Ended December 31,		
	2011	2010	2009
Warrants to purchase common stock			3,759
Options to purchase common stock	1,038	3,211	2,843
Restricted stock units			38
Total	1,038	3,211	6,640

***Stock-Based Compensation***

We account for compensation cost for all stock-based awards at fair value on the date of grant. The fair value is recognized as expense over the service period, net of estimated forfeitures, using the straight-line method for stock options and restricted stock units and using the ratable method for awards under our employee stock purchase program. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. We primarily consider historical experience when estimating expected forfeitures.

***Recent Accounting Pronouncements***

In May 2011, the Financial Accounting Standards Board, or the FASB, issued guidance which changes certain fair value measurement principles and increases disclosure requirements, particularly for fair value measurements subject to significant judgment and is effective for fiscal years beginning after December 15, 2011. The adoption of this amendment will not have a material impact on our results of operations or financial position.

In June and December 2011, the FASB issued amended guidance on the presentation of comprehensive income in financial statements. The amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. The amendment eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this amendment will not have a material impact on our results of operations or financial position.

In September 2011, the FASB issued amended guidance related to the goodwill impairment test which allows companies to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The amendment is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this amendment will not have a material impact on our results of operations or financial position.

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. Fair Value Measurement**

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

	December 31, 2011				December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	\$ 48,518	\$	\$	\$ 48,518	\$ 25,046	\$	\$	\$ 25,046
Certificates of deposit	7,300		(6)	7,294				
Corporate debt securities	50,371	7	(34)	50,344				
Obligations of U.S. government agencies	18,433	3	(1)	18,435				
<b>Total available-for-sale securities</b>	<b>\$ 124,622</b>	<b>\$ 10</b>	<b>\$ (41)</b>	<b>\$ 124,591</b>	<b>\$ 25,046</b>	<b>\$</b>	<b>\$</b>	<b>\$ 25,046</b>

	December 31, 2011	December 31, 2010
Available-for-sale securities	\$ 124,591	\$ 25,046
Cash	33,307	19,748
Restricted cash		400
<b>Totals</b>	<b>\$ 157,898</b>	<b>\$ 45,194</b>

Reported as	December 31, 2011	December 31, 2010
Amounts classified as cash and cash equivalents	\$ 82,076	\$ 44,794
Amounts classified as restricted cash		400
Amounts classified as marketable securities	75,822	
<b>Totals</b>	<b>\$ 157,898</b>	<b>\$ 45,194</b>

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

Gross unrealized losses on investments as of December 31, 2011, related to the available-for-sale securities were insignificant and we believe the impairment was temporary. In determining that the decline in fair value of these securities was temporary, we considered the length of time each security was in an unrealized loss position and the extent to which fair value was less than cost. In addition, we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before the recovery of their amortized cost basis.

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	December 31, 2011			December 31, 2010	
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Total Estimated Fair Value
Money market funds	\$ 48,518	\$	\$ 48,518	\$ 25,046	\$ 25,046
Certificates of deposit		7,294	7,294		
Corporate debt securities		50,344	50,344		
Obligations of U.S. government agencies		18,435	18,435		
<b>Total available-for-sale securities</b>	<b>\$ 48,518</b>	<b>\$ 76,073</b>	<b>\$ 124,591</b>	<b>\$ 25,046</b>	<b>\$ 25,046</b>

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

There were no transfers between Level 1 and Level 2 of the fair value hierarchy in 2011.

In 2011, we repaid in full our long-term debt (see Note 6). Prior to the extinguishment of our long-term debt, we estimated the fair value of our long-term debt using a discounted cash flow analysis based on our incremental borrowing rates for similar types of borrowing arrangements. The carrying amount and the estimated fair value of our long-term debt were as follows (in thousands):

	December 31, 2011		December 31, 2010	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Long-term debt	\$	\$	\$ 40,693	\$ 40,864

**4. Certain Balance Sheet Items**

Inventories consisted of the following (in thousands):

	December 31,	
	2011	2010
Raw materials	\$ 1,937	\$ 2,986
Work in process	524	705
Finished goods	1,448	1,355

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

Total inventories	\$ 3,909	\$ 5,046
-------------------	----------	----------

F-15

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Leasehold improvements	\$ 763	\$ 763
Computer equipment	2,046	1,483
Computer software	4,010	4,010
Furniture and fixtures	556	593
Machinery and equipment	76	
Construction-in-progress	689	73
<b>Subtotal</b>	<b>8,140</b>	<b>6,922</b>
Less accumulated depreciation and amortization	(6,583)	(6,232)
<b>Property and equipment, net</b>	<b>\$ 1,557</b>	<b>\$ 690</b>

Accrued liabilities consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Accrued personnel expense	\$ 11,643	\$ 8,060
Government rebates reserve	10,631	6,588
Sales returns reserves	4,302	3,539
Accrued transaction and integration costs	2,409	
Accrued gross to net items	1,747	1,376
Accrued professional fees and services	1,612	2,170
Accrued inventory and cost of sales	846	804
Other	1,593	1,035
<b>Total accrued liabilities</b>	<b>\$ 34,783</b>	<b>\$ 23,572</b>

**5. Goodwill and Intangible Assets**

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

	<b>December 31,</b>	
	<b>2011</b>	<b>2010</b>
Goodwill	\$ 38,213	\$ 38,213

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



Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

		December 31, 2011			December 31, 2010		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology	Xyrem	\$ 39,700	\$ 27,185	\$ 12,515	\$ 39,700	\$ 23,014	\$ 16,686
Developed technology	Luvox CR	9,700	8,449	1,251	9,700	5,446	4,254
Trademarks		2,600	1,781	819	2,600	1,507	1,093
Total		\$ 52,000	\$ 37,415	\$ 14,585	\$ 52,000	\$ 29,967	\$ 22,033

F-16

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Based on intangible assets recorded as of December 31, 2011, and assuming the underlying assets of Jazz Pharmaceuticals, Inc. 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	\$ 5,696
2013	4,445
2014	4,444
Total	\$ 14,585

**6. Debt and Financing Obligations*****Term Loan and Revolving Credit Facility***

In December 2011, we terminated a credit agreement we entered into in June 2010, which was scheduled to mature in June 2013. The credit agreement included a \$15.0 million revolving credit facility and a \$50.0 million three-year term loan which provided for quarterly principal payments of \$4.2 million. In July 2011, we repaid all amounts due under the term loan. In 2011, as a result of the early repayment of the term loan and the termination of the credit agreement, we recorded a loss on extinguishment of debt of \$1.2 million, which consisted of a \$0.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount and the remainder related to a prepayment penalty and a termination fee. In 2010, we repaid \$119.5 million principal amount due under a previous debt agreement. As a result of the repayment of amounts due under the previous debt agreement, we recorded a loss on extinguishment of debt of \$12.3 million in 2010, which consisted of a \$3.8 million non-cash charge related to the write-off of unamortized debt issuance costs and a debt discount and an \$8.5 million prepayment penalty.

As of December 31, 2010, the \$41.7 million principal amount of the term loan was recorded net of a debt discount of \$1.0 million related to fees paid under the credit agreement. Borrowings under the term loan and the revolving credit facility bore interest at a variable rate which was 5.75% in 2010 and 3.75% for most of the period in 2011 in which there were borrowings outstanding.

**7. Other Long Term Liabilities*****Deferred Revenue***

We have an agreement with UCB under which UCB has the right to market Xyrem for certain indications in various countries outside the United States. We recognized contract revenues of \$1.1 million during each of 2011, 2010, and 2009 related to two upfront payments received from UCB in 2006 totaling \$15.0 million. In 2009, we recognized a \$10.0 million milestone payment which was received from UCB in 2008. As of December 31, 2011, \$9.1 million was recorded as deferred revenues related to this agreement, of which \$1.1 million is a current liability. The deferred revenue balance is being recognized ratably through 2019.

***Purchased Product Rights Liability***

In 2007, we entered into a product license agreement with Solvay Pharmaceuticals, Inc., which was subsequently acquired by Abbott Laboratories, for the rights to market Luvox CR and Luvox in the United States which agreement was subsequently amended. Under the amended agreement we paid \$4.5 million, \$4.0 million and \$6.0 million in 2011, 2010 and 2009, respectively, and will make our final payments totaling \$4.5 million in 2012.



**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Liability Under Government Litigation Settlement***

In 2007, we and Orphan Medical entered into agreements with a number of government entities to settle various matters associated with an investigation relating to the sale and marketing of Xyrem by Orphan Medical, which we acquired in June 2005. Under these agreements we paid \$4.2 million, \$3.0 million and \$2.5 million in 2011, 2010 and 2009, respectively. We paid our remaining obligation of \$7.3 million in January 2012.

**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 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 December 31, 2011 and December 31, 2010. 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 a noncancelable operating lease for our office building located in Palo Alto, California which expires in August 2017, is renewable through 2019 and is subject to an annual rent escalation clause. We are also obligated to make payments under noncancelable operating leases for automobiles used by our sales force. Rent expense under all operating leases was as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Rent expense	\$ 2,593	\$ 2,323	\$ 2,738

Future minimum lease payments under our noncancelable operating leases at December 31, 2011, were as follows (in thousands):

Year ending December 31,	Lease Payments
2012	\$ 1,898
2013	1,169
2014	366
2015	1
2016	

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

Total

\$ 3,434

F-18

---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In February 2012, we renewed the operating lease for our Palo Alto office building and as a result, we are obligated to make additional payments of \$0.5 million, \$2.1 million, \$2.2 million, \$2.2 million, \$2.3 million and \$1.6 million in 2012, 2013, 2014, 2015, 2016 and 2017.

As of December 31, 2011 and 2010, we had \$5.7 million and \$2.1 million, respectively, of noncancelable purchase commitments under agreements with contract manufacturers, all of which were due within one year.

As of December 31, 2011, we were required to pay our investment banker a fee of \$1.5 million contingent upon the completion of the merger with Azur Pharma.

***Legal Proceedings***

On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it filed an abbreviated new drug application, or ANDA, with the U.S. Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleges that all five patents listed for Xyrem in the FDA's approved drug products with therapeutic equivalence evaluation documents, or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States District Court for the District of New Jersey. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) 30 months from our October 18, 2010 receipt of Roxane's Paragraph IV certification notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. An additional method of use patent covering the distribution system for Xyrem issued in December 2010 and is listed in the Orange Book, and we amended our lawsuit against Roxane on February 4, 2011 to include the additional patent in the litigation in response to Roxane's Paragraph IV Certification against this patent. An additional method of use patent covering the distribution system for Xyrem issued in February 2011 and is listed in the Orange Book, and we amended our lawsuit on May 2, 2011 to include this additional patent in response to Roxane's Paragraph IV Certification against it. We cannot predict the outcome of this matter.

In August 2009, we received a Paragraph IV Certification from Actavis Elizabeth, LLC, or Actavis, advising that Actavis had filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received a Paragraph IV Certification notice from Anchen Pharmaceuticals, Inc., now owned by Par Pharmaceutical Companies, Inc., or Anchen, advising that Anchen 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. Anchen's Paragraph IV Certification alleged that the Alkermes patent will not be infringed by Anchen's manufacture, use or sale of the generic product for which the ANDA was submitted and that the Alkermes patent 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, Anchen, and Anchen Incorporated, the parent of Anchen, in the United States District Court for the District of Delaware claiming infringement of the Alkermes patent by the defendants in response to the Paragraph IV Certifications filed by Actavis and Anchen. On October 14, 2009, we and Elan, as plaintiffs, also filed a lawsuit in the United States District Court for the Central District of California against Anchen claiming infringement of the Alkermes patent based upon Anchen's Paragraph IV Certification. In both cases, the plaintiffs were seeking a permanent injunction that prevented Actavis and Anchen from introducing a generic version of Luvox CR prior to the expiration of the Alkermes patent. On August 25, 2010, we and Elan entered

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

into settlement agreements with Anchen. Under the agreements, we, Elan and Anchen agreed to dismiss all of the claims brought in the litigation without prejudice, Anchen agreed not to contest the validity or enforceability of the Alkermes patent in the United States, and we, Elan and Anchen agreed to release each other from all claims arising in the litigation or relating to the product Anchen intends to market under its ANDA. In addition, we granted a sublicense to Anchen of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicense is non-transferable, non-sublicensable and royalty-free and is exclusive even as to us and Alkermes (except with respect to Luvox CR) for a period of time. The sublicense will commence on February 15, 2013 or earlier upon the occurrence of certain events. On October 5, 2010, the United States District Court for the Central District of California dismissed the case against Elan without prejudice. On the same date, the United States District Court for the District of Delaware also dismissed the case against Anchen without prejudice. The lawsuit against Actavis is pending in the United States District Court for the District of Delaware. The court has scheduled a Markman hearing for July 24, 2012 and a pretrial conference for March 5, 2013. We cannot predict or determine the outcome of this matter. 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. Torrent's Paragraph IV Certification alleges that the Alkermes patent will not be infringed by the manufacture, use, sale or offer for sale of the generic product for which the ANDA was submitted and that the Alkermes patent is invalid. 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 by Torrent in response to Torrent's Paragraph IV Certification. We are seeking a permanent injunction that prevents Torrent from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. We cannot predict the outcome of this litigation.

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. Common Stock***Unregistered Sales of Equity Securities*

In 2009, we completed a private placement of units consisting of 1,895,734 shares of common stock and warrants to purchase 947,867 shares of our common stock at a price of \$3.6925 per unit for net proceeds of \$6.8 million. The warrants are exercisable at any time through July 2016, subject to certain restrictions. The \$2.7 million fair value of the warrants was recorded in stockholders' deficit and was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free rate of 3.1%, volatility of 92%, a term of 7.0 years and a dividend yield of 0%.

*Authorized But Unissued Common Stock*

We had reserved the following shares of authorized but unissued common stock (in thousands):

	<b>As of December 31, 2011</b>
2007 Equity Incentive Plan	7,529
2007 Employee Stock Purchase Plan	92
Amended and Restated 2007 Non-Employee Directors Stock Option Plan	591
Amended and Restated Directors Deferred Compensation Plan	197
Exercise of warrants	3,109
Total	11,518





**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Warrants**

As of December 31, 2011, we had shares of common stock issuable under the following warrants (in thousands):

<b>Warrants Issued</b>	<b>Expiration Date</b>	<b>Shares of Common Stock</b>	<b>Exercise Price</b>
Warrants issued in 2005 in conjunction with long-term debt	June 24, 2012	550	\$ 9.34
Warrants issued in 2008 in conjunction with long-term debt	March 16, 2013	471	\$ 9.34
Warrants issued in 2008 in conjunction with registered direct public offering	July 20, 2014	1,140	\$ 7.37
Warrants issued in 2009 in conjunction with private placement	July 5, 2016	948	\$ 4.00
		3,109	

The fair values of these warrants were recorded in stockholders' equity (deficit) when they were originally issued.

**10. Stock-Based Compensation****2007 Equity Incentive Plan**

In 2007, our board of directors adopted, and our stockholders approved, the 2007 Equity Incentive Plan, or the 2007 Plan, which provided for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, or RSUs, stock appreciation rights, performance stock awards and other forms of equity compensation to employees, including officers, non-employee directors and consultants. All of the grants under the 2007 Plan were granted to employees and vest ratably over service periods of three to five years and expire no more than ten years after the date of grant. As of December 31, 2011, a total of 10,022,014 shares of our common stock had been authorized for issuance under the 2007 Plan.

**2007 Employee Stock Purchase Plan**

In 2007, employees became eligible to participate in the ESPP. The ESPP allowed eligible employee participants to purchase shares of our common stock at a discount of 15% through payroll deductions. The ESPP consisted of a fixed offering period of 24 months with four purchase periods within each offering period. The number of shares available for issuance under our ESPP during any six month purchase period was 175,000 shares. As of December 31, 2011, a total of 1,750,000 shares of our common stock had been authorized for issuance under the ESPP.

**Amended and Restated 2007 Non-Employee Directors Stock Option Plan**

In 2007, our board of directors adopted, and our stockholders approved, the 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Option Plan. The 2007 Directors Option Plan provided for the automatic grant of nonstatutory stock options to purchase shares of our common stock to our non-employee directors which vest over a period of one to three years. In addition, the 2007 Directors Option Plan provides the source of shares to fund distributions made prior to August 15, 2010 under the Directors Deferred Compensation Plan described below. As of December 31, 2011, a total of 671,463 shares of our common stock had been authorized for issuance under the 2007 Directors Option Plan.

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Amended and Restated Directors Deferred Compensation Plan***

In 2007, our board of directors adopted the Directors Deferred Compensation Plan, the Directors Plan. The Directors Plan allowed each non-employee director to elect to defer receipt of his or her retainer fee to a future date or dates. Amounts deferred were credited as shares of common stock to a phantom stock account the number of which were based on the amount of the retainer fees deferred divided by the market value of our common stock on the first trading day of the first open window period following the date the retainer fees were deemed earned. We recorded expense of \$0.4 million, \$0.2 million and \$0.2 million related to retainer fees earned and deferred in 2011, 2010 and 2009, respectively. Upon termination of a director's service, the deferred shares are issued. As of December 31, 2011, 99,980 shares of common stock were unissued related to retainer fees deferred.

***Stock Based Compensation***

The table below shows, for all stock option grants, the weighted-average assumptions used in the Black-Scholes option pricing model and the resulting weighted-average grant date fair value of stock options granted in each of the past three years:

	Year Ended December 31,		
	2011	2010	2009
Grant date fair value	\$ 17.38	\$ 7.84	\$ 1.34
Volatility	72%	85%	91%
Expected term (years)	5.2	6.0	6.1
Range of risk-free rates	0.0-2.7%	1.5-3.1%	1.8-3.1%
Expected dividend yield	0.0%	0.0%	0.0%

We use a weighting of the historic volatility of a peer group, the historic volatility of our own common stock and the implied volatility of our own common stock to estimate future volatility for stock option grants and we used the implied volatility of our own common stock to estimate future volatility for grants under our ESPP. The expected term of stock option grants represents the weighted-average period the awards are expected to remain outstanding. For stock options granted in 2011, we estimated the weighted-average expected term based on historical exercise data. Prior to 2011, the expected term was estimated by assuming stock options would be exercised at the mid-point between the vest date and the contractual term. The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of our stock option grants. The expected dividend yield assumption was based on our history and expectation of dividend payouts.

Stock-based compensation expense related to stock options, RSUs, shares of common stock credited to the directors' phantom stock accounts under the Directors Plan and grants under our ESPP was as follows (in thousands):

	Year Ended December 31,		
	2011(1)	2010	2009
Selling, general and administrative	\$ 15,592	\$ 5,924	\$ 4,400
Research and development	4,488	2,004	1,456
Cost of product sales	624	291	101
Total stock-based compensation expense	\$ 20,704	\$ 8,219	\$ 5,957

(1)

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

Includes expense of \$7.3 million related to the acceleration of vesting in December 2011 of certain non-qualified stock options held by 17 executives and non-employee directors in connection with the merger of which \$6.9 million was recorded in selling, general and administrative and \$0.4 million was recorded in research and development.

F-22

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes information as of December 31, 2011 and activity during 2011 related to our stock option plans:

	Shares Subject to Outstanding Options (In thousands)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2011	5,541	\$ 10.39		
Options granted	1,571	29.41		
Options exercised	(1,419)	9.07		
Options forfeited	(185)	15.15		
Options expired	(2)	13.33		
Outstanding at December 31, 2011	5,506	16.00	6.9	\$ 125,793
Vested and expected to vest at December 31, 2011	5,181	15.58	6.8	120,542
Exercisable at December 31, 2011	3,647	13.69	6.1	91,951

Aggregate intrinsic value shown in the table above is equal to the difference between the exercise price of the underlying stock options and the fair value of our common stock for stock options that were in the money. The aggregate intrinsic value of stock options exercised was \$33.5 million, \$9.7 million and \$18,000, during 2011, 2010 and 2009, respectively. We issued new shares of common stock upon exercise of stock options.

As of December 31, 2011, total compensation cost not yet recognized related to unvested stock options was \$16.5 million, which is expected to be recognized over a weighted-average period of 2.6 years. As of December 31, 2011, total compensation cost not yet recognized related to grants under the ESPP was \$1.4 million, which is expected to be recognized over a weighted-average period of less than one year.

**11. Income Taxes**

During 2011 and 2010, we 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. Prior to 2010, we made no provision for income taxes due to our history of losses. All of our income and losses have resulted from domestic operations.

A reconciliation of income tax at the United States statutory income tax rate and our provision for income taxes is as follows (in thousands):

	2011	December 31, 2010	2009
Income tax at federal statutory rate	\$ 43,744	\$ 11,472	\$ (2,392)
Add (deduct):			
Acquisition-related costs	3,552		
Research and other tax credits	(1,323)	(380)	(965)
Stock-based compensation	670	1,083	1,401
Other	353	(80)	316
Decrease in federal valuation allowance:			
Utilization of federal net operating loss carryforwards	(55,271)	(16,975)	
Other	8,275	4,880	1,640

Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

Provision for income taxes	\$	\$	\$
----------------------------	----	----	----

F-23

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Deferred income taxes reflect the tax effects of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of our net deferred tax assets were as follows (in thousands):

	December 31,	
	2011	2010
Deferred tax assets:		
Federal and state net operating loss carryforwards	\$ 67,762	\$ 120,473
Federal and state tax credit carryforwards	15,140	14,720
Intangible assets	8,309	4,297
Stock-based compensation	6,293	2,591
Other	13,684	13,438
<b>Total deferred tax assets</b>	<b>111,188</b>	<b>155,519</b>
Valuation allowance	(111,188)	(155,519)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Realization of our deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence, management believes it more likely than not that our deferred tax assets are not recognizable and will not be recognizable until we have sufficient taxable income. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by \$44.3 million, \$7.1 million, and \$2.1 million in 2011, 2010 and 2009, respectively. The decreases in the valuation allowance in 2011 and 2010 were primarily due to our utilization of net operating losses.

As of December 31, 2011, we had net operating loss carryforwards and tax credit carryforwards for federal income tax purposes of approximately \$197.2 million and \$16.2 million, respectively, available to reduce future income subject to income taxes. The federal net operating loss carryforwards will expire, if not utilized, in the tax years 2021 to 2029, and the federal tax credits will expire, if not utilized, in the tax years 2017 to 2031. In addition, we had approximately \$228.7 million of net operating loss carryforwards and \$3.6 million of tax credit carryforwards as of December 31, 2011 available to reduce future taxable income for state income tax purposes. The state net operating loss carryforwards will expire, if not utilized, in the tax years 2012 to 2031. The state tax credits have no expiration date.

Approximately \$35.3 million of both the federal and state net operating loss carryforwards as of December 31, 2011 resulted from exercises of employee stock options and certain sales by employees of shares issued under other employee stock programs. We have not recorded the tax benefit of the deduction related to these exercises and sales as deferred tax assets on our balance sheet. When we realize the tax benefit as a reduction to taxable income in our tax returns, we will account for the tax benefit as a credit to stockholders' equity rather than as a reduction of our income tax provision in our financial statements.

Utilization of our net operating loss carryforwards and tax credit carryforwards is subject to annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of the net operating loss before utilization. We have completed detailed reviews of our ownership changes in accordance with the Internal Revenue Code, and we have confirmed that it is more likely than not that we have not experienced an ownership change since the date of our initial Series B preferred stock funding in 2004 through December 31, 2011. However, approximately \$38.0 million of net operating losses carryforwards acquired in connection with our purchase of a company in

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

2005 are only available ratably through 2019 and approximately \$6.0 million of orphan tax credits acquired in connection with the purchase are available only from 2019 to 2024, as a result of an annual limitation due to a change in ownership of the purchased company.

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have reduced our gross deferred tax assets for certain tax benefits which we judge may not be sustained upon examination, and we have provided an offset through equal reductions in our deferred tax asset valuation allowance. A reconciliation of our unrecognized tax benefits follows (in thousands):

	December 31,		
	2011	2010	2009
Balance at the beginning of the year	\$ 4,852	\$ 4,711	\$ 4,010
Additions based on tax positions related to the current year	242	164	560
Additions for tax positions of prior years	(1,330)		147
Lapse of applicable statute of limitations		(23)	(6)
Balance at the end of the year	\$ 3,764	\$ 4,852	\$ 4,711

There were no interest or penalties related to unrecognized tax benefits. Substantially all of the unrecognized tax benefit, if recognized, would affect our tax expense before taking our valuation allowance into consideration. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. We file income tax returns in the United States federal jurisdiction and various state jurisdictions, which typically have three tax years open at any point in time. Because of our net operating loss and tax credit carryforwards, substantially all of our tax years remain open to federal and state tax examination.

**12. Related Party Transactions**

*Long-term debt.* In 2010, we repaid in full all of our then outstanding senior secured notes, of which \$6.8 million principal amount was paid to an entity affiliated with Kohlberg, Kravis & Roberts & Co. L.P., or KKR, a significant stockholder. In addition, in 2010, we paid prepayment penalties and a fee to the holders of the senior secured notes totaling \$8.5 million of which \$484,000 was paid to the KKR affiliate. Cash paid for interest with respect to then outstanding senior secured notes held by the KKR affiliate was \$461,000 and \$1.3 million in 2010 and 2009, respectively. All payments to KKR were in proportion to its ownership of the senior secured notes.

The exercise price of all warrants to purchase common stock issued to the holders of the then outstanding senior secured notes was reduced to \$9.34 per share as a result of an amendment to the agreement governing the senior secured notes in 2009. This included warrants to purchase 70,156 shares of our common stock held by the KKR affiliate the exercise price of which was reduced from \$20.36 to \$9.34 per share.

*Common Stock Offerings.* In a private placement we completed in 2009, 1,858,486 shares of common stock and a warrant to purchase 929,243 shares of common stock were acquired by Longitude Venture Partners, L.P. and 37,248 shares of common stock and a warrant to purchase 18,624 shares of common stock were acquired by Longitude Capital Associates, L.P. In July 2009, Patrick G. Enright was elected to our board of directors in connection with the closing of the private placement. Mr. Enright is a managing member of Longitude Capital Partners, LLC, the sole general partner of Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P. In addition, in 2010 we issued 7,000,000 shares of our common stock in an underwritten public offering of which 821,851 shares and 16,472 shares were purchased from the underwriter by Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P., respectively. The remaining shares were purchased from the underwriter by third party investors on the same terms and conditions.

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. 401(k) Plan**

We provide a qualified 401(k) savings plan for our employees. All employees are eligible to participate, provided they meet the requirements of the plan. While we may elect to match employee contributions, no such matching contributions have been made through December 31, 2011.

**14. Segment and Other Information**

We have determined that we operate in one business segment which is the development and commercialization of pharmaceutical products.

The following is a summary of our total revenues (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Xyrem	\$ 233,348	\$ 142,630	\$ 96,763
Luvox CR	33,170	27,376	18,345
Product sales, net	266,518	170,006	115,108
Royalties and contract revenues	5,759	3,775	13,341
Total revenues	\$ 272,277	\$ 173,781	\$ 128,449

The following table presents a summary of our total revenues attributed to domestic and foreign sources (in thousands):

	Year Ended December 31,		
	2011	2010	2009
United States	\$ 265,718	\$ 169,317	\$ 114,080
Europe	6,224	4,169	14,011
All other	335	295	358
Total	\$ 272,277	\$ 173,781	\$ 128,449

The following table presents a summary of revenues from customers who represent at least 10% of our total revenues:

	Year Ended December 31,		
	2011	2010	2009
Express Scripts	85%	82%	75%
UCB(1)	*	*	11%

(1) In 2009, we recognized, as revenue, a \$10.0 million nonrefundable milestone payment received from UCB in 2008.



\* Represented less than 10% of our total revenues.

F-26

---

**Table of Contents**

**JAZZ PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. Subsequent Event**

On January 18, 2012, pursuant to an Agreement and Plan of Merger and Reorganization, or Merger Agreement, dated as of September 19, 2011, as amended, a wholly-owned subsidiary of Jazz Pharmaceuticals plc (formerly known as Azur Pharma Public Limited Company, or Azur Pharma) merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the merger and becoming a wholly-owned subsidiary of Jazz Pharmaceuticals plc.

At the effective time of the merger and pursuant to the Merger Agreement, each share of the common stock, par value \$0.0001 per share, of Jazz Pharmaceuticals, Inc. issued and outstanding immediately prior to the effective time of the merger was canceled and automatically converted into and became the right to receive one ordinary share, nominal value \$0.0001 per share, of Jazz Pharmaceuticals plc. Further, 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. 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.

Immediately prior to the merger and in order to effect the transactions contemplated by the Merger Agreement, the number of ordinary shares of Jazz Pharmaceuticals plc then outstanding were reduced based on a ratio of 0.2883 of an ordinary share of Jazz Pharmaceuticals plc for each whole ordinary share then held by the historic shareholders of Jazz Pharmaceuticals plc (such reduction, the Azur Reorganization). Following the Azur Reorganization and immediately after giving effect to the issuance of ordinary shares to the former stockholders of Jazz Pharmaceuticals, Inc. in the merger, approximately 43,838,000, or 78%, of the ordinary shares of Jazz Pharmaceuticals plc were held by the former stockholders of Jazz Pharmaceuticals, Inc., and the remaining approximately 12,360,000, or 22%, of the ordinary shares were held by the persons and entities who acquired ordinary shares of Jazz Pharmaceuticals plc prior to the merger. Jazz Pharmaceuticals, Inc. is treated as the acquiring company in the merger for accounting purposes, and the merger is being accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. We believe the merger will result in a company with a diversified product portfolio and significantly enhanced financial and other resources which will allow us to pursue additional product growth opportunities.

The merger will be accounted for using the acquisition method of accounting, with Jazz Pharmaceuticals, Inc. being treated as the accounting acquirer under U.S. GAAP. Under the acquisition method of accounting, assets and liabilities of Azur Pharma will be, as of completion of the merger, recorded at their respective fair values and added to those of Jazz Pharmaceuticals, Inc. including an amount for goodwill representing the difference between the acquisition consideration and the fair value of the identifiable net assets. Financial statements of Jazz Pharmaceuticals plc issued after the completion of the merger will include the operations of Azur Pharma beginning with the closing date, but will not be restated retroactively to include the historical financial position or results of operations of Azur Pharma for the periods prior to the closing.

Following the completion of the merger, the earnings of Jazz Pharmaceuticals plc will reflect acquisition accounting adjustments, for example, amortization of identified intangible assets. Goodwill and acquired in-process research and development assets resulting from the merger will not be amortized but instead will be tested for impairment at least annually. The final determination of acquisition consideration will be determined after completion of an analysis to determine the fair values of Azur Pharma assets and liabilities.

During 2011 we recognized as a component of selling, general and administrative expense, transaction costs of \$11.2 million which included acquisition-related costs of \$10.1 million and integration costs of \$1.1 million.

**Table of Contents****JAZZ PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We are in the process of determining fair values of the assets acquired and liabilities assumed, and completing the required supplemental pro forma revenue and earnings information for this acquisition. We expect to include a preliminary determination of the acquisition consideration and detail of the assets acquired and liabilities assumed in our consolidated financial statements for the quarter ending March 31, 2012.

**16. Quarterly Financial Data (Unaudited)**

The following interim financial information presents our 2011 and 2010 results of operations on a quarterly basis (in thousands, except per share amounts):

	<b>2011</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Revenues	\$ 50,881	\$ 64,567	\$ 73,293	\$ 83,536
Gross margin(1)	47,094	60,094	68,315	77,073
Net income	21,827	33,202	32,482	37,473
Net income per share, basic	0.54	0.81	0.77	0.88
Net income per share, diluted	0.48	0.71	0.69	0.79

	<b>2010</b>			
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Revenues	\$ 35,173	\$ 40,486	\$ 44,753	\$ 53,369
Gross margin(1)	31,401	36,726	40,747	47,573
Net income (loss)	1,464	(6,388)	13,243	24,459
Net income (loss) per share, basic	0.05	(0.18)	0.34	0.62
Net income (loss) per share, diluted	0.04	(0.18)	0.32	0.56

(1) Gross margin excludes amortization of acquired developed technology of \$1.8 million in each quarter of 2011 and 2010. The tables above include the following unusual or infrequently occurring items:

Transaction costs of \$6.0 million and \$5.3 million related to the merger with Azur Pharma were recorded in the three months ended September 30, 2011 and in the three months ended December 31, 2011, respectively;

Stock-based compensation expense of \$7.3 million recorded in the three months ended December 31, 2011 as a result of the vesting acceleration of non-qualified stock options held by certain executives and non-employee directors;

A loss on extinguishment of debt of \$1.1 million and \$12.3 million in the three months ended September 30, 2011 and in the three months ended June 30, 2010, respectively;

Revenue of \$2.0 million and related deferred product costs of \$674,000 recognized as a result of a change in the timing of when Luvox CR revenue is recognized in the three months ended December 31, 2010.



**Table of Contents****Schedule II****Valuation and Qualifying Accounts****(In thousands)**

		Balance at beginning of period	Additions	Additions charged to costs and expenses(3)	Deductions	Balance at end of period
For the year ended December 31, 2011						
Allowance for doubtful accounts	(1)	\$ 50	\$	\$ 3	\$ (3)	\$ 50
Allowance for sales discounts	(1)	420		3,604	(3,728)	296
Allowance for chargebacks	(1)	12		451	(443)	20
Allowance for wholesaler fees	(2)	893		5,251	(5,258)	886
Allowance for coupon programs	(2)	270		6,132	(5,817)	585
Allowance for managed care rebates	(2)	32		260	(146)	146
For the year ended December 31, 2010						
Allowance for doubtful accounts	(1)	\$ 50	\$	\$ (9)	\$ 9	\$ 50
Allowance for sales discounts	(1)	238		3,829	(3,647)	420
Allowance for chargebacks	(1)			233	(221)	12
Allowance for wholesaler fees	(2)	613	(63)	5,347	(5,004)	893
Allowance for coupon programs	(2),(4)		63	2,243	(2,036)	270
Allowance for managed care rebates	(2)		18	95	(81)	32
For the year ended December 31, 2009						
Allowance for doubtful accounts	(1)	\$ 50	\$	\$ 111	\$ (111)	\$ 50
Allowance for sales discounts	(1)	126		2,068	(1,956)	238
Allowance for chargebacks	(1)			82	(82)	
Allowance for wholesaler fees	(2),(4)	426	43	4,362	(4,218)	613

**Notes**

(1) Shown as a reduction of accounts receivable.

(2) Included in accrued liabilities.

(3) All charges except charges related to doubtful accounts are reflected as a reduction of revenue.

(4) In 2009, the allowance for wholesaler fees included the allowance for coupon programs.

The schedule above does not include government rebates and product returns reserve which are reported in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report on Form 10-K.

**Table of Contents****EXHIBIT INDEX****Exhibit**

<b>Number</b>	<b>Description of Document</b>
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500) filed with the Commission 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).
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).
3.2A	Fifth Amended and Restated Certificate of Incorporation of Jazz Pharmaceuticals, Inc.
3.2B	Amended and Restated Bylaws of Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.4 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
4.1A	Reference is made to Exhibit 3.1 with respect to Jazz Pharmaceuticals plc.
4.1B	Reference is made to Exhibits 3.2A and 3.2B with respect to Jazz Pharmaceuticals, Inc.
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.
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Series BB Preferred Stock Warrants originally issued by Jazz Pharmaceuticals, Inc.
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc.
4.5	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc.
4.6	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. on July 7, 2009.

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description of Document</b>
4.7A*	Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
4.7B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein.
4.8	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc s current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1A+*	Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.21 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.1B+	Jazz Pharmaceuticals plc 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.5 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.2+*	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the Jazz Pharmaceuticals, Inc. 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.22 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.3A+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.3 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.3B+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland.
10.3C+*	Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.23 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.4+*	Form of Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.24 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007).
10.5	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.50 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007).
10.6	Quality Agreement, dated as of March 13, 2007, by and between Jazz Pharmaceuticals, Inc. and Patheon Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.51 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).
10.7	Commercial Lease, dated as of June 2, 2004, by and between Jazz Pharmaceuticals, Inc. and The Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.52 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007).
10.8A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc. and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57A in Jazz Pharmaceuticals, Inc. s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.8B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney's Office for the Eastern District of New York and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57B in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.8C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.57C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.8D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.57D in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007).
10.9+*	Form of Letter, amending outstanding options granted under Jazz Pharmaceuticals, Inc.'s 2003 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.60 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
10.10+*	Form of Stock Award Grant Notice and Stock Award Agreement under Jazz Pharmaceuticals, Inc.'s 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.73 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008).
10.11	Revision of Payment Terms of the Plea Agreement dated as of July 17, 2007 between the U.S. Attorney for the Eastern District of New York and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.82 in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009).
10.12	Amendment to Settlement Agreement, signed by the Company on February 6, 2009, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc. and Orphan Medical, Inc. (incorporated herein by reference to Exhibit 10.83 in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009).
10.13	First Amendment of Lease, dated June 1, 2009, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University (incorporated herein by reference to Exhibit 10.86 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 4, 2009).
10.14	Form of Indemnification Agreement between Jazz Pharmaceuticals, Inc. and its officers and directors (incorporated herein by reference to Exhibit 10.89 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).
10.15+	Offer Letter from Jazz Pharmaceuticals, Inc. to Kathryn Falberg (incorporated herein by reference to Exhibit 10.92 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on December 3, 2009).
10.16	Supply Agreement, dated as of April 1, 2010, by and between Jazz Pharmaceuticals, Inc. and Siegfried (USA) Inc. (incorporated herein by reference to Exhibit 10.54 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2010, as filed with the SEC on May 6, 2010).
10.17A+*	Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.25 in Jazz Pharmaceuticals, Inc.'s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).



**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.17B+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.26 in Jazz Pharmaceuticals, Inc. s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007).
10.17C+*	Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.17D+*	Form of Stock Option Agreement and Form of Option Grant Notice under the Jazz Pharmaceuticals, Inc. Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.17E+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 99.4 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.18A+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.18B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 99.2 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.18C+*	Jazz Pharmaceuticals, Inc. 2007 Employee Stock Purchase Plan Offering Document, as amended and restated (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.19+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Offering Document.
10.20A+*	Jazz Pharmaceuticals, Inc. Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.20B+	Jazz Pharmaceuticals plc Amended and Restated Directors Deferred Compensation Plan (incorporated herein by reference to Exhibit 99.6 in Jazz Pharmaceuticals plc s registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).
10.21+	Separation Agreement, dated January 6, 2011, by and between Jazz Pharmaceuticals, Inc. and Robert Myers (incorporated herein by reference to Exhibit 10.53 in Jazz Pharmaceuticals, Inc. s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
10.22	Master Services Agreement, dated April 15, 2011, by and between Jazz Pharmaceuticals, Inc., CuraScript, Inc. and Express Scripts Specialty Distribution Services, Inc. (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2011, as filed with the SEC on May 9, 2011).
10.23+	Offer Letter from Jazz Pharmaceuticals, Inc. to Jeffrey Tobias, M.D. (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 8, 2011).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.24+	Form of Notice to Option Holder Re: Outstanding Nonstatutory Stock Options to Purchase Shares of Jazz Pharmaceuticals, Inc.'s Common Stock (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 28, 2011).
10.25	Form of Indemnification Agreement between Jazz Pharmaceuticals plc and its officers and directors (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.26	Escrow Agreement made and entered into as of January 18, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., Seamus Mulligan, solely in his capacity as Indemnitors' Representative, and Deutsche Bank National Trust Association, as escrow agent (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.27+	Separation Agreement, dated January 18, 2012, by and between Jazz Pharmaceuticals plc and Carol Gamble.
10.28	Lease Agreement, dated October 20, 2008, between Seamus Mulligan, as lessor, and Jazz Pharmaceuticals plc, as lessee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.29+	Employment Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.30	Noncompetition Agreement by and between Seamus Mulligan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's registration statement on Form S-4 (File No. 333-177528), as filed with the SEC on October 26, 2011).
10.31	Second Amendment of Lease, dated February 28, 2012, by and between Jazz Pharmaceuticals, Inc. and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University.
10.32+	Jazz Pharmaceuticals plc Non-Employee Director Compensation Arrangements.
10.33+	Jazz Pharmaceuticals plc Cash Bonus Plan.
10.34+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan.
10.35+	Form of Option Grant Notice and Form of Stock Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.
10.36+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.
10.37+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.
10.38+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc Amended and Restated 2007 Equity Incentive Plan.
10.39A+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.1 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.39B+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland.
10.40+	Form of Option Grant Notice and Form of Stock Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.41+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.42+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.43+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan.
10.44+	Jazz Pharmaceuticals, Inc. 2011 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2011, as filed with the SEC on May 9, 2011).
10.45+	Jazz Pharmaceuticals, Inc. Non-Employee Director Compensation Arrangements, as amended and restated (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals, Inc. s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2010, as filed with the SEC on November 5, 2010).
10.46+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan, as amended as of February 8, 2011 (incorporated herein by reference to Exhibit 10.54 in Jazz Pharmaceuticals, Inc. s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2010, as filed with the SEC on March 8, 2011).
10.47+	Jazz Pharmaceuticals, Inc. Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.81 in Jazz Pharmaceuticals, Inc. s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009).
21.1	Subsidiaries of Jazz Pharmaceuticals, Inc.
21.2	Subsidiaries of Jazz Pharmaceuticals Public Limited Company.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereto).
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
101.DEF++	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB++	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE++	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

## Edgar Filing: Jazz Pharmaceuticals plc - Form 10-K

- \* Indicates an instrument, agreement or compensatory arrangement or plan assumed by Jazz Pharmaceuticals plc in the merger and no longer binding on Jazz Pharmaceuticals, Inc.

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

**Table of Contents**

- \*\* The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
- ++ Pursuant to applicable securities laws and regulations, the Registrant is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Registrant has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fails to comply with the submission requirements. These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.