Jazz Pharmaceuticals plc
Form 10-K
February 25, 2014
Table of Contents

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

FORM 10-K

(Mark One)

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2013

or

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to
Commission File Number: 001-33500

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

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

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

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

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

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý 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 ý
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

Indicate by check mark 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 x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨
(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of June 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $3,527,521,407 based upon the last sale price reported for the registrant's ordinary shares on such date on the NASDAQ Global Select Market. The calculation of the aggregate market value of voting and non-voting common equity excludes 6,924,013 ordinary shares of the registrant held by executive officers, directors, and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of February 19, 2014, a total of 58,068,360 ordinary shares, nominal value $0.0001 per share, of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2014 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

JAZZ PHARMACEUTICALS PLC
2013 ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

We own or have rights to various copyrights, trademarks, and trade names used in our business in the United States and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Xyrem Success Program®, Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase®, Defitelio® (defibrotide), Prialt® (ziconotide) intrathecal infusion, FazaClo® (clozapine, USP), Versacloz™ (clozapine) oral suspension, Asparec™ (mPEG-r-crisantaspase), Leukotac™ (inolimomab), ProstaScint® (capromab pendetide), JumpStart™ and NAVIGATOR Reimbursement and Access Program™. This report also includes trademarks, service marks, and trade names of other companies.

2

Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, or the Exchange Act, 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," "pla "anticipate," "believe," "estimate," "project," "predict," "intend," "continue," "potential," "possible," "foreseeable," "likely" a 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 our forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, or the Azur Merger, in connection with which Azur Pharma was re-named Jazz Pharmaceuticals plc and we became the parent company of and successor to Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. becoming our wholly-owned subsidiary. Jazz Pharmaceuticals, Inc. was treated as the acquiring company in the Azur Merger for accounting purposes, and as a result, the historical consolidated financial statements of Jazz Pharmaceuticals, Inc. became our consolidated financial statements. In this report, unless otherwise indicated or the context otherwise requires, all references to "Jazz Pharmaceuticals," "the registrant," "we," "us," and "our" refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, except when the context makes clear that the time period being referenced is prior to the Azur Merger, in which case such terms are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. The disclosures in this report relating to the pre-Azur Merger business of Jazz Pharmaceuticals pertain to the business of Jazz Pharmaceuticals, Inc. prior to the Azur Merger.

PART I

Item 1. Business

Overview

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

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

In 2013 and to date in 2014, we have made substantial progress in the execution of our strategy. Our strong revenue growth continued, primarily from the sales of our lead marketed products, Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in markets outside of the United States. We acquired the product Defitelio® (defibrotide) as a result of our acquisition pursuant to a tender offer of approximately 98% of the outstanding and fully diluted voting securities of Gentium S.p.A., or Gentium, as of February 21, 2014, for an aggregate acquisition cost of approximately $993 million, which we refer to as the Gentium Acquisition. For a

detailed discussion of the Gentium Acquisition, see Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In October 2013, the European Commission granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe hepatic veno-occlusive disease, or severe VOD, in adults and children undergoing hematopoietic stem cell transplantation, or HSCT, therapy. We plan to launch Defitelio in selected European Union, or EU, countries during 2014, and expect to begin these efforts in the first half of 2014 after Defitelio’s patient registry has been established and is open for

Table of Contents

recruitment, subject to the receipt of a positive recommendation by the Pharmacovigilance Risk Assessment Committee, or PRAC, at the European Medicines Agency, or EMA, on the patient registry design. We are engaged in pricing and reimbursement submissions in applicable EU countries in preparation for planned launches in these countries. We intend eventually to promote Defitelio in all EU markets where it has marketing authorization. In February 2014, we launched Versacloz™ (clozapine) oral suspension in the United States for treatment-resistant schizophrenia and for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorders.

As a result, going into 2014, we have a portfolio of approved products that address medical needs in the following therapeutic areas, including:

Narcolepsy: Xyrem, the only product approved by the United States Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy;

Hematology/Oncology: Erwinaze, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to E. coli-derived asparaginase, and Defitelio, for the treatment of severe VOD in adults and children undergoing HSCT therapy;

Pain: Prialt® (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for the management of severe chronic pain for patients who are intolerant of or refractory to other treatments; and

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

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

In addition, we made significant progress and investment in expanding our product development pipeline. In February 2013, we licensed rights to JZP-386, an early-stage investigational compound being developed for potential use in narcolepsy, from Concert Pharmaceuticals, Inc., or Concert. In January 2014, we acquired rights to JZP-110 (formerly known as ADX-N05), a late-stage investigational compound being developed for potential treatment of excessive daytime sleepiness, or EDS, in patients with narcolepsy from Aerial BioPharma LLC, or Aerial. We also intend to pursue development of JZP-110 for EDS in patients with obstructive sleep apnea, or OSA. In addition to its existing approved indication in the EU, Defitelio has the potential to be developed for approval in other indications, and for approval in countries outside the EU, including the United States. We are currently assessing what we believe would be the optimal path for potential approval of defibrotide in the United States. Finally, we are conducting ongoing trials involving Asparec™ (mPEG-r-crisantaspase), a pegylated recombinant Erwinia asparaginase for the treatment of patients with ALL with E. coli asparaginase hypersensitivity, and Leukotac™ (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft versus host disease, or GvHD.

Our development pipeline projects also include line extensions for existing products and the generation of additional clinical data for existing products. We plan to conduct a clinical trial to further evaluate the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase.

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

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

Our Products

Xyrem® (sodium oxybate) oral solution

Xyrem is the only treatment approved by the FDA for both EDS and cataplexy in patients with narcolepsy. Sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a formulation of the sodium salt of gamma-hydroxybutyrate, an endogenous neurotransmitter and metabolite of gamma-aminobutyric acid. Xyrem was approved for the treatment of cataplexy in patients with narcolepsy in 2002 and was approved for EDS in patients with

narcolepsy in 2005. The American Academy of Sleep Medicine recommended Xyrem as a standard of care for the treatment of both EDS and cataplexy associated with narcolepsy.

Narcolepsy is a chronic neurological disorder caused by a loss of neurons that produce the neurotransmitter hypocretin (also known as orexin), which is hypothesized to stabilize sleep-wake states. The primary symptoms of narcolepsy include EDS, cataplexy, sleep paralysis, hypnogogic hallucinations and disrupted nighttime sleep. EDS is an essential symptom of

Table of Contents

narcolepsy, is present in all narcolepsy patients and 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 facial muscles to the complete loss of muscle tone resulting in postural collapse. It may also impair a patient's vision or speech. 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.

Narcolepsy may affect many areas of life, including limiting a patient's education and employment opportunities and leading to driving or machinery accidents or difficulties at work resulting in disability or job dismissal. Patients with narcolepsy may also suffer from significant medical comorbidities, including social anxiety disorder, OSA, bipolar disorder, depression, hypercholesterolaemia, diseases of the digestive system, cardiovascular diseases, upper respiratory tract diseases and hypertension.

It is estimated that narcolepsy affects approximately 1 in 2,000 people in the United States, or approximately 157,000 people. Less than half of those people have been definitively diagnosed with narcolepsy. In the fourth quarter of 2013, the average number of patients receiving Xyrem treatment was approximately 11,250 patients in the United States, and we believe that there are significantly more patients with narcolepsy and cataplexy and/or EDS who might benefit from treatment with Xyrem. In an effort to reach more patients, we are seeking to expand the base of physicians who prescribe Xyrem through a number of initiatives, including increased outreach to prescribers who treat narcolepsy and through physician disease education.

In 2013, net product sales of Xyrem were $569.1 million, which represented 65.8% of our total net product sales.

We promote Xyrem in the United States through a specialty sales force of approximately 100 sales professionals dedicated to Xyrem. Our marketing, sales and distribution of Xyrem are subject to a risk management and controlled distribution system, which we refer to as the Xyrem Risk Management Program, that was required in conjunction with Xyrem's approval by the FDA to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. Elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require a risk evaluation and mitigation strategy, or REMS, are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The Xyrem Risk Management Program, however, is not in the form that is now required for REMS documents. The FDAAA requires that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA has notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiate dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we will initiate dispute resolution procedures with the FDA by the end of February 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

Three companies have notified us that they have filed abbreviated new drug applications, or ANDAs, with the FDA seeking FDA approval to market a generic version of Xyrem. We initiated lawsuits against each of these companies, and the litigation proceedings are ongoing. In January 2014, the FDA held an initial meeting with us and current

Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). We also expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared system REMS for Xyrem (sodium oxybate), licensing or sharing our REMS, or the FDA's response to a certification that a third party had been unable to obtain a license. See the discussion under "Government Regulation" in this Item 1.

Under our current Xyrem Risk Management Program, all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or ESSDS. Xyrem may not be stocked in retail pharmacies. Physicians and patients must enroll in the Xyrem Success Program®, which is part of our Xyrem Risk Management Program, prior to fulfillment of Xyrem prescriptions. Each physician and patient receives materials concerning the risks and benefits of the product before the physician can prescribe, or a patient

Table of Contents

can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and must speak with the patient before each shipment of Xyrem is sent 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 up to a one-month supply, and refill orders may be for up to a three-month supply. ESSDS also provides reimbursement support to patients by coordinating insurance coverage for Xyrem, and as applicable, referring qualified patients to various patient savings or assistance programs.

Pursuant to our agreement, ESSDS exclusively distributes Xyrem in the United States 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 not less than 120 days before the end of the then current term. 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 that ESSDS provides to us and the related intellectual property, including intellectual property related to the patient database, to any new pharmacy that we may we engage.

Xyrem is a controlled substance in the United States, and therefore its manufacturing and distribution are highly restricted. The finished product and active pharmaceutical ingredient for Xyrem are each manufactured for us by a single source contract manufacturer.

Outside of 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 Mexico and 22 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.

We have fourteen U.S. patents covering Xyrem, which expire at various times from December 2019 to June 2024. Our issued patents relate to Xyrem’s stable and microbially resistant formulation, its manufacturing process and its method of use, including its restricted distribution system. There are currently three Xyrem ANDA applicants and we are involved in litigation with all three companies. For a description of these matters, please see Item 3. “Legal Proceedings.”

Erwinaze® (asparaginase Erwinia chrysanthemi)

Erwinaze, a biologic product, is used in conjunction with chemotherapy to treat patients with ALL who have developed hypersensitivity to E. coli-derived asparaginase. Erwinaze is an asparaginase, a type of enzyme that can deprive leukemic cells of an amino acid essential for their growth. It is derived from a rare bacterium (Erwinia chrysanthemi) and is immunologically distinct from E. coli-derived asparaginase and suitable for patients with hypersensitivity to E. coli-derived treatments. For ALL patients with hypersensitivity to E. coli-derived asparaginase, Erwinaze is a crucial component of their therapeutic regimen. Erwinaze is currently approved in the United States for administration via intramuscular injection in conjunction with chemotherapy. Erwinaze was originally developed by Public Health England, a U.K. national executive agency, or PHE. Erwinaze was approved by the FDA under a biological license application, or BLA, and was launched in the United States in November 2011. Outside of the United States, Erwinaze is sold under the name Erwinase pursuant to marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere.

ALL is the most common childhood cancer. Based on data from the U.S. National Cancer Institute, the U.S. Census Bureau and the American Cancer Society, we estimate that approximately 5,000 to 6,000 new cases of ALL were diagnosed in the United States in 2013. Approximately 50% of ALL patients were diagnosed under age 15 and approximately 20% were diagnosed between 15 and 39 years of age, which suggests that approximately 3,500 to 4,200 ALL patients were pediatric, adolescent and young adults. A study published by Dana Farber Cancer Institute, with median follow-up of 57 months, concluded that the intensive use of high-dose asparaginase has an important role in the treatment of children with ALL. Data reported in two papers published in Pediatric Blood & Cancer and Journal of Clinical Oncology suggest that approximately 20% of ALL patients develop hypersensitivity to E. coli-derived asparaginase. Current treatment guidelines and protocols recommend switching a patient receiving E. coli-derived asparaginase to treatment with Erwinaze if the patient’s hypersensitivity reaction to the E. coli-derived asparaginase is

Grade 2-4, indicating that the hypersensitivity reaction has resulted in an intervention or interruption in infusion occurring in the patient's treatment regimen. While pediatric treatment protocols commonly include asparaginase, adult protocols do not. A retrospective comparison to determine whether the outcome for adolescent and young adult ALL patients differed depending on their enrollment in pediatric compared with adult cooperative group trials showed that the seven-year overall survival rate among the adolescent and young adult ALL patients treated on pediatric protocols was 67% compared to 46% for those patients treated on adult protocols. As more treatment protocols incorporate the use of asparaginase-based regimens in adult centers, we expect to see increased use of Erwinaze. In addition, we believe that Erwinaze has the potential for use in patients with silent hypersensitivity, a situation in which E. coli-derived asparaginase may induce antibodies that can neutralize the enzyme or increase its clearance, thereby depriving patients of its therapeutic benefits, without manifesting the clinical symptoms of hypersensitivity. In February 2013, a third party introduced an assay to determine the enzyme activity of asparaginase in patients who have been treated with any E. coli-

Table of Contents

derived asparaginase or Erwinaze. With this assay, physicians may be able to monitor asparaginase levels to identify patients with silent hypersensitivity and maintain asparaginase activity by switching asparaginase preparations. We expect broad adoption of this assay to be limited until its use is included in existing pediatric and adult treatment protocols.

We promote Erwinaze in the United States through a specialty sales force of approximately 25 sales professionals. We provide reimbursement support through our JumpStart™ Access & Reimbursement Solutions program, a dedicated Erwinaze call center. Our field-based and office-based reimbursement team provides additional reimbursement support, dealing specifically with the more complex needs of physicians and payors.

In Europe and elsewhere around the world, Erwinase is sold pursuant to marketing authorizations, named patient programs, temporary use authorizations or similar authorizations. By the time of the planned launch of Defitelio, as described below, our hematology and oncology sales force outside of the United States is expected to have approximately 35 sales professionals responsible for promoting Erwinase and Defitelio in approved markets and approximately 15 medical science liaisons and medical directors responsible for responding to medical information requests and for providing information consistent with local treatment protocols.

In 2013, net product sales of Erwinaze/Erwinase were $174.3 million, which represented 20.1% of our total net product sales.

Erwinaze is exclusively licensed to us for worldwide marketing, sales and distribution by PHE, which also manufactures the product for us. PHE is our sole supplier for Erwinaze. We are obligated to make tiered royalty payments to PHE based on worldwide net sales of Erwinaze and Erwinase.

Although Erwinaze is not covered by any patents, Erwinaze has orphan drug marketing exclusivity in the United States through 2018 (seven years from its FDA approval), and we expect to receive data exclusivity for Erwinaze in the United States through 2023 under the U.S. Biologics Price Competition and Innovation Act, or BPCIA.

Defitelio® (defibrotide)

Defibrotide, the active pharmaceutical ingredient in Defitelio, is the sodium salt of a complex mixture of single-stranded oligodeoxyribonucleotides derived from porcine DNA. In in vitro studies, defibrotide has shown a number of pharmacological effects that suggest it has a role in both protection of the endothelial cells that form the inner lining of blood vessels and the restoration of the balance between clot formation and breakdown in the blood. Gentium historically focused the development of defibrotide on the treatment and prevention of VOD, a potentially life-threatening complication of HSCT. Stem cell transplantation is a frequently used treatment modality for hematologic cancers and other conditions in both adults and children. Certain high-dose conditioning regimens used as part of HSCT can damage the lining cells of hepatic vessels which is thought to lead to the development of VOD, a blockage of the small vessels in the liver, that leads to liver failure and can result in significant dysfunction in other organs such as the kidneys and lungs. The condition is also referred to as “sinusoidal obstruction syndrome.” Severe VOD is the most extreme form of VOD and is associated with multi-organ failure and high rates of morbidity and mortality. An analysis of retrospective data, prospective cohort studies and clinical trials published between 1979 and 2007 found that the 100-day mortality rate in severe VOD cases is greater than 80%. Based on data from published surveys and our market research, we estimate that of the approximately 35,000 patients undergoing HSCT annually in the EU, approximately 6,300 are considered at high risk for the development of VOD, and the incidence of VOD is approximately 3,600 patients. Our review of relevant literature and market research also suggests that about one-third to two-thirds of VOD patients may be eligible for treatment using defibrotide.

Defibrotide has been granted orphan drug designation to treat severe VOD and to prevent VOD by the FDA, by the EMA and by the Korean Ministry of Food and Drug Safety. The Commonwealth of Australia-Department of Health has granted defibrotide orphan drug designation for the treatment of severe VOD. In November 2013, the EMA also granted orphan drug designation to defibrotide for the prevention of GvHD, another potentially fatal complication of HSCT that afflicts up to 50% of all donor transplant patients.

In October 2013, the European Commission granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe VOD in adults and children undergoing HSCT therapy. Defitelio is the first approved treatment in the EU for this potentially life-threatening condition. Defitelio has generally been

well-tolerated; the most frequent adverse reactions observed during pre-marketing use of the product are hemorrhage, hypotension and coagulopathy.

We plan to launch Defitelio in selected EU countries during 2014, and expect to begin these efforts in the first half of 2014 after Defitelio's patient registry has been established and is open for recruitment, subject to the receipt of a positive recommendation by the PRAC on the patient registry design. We are engaged in pricing and reimbursement submissions in applicable EU countries in preparation for planned launches in those countries. We intend eventually to promote Defitelio in all EU markets where it has marketing authorization. We expect to promote Defitelio along with Erwinase to many of the same hematology and oncology specialists, and believe that we can benefit from the operational synergy in commercializing these

Table of Contents

products to the same targeted audience. Defitelio is currently available in approximately 40 countries through ten distribution partnerships on a named patient basis.

Under a license and supply agreement, Gentium has licensed the rights to commercialize defibrotide for the treatment and prevention of VOD in North America, Central America and South America, subject to receipt of marketing authorization in the applicable territory, if any, to Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau. Pursuant to the terms of the license and supply agreement, Sigma-Tau has agreed to reimburse us for certain costs associated with the development of defibrotide. In addition, we are entitled to certain milestone payments following regulatory approval in the United States and to royalty payments equal to 7% of Sigma-Tau's net sales of defibrotide as well as a supply margin equal to the greater of 31% of net sales or €50 (approximately $68) per unit of defibrotide finished product.

There are currently no approved treatments for severe VOD in the United States. Defibrotide is being distributed to patients diagnosed with severe VOD in the United States through an expanded access program pursuant to a treatment investigational new drug, or IND, protocol. Defibrotide also received Fast Track designation by the FDA to treat severe VOD. The Fast Track program is designed to enable more frequent interactions with the FDA during drug development and to expedite the FDA's review of a new drug candidate. We are currently assessing what we believe would be the optimal path for potential approval of defibrotide in the United States.

The drug substance defibrotide was developed and is manufactured in a facility in Italy that we acquired through the Gentium Acquisition. The finished product is manufactured for us by a single source contract manufacturer. The unique process of deriving defibrotide from porcine DNA is extensive and uses both chemical and biological processes which rely on complex characterization methods. We have a portfolio of U.S. and non-U.S. patents and patent applications relating to various compositions of defibrotide, methods of use and methods of characterization, which will expire at various times between April 2017 and June 2032.

Prialt® (ziconotide) intrathecal infusion

Prialt is an intrathecally administered 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 with Prialt, pain relief can be maintained over time without cumulative toxicity. Prialt is the only FDA-approved non-opioid intrathecal analgesic.

Azur Pharma acquired the rights to Prialt from Elan Pharmaceuticals, Inc. (subsequently acquired by Perrigo Company plc), or 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, or Eisai, which consist of 34 countries outside of the United States, mainly in Europe. We supply Prialt to Eisai. Azur Pharma paid Elan $5 million on the closing of the transaction, with an additional $12 million in deferred payments, which we paid to Elan in 2012. We are also obligated to pay up to a maximum aggregate amount of $120 million in tiered contingent payments, with the first such payment becoming due if net sales of at least $75 million are achieved in a calendar year, as well as a tiered royalty payment in the teens based on net sales.

We promote Prialt through a specialty sales force of approximately 30 sales professionals. We use a centralized distribution system for Prialt, the NAVIGATOR Reimbursement and Access Program™. This distribution system provides a simplified single point of access to Prialt, offering reimbursement and insurance support that is intended to reduce the burden on physicians and patients and providing information and support through a dedicated Prialt call center outsourced to a third party vendor. Our field-based reimbursement team provides additional support, dealing specifically with the more complex needs of physicians and payors. In 2013, we expanded our collaboration with Medtronic Inc., the maker of SynchroMed® II programmable implantable pumps approved by the FDA for use with Prialt, to enhance our ability to access physicians and provide education regarding the use of Prialt.

The finished product and active pharmaceutical ingredient are each manufactured for us by a single source contract manufacturer. We have three U.S. patents covering Prialt, which will expire from June 2015 to December 2016.

Psychiatry Products

We market FazaClo HD and FazaClo LD, each of which is an orally disintegrating tablet formulation of clozapine that is indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia and for reduction in the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective

Table of Contents

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 dosage strength presentations, was approved by the FDA in February 2004 with respect to the 25mg and 100mg tablets and in May 2007 for the 12.5mg tablets. Azur Pharma acquired the rights to FazaClo LD from Avanir Pharmaceuticals, Inc., or Avanir, in August 2007. FazaClo HD, comprising the two high dosage strengths of 150mg and 200mg tablets, was developed by Azur Pharma and received FDA approval in July 2010.

In February 2014, we launched Versacloz, an oral suspension formulation of clozapine, for treatment-resistant schizophrenia and for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorders. Versacloz was approved by the FDA for both indications in February 2013. In February 2010, Azur Pharma entered into a license and supply agreement with Douglas Pharmaceuticals America Limited, or Douglas Pharmaceuticals, and obtained an exclusive license to market, distribute and sell Versacloz in the United States and Mexico from Douglas Pharmaceuticals. The initial term of the license and supply agreement expires 10 years after the first commercial sale of Versacloz in the United States, subject to automatic extension for additional five-year terms unless terminated by either party subject to certain conditions.

According to Symphony Health Solutions, the U.S. clozapine market is dominated by generics, which accounted for approximately 95.3% of clozapine prescription volumes in 2013. Our FazaClo HD and FazaClo LD products accounted for approximately 1.3% and 3.4%, respectively, of clozapine prescription volumes in 2013. An authorized generic version of FazaClo LD launched in August 2012. Other clozapine generics are referenced to Clozaril, a standard immediate release tablet formulation of clozapine from Novartis Pharmaceuticals Corporation. FazaClo HD and FazaClo LD incorporate the DuraSolv® orally disintegrating tablet technology that 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 HD and FazaClo LD (including its authorized generic version) are currently the only orally disintegrating tablet formulations of clozapine available in the United States. Versacloz is currently the only oral suspension formulation of clozapine available in the United States.

Versacloz is sold under an approved REMS. FazaClo HD and FazaClo LD are sold under a risk management plan in the United States. One element of the risk management plan for FazaClo HD and FazaClo LD is a patient registry. The FDA requires that patients being prescribed any clozapine product, including FazaClo HD, FazaClo LD and Versacloz, must be enrolled in an FDA-approved patient registry, a database monitoring patients' white blood cell counts and absolute neutrophil counts to permit early detection of clozapine-induced leukopenia or agranulocytosis. The authorized generic form of FazaClo LD is part of the FazaClo HD and FazaClo LD patient registry. Similarly, as part of the REMS for Versacloz, patients who are prescribed Versacloz are required to be enrolled in the Versacloz patient registry.

The FazaClo HD and FazaClo LD risk management plan is not in the form that is now required for a REMS. In 2012, the FDA notified us, along with other holders of applications for products containing clozapine, that a single shared system should be used to implement the REMS for this entire class of products, including Versacloz. We are working with other manufacturers of clozapine products to address the FDA's requirements.

We promote FazaClo HD, FazaClo LD and Versacloz in the United States through a specialty sales force of approximately 25 sales professionals, with the support of our in-house registry team and a team of clinical compliance liaisons, who provide patient registry support services for FazaClo HD, FazaClo LD and Versacloz.

FazaClo HD and FazaClo LD are covered by three U.S. formulation patents. All are licensed by us, one from Ethypharm S.A., expiring in December 2017, and the other two from CIMA, expiring April 2018. The patentability of certain claims of two formulation patents that we license from CIMA and which cover FazaClo HD and FazaClo LD were confirmed by the U.S. Patent and Trademark Office, or the USPTO, in 2013. Versacloz is covered by a U.S. formulation patent and a pending U.S. patent application that we license from Douglas Pharmaceuticals. The patent expires in May 2028. We have single source third party suppliers for each of FazaClo LD, FazaClo HD and Versacloz.

Three generic manufacturers have filed ANDAs requesting approval to market generic versions of FazaClo LD, and one of them, Teva, has also submitted an ANDA requesting approval to market a generic version of FazaClo HD. Azur Pharma brought lawsuits against each of them and settled the lawsuit with Teva in 2011. In the settlement

agreement, Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicenses for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product in August 2012.

Research and Development

Our development pipeline projects currently include clinical development of new product candidates, line extensions for existing products and the generation of additional clinical data for existing products. These projects are concentrated in our

Table of Contents

sleep and hematology and oncology therapeutic areas, where we believe we will be able to leverage our existing specialty commercial expertise and infrastructure, as well as our strong clinical, medical and commercial teams.

In the sleep area, we have two product candidates under development.

- JZP-110. JZP-110 is a novel, investigational compound in clinical development for the treatment of EDS in patients with narcolepsy. While the mechanism of action is not fully understood, the molecule has demonstrated wake-promoting properties in pre-clinical and clinical studies. We intend to pursue Phase 3 clinical trials in the treatment of EDS in patients with narcolepsy, as well as EDS in patients with OSA. We plan to discuss our development plans with the FDA and intend to initiate our Phase 3 clinical program for JZP-110 as quickly as practicable thereafter, subject to the availability of clinical trial materials. In January 2014, we entered into an asset purchase agreement with Aerial to acquire the worldwide development, manufacturing and commercial rights to JZP-110, other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights. Under the agreement, we made an upfront payment totaling $125 million in January 2014 and are also obligated to make certain milestone payments, in an aggregate amount of up to $272 million, based on development, regulatory and sales milestones and to pay tiered royalties from high single digits to mid-teens based on potential future sales of JZP-110.
- JZP-386. We are conducting pre-clinical research and development work on JZP-386, a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem. We licensed JZP-386 from Concert in February 2013, for potential use in patients with narcolepsy. We submitted an investigational medicinal product dossier, or IMPD, for JZP-386 in Europe at the end of 2013 and received approval of the IMPD in January 2014. We intend to begin our first study of JZP-386 in humans in 2014, subject to the availability of clinical trial materials.

In the hematology and oncology area, we are conducting several clinical studies as well as evaluating one compound for further development.

- Asparec. We are conducting a Phase 1 clinical trial in Europe of Asparec, a pegylated recombinant Erwinia asparaginase being developed for the treatment of patients with ALL with E. coli asparaginase hypersensitivity. In June 2013, the FDA granted Fast Track designation to the investigation of Asparec for the treatment of ALL. We have reviewed our development plans with the FDA and are working with investigators to initiate our first study of Asparec in children. We license worldwide rights to develop and commercialize Asparec from Alizé Pharma II, or Alizé Under our license agreement with Alizé, we are subject to contractual obligations to meet certain development milestones within certain timeframes.
- Defibrotide. A prior new drug application, or NDA, submission by Gentium seeking approval in the United States for defibrotide for the treatment of severe VOD was voluntarily withdrawn from consideration in order to address issues raised by the FDA. We are currently assessing what we believe would be the optimal path for potential approval of defibrotide in the United States, which may include filing a new application with existing clinical data or generating additional clinical data before a new application is ready for submission and FDA review. We are also assessing the potential for approval of defibrotide in other countries and for additional development of defibrotide in other indications. For example, prior to the Gentium Acquisition, Gentium had completed a randomized controlled study of defibrotide for the prevention of VOD in pediatric HSCT patients.
- Erwinaze. We are preparing to initiate a clinical trial to further evaluate the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase. We have identified a principal investigator for this study, have finalized the study protocol and will begin the process of identifying, recruiting and initiating study sites. We expect to begin this planned trial in the first half of 2014. In 2013, we also completed a pharmacokinetic clinical trial of the intravenous administration of Erwinaze in North America. Based on data collected in the study, which met the primary end point, we submitted an amendment to the Erwinaze BLA to the FDA to allow intravenous administration of Erwinaze. The FDA determined that the data should be submitted as a supplemental BLA, or sBLA, and refused to file the initial submission. As a result, we plan to resubmit the data as an sBLA in the first quarter of 2014.
- Leukotac. We are also conducting a Phase 3 clinical trial in Europe of Leukotac (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute GvHD. We acquired the rights to Leukotac from

Biotest AG.

For the years ended December 31, 2013, 2012 and 2011, we recorded $46.6 million, $20.5 million and $14.1 million, respectively, in research and development expenses. For 2014 and beyond, we expect that our research and development expenses will increase substantially from these historical levels, particularly as we initiate our various planned clinical trials and development work.

Table of Contents

Sales and Marketing

Our commercial activities in the United States are dedicated to our marketed products Xyrem, Erwinaze, Prialt, FazaClo HD, FazaClo LD and Versacloz, as well as providing support for sales of certain of our other products. We currently have approximately 180 trained, experienced sales professionals who detail our marketed products to physicians in specialties appropriate for each marketed product in the United States.

In Europe, we promote Erwinase to hematology and oncology specialists. By the time we begin our planned launch of Defitelio in selected EU countries, our hematology and oncology team is expected to have approximately 35 hematology field specialists responsible for promoting Erwinase and Defitelio in approved markets, and we believe that we can benefit from the operational synergy of commercializing these products to the same targeted audience. In markets where Erwinase is not currently approved, approximately 15 medical science liaisons and medical directors are responsible for responding to medical information requests and for providing information consistent with local treatment protocols. In addition, we sell products in oncology, oncology supportive care and critical care outside of the United States through a network of local distributors and wholesalers in more than 80 countries.

Our commercial activities include marketing and related services and commercial support services. 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.

We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. We believe that the size of our sales force is appropriate to effectively reach our target audience for our marketed products in the specialty markets in which we currently operate. Continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization in the United States and internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization.

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 neurology, oncology, pain, psychology and other products. Many of these companies, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. They can spend more on, and have more expertise in, research and development, regulatory, manufacturing, distribution and sales activities. As a result, our competitors may obtain FDA, European Commission or other regulatory approvals for their product candidates more rapidly than we may and may market their products more effectively than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our ability to continue to grow 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 Endo Health Solutions Inc., Forest Laboratories, Inc., Shire Pharmaceuticals, Inc., Teva and Valeant. These established companies may have a competitive advantage over us due to their size and financial resources.

We also face competition from manufacturers of generic drugs. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available.

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® (sodium oxybate) oral solution. Xyrem is the only product approved for the treatment of both cataplexy and EDS in patients with narcolepsy. No product other than Xyrem is approved for the treatment of cataplexy. The only

other products approved by the FDA for the treatment of EDS in patients with narcolepsy are Provigil® (modafinil) and Nuvigil® (armodafinil), which are marketed by Teva, and the generic versions of Provigil. Provigil, its generic equivalents and Nuvigil are also approved for improving wakefulness in patients with EDS associated with treated OSA or shift work disorder. Xyrem is often used in conjunction with stimulants and wake-promoting drugs, which are administered during the day.

Table of Contents

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 EDS 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.
Three companies have notified us that they have filed abbreviated new drug applications, or ANDAs, with the FDA seeking FDA approval to market a generic version of Xyrem. We initiated lawsuits against each of these companies, and the litigation proceedings are ongoing. If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.

- Erwinaze® (asparaginase Erwinia chrysanthemi). Erwinaze is a biologic product used in conjunction with chemotherapy and is indicated for patients with ALL who have developed hypersensitivity to E. coli-derived asparaginase. While there is currently no direct competition to Erwinaze to treat ALL patients with hypersensitivity to E. coli-derived asparaginase, other companies are developing new treatments for ALL, including new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL and new treatment protocols for ALL that may not include asparaginase-containing regimens. Any of these potential new treatments could reduce the market for Erwinaze. As a biologic product, Erwinaze also faces potential competition from biosimilar products.
- Defitelio® (defibrotide). Defitelio is the first approved treatment in the EU for the treatment of severe VOD in HSCT. Various anti-clotting strategies have been tried by researchers with mixed results, including Activase (Alteplase), a recombinant tissue plasminogen activator, marketed by Genentech, Inc., generic heparin sodium injection, and Thrombate III (antithrombin III (human)), marketed by Grifols Therapeutics, Inc. While there is currently no direct competition to Defitelio to treat severe VOD, changes in the types of conditioning regimens used as part of HSCT may affect the incidence rate of VOD and demand for Defitelio.
- Prialt® (ziconotide) intrathecal infusion. Prialt is the only FDA-approved non-opioid intrathecal analgesic. It competes with intrathecally administered 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.
- FazaClo® HD (clozapine, USP) and FazaClo LD (clozapine, USP) Orally Disintegrating Tablets and Versacloz™ (clozapine) oral suspension. FazaClo HD, FazaClo LD and the authorized generic version of FazaClo LD launched in 2012 are the only orally disintegrating tablet formulations of clozapine available. FazaClo HD and FazaClo LD compete against the authorized generic of Fazaclo LD. Versacloz is currently the only oral suspension formulation of clozapine available in the United States. The substantial majority of prescriptions for clozapine are generic tablets, which also compete with FazaClo HD, FazaClo LD and Versacloz. In addition, prior to prescribing clozapine, most physicians choose other branded products as treatment options, including Latuda® (lurasidone hydrochloride), marketed by Sunovion Pharmaceuticals Inc., Risperdal® Consta® (risperidone), marketed by Janssen Pharmaceuticals, Inc., Seroquel® (quetiapine fumarate), marketed by AstraZeneca Pharmaceuticals LP, and Zyprexa® (olanzapine), marketed by Lilly USA, LLC.

With respect to all of our products and product candidates, we believe that our ability to successfully compete will depend on, among other things:

- the existence of competing or alternative products in the marketplace, including generic competition, and the relative price of those products;
- the efficacy, safety and reliability of our products and product candidates compared to competing or alternative products;
- product acceptance by physicians, other health care providers and patients;
- protection of our proprietary rights;
- obtaining reimbursement for our products in approved indications;

our ability to complete clinical development and obtain regulatory approvals for our product candidates, and the timing and scope of regulatory approvals;

- our ability to supply commercial quantities of a product to the market; and
- our ability to recruit, retain and develop skilled employees.

Table of Contents

Customers and Information About Geographic Areas

In the United States, Xyrem is sold to one specialty pharmacy, ESSDS, which ships Xyrem directly to patients, Erwinaze is sold through an exclusive wholesaler and distributor, Accredo Health Group, Inc., to hospitals, and Prialt is sold through an exclusive wholesale distributor and pharmacy, BioScrip, Inc., to medical facilities. The other products that we sell in the United States are sold primarily to distributors who distribute the product to pharmacies and hospitals. In 2013, the principal distributors for our other 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.

Outside of the United States, UCB has rights to market Xyrem in 54 countries and Valeant has rights for Canada. Xyrem is currently sold in 23 countries by UCB and in Canada by Valeant. We distribute Erwinase through Durbin PLC, a U.K. based wholesaler and distributor, to hospitals and local wholesalers in Europe where we market Erwinase directly and, in markets where we do not market Erwinase directly, to local distributors and wholesalers in Europe and elsewhere in the world. We plan to launch Defitelio in the EU during 2014 and initially expect to continue to distribute Defitelio through Gentium's legacy distribution partner IDIS Ltd, a U.K. based company. We also sell other products both directly and through local distributors and wholesalers in Europe and elsewhere in the world in accordance with local regulatory approval status. Eisai has rights to market Prialt in 34 countries outside of the United States. While we retain the rights to Prialt in the rest of the non-U.S. territories, we are not currently selling the product outside of the United States. We do not have rights outside of the United States to our psychiatry products.

Information on our total revenues attributed to United States and non-U.S. sources and customers who represented at least 10% of our total revenues in each of 2013, 2012 and 2011, as well as the location of our long-lived assets, is included in Note 14 to our consolidated financial statements.

Our worldwide headquarters are in Dublin, Ireland, and we have offices in Philadelphia, Pennsylvania and Palo Alto, California in the United States, as well as in Oxford, United Kingdom, Lyon, France, Villa Guardia (Como), Italy, Zug, Switzerland and elsewhere in Europe.

Manufacturing

Other than the manufacturing plant in Italy where we produce some active pharmaceutical ingredients, including the defibrotide drug substance, discussed in more detail below, we do not currently have our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. Currently, we have a single source of supply for each of our marketed products and for the active pharmaceutical ingredients used in these products. Our ability to develop and deliver products in a timely and competitive manner depends on our third party suppliers and manufacturers being able to continue to meet our ongoing commercial needs (except with respect to the defibrotide drug substance, which we manufacture for ourselves). Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. These difficulties can be heightened when a supplier or manufacturer is required to scale up to produce increased quantities to meet growing demand.

In April 2010, we entered into an agreement with Siegfried (USA) Inc., subsequently renamed Siegfried USA, LLC, or Siegfried, for the supply of sodium oxybate, the active pharmaceutical ingredient of Xyrem. Siegfried was approved by the FDA as our supplier in November 2011. Although Siegfried has been our only supplier of sodium oxybate since 2012, we have the right to purchase a portion of our worldwide requirements of sodium oxybate from other suppliers. Under our agreement, we provide periodic rolling forecasts to Siegfried, and a portion of each rolling forecast constitutes a firm purchase order. The agreement with Siegfried expires in April 2018, 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. Either party has the right to terminate the agreement in the event of the other party's uncured material breach or insolvency. 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 exclusively from Patheon (except in very limited circumstances), and Patheon has agreed to manufacture, supply and package, our worldwide supply of Xyrem. The current term of the agreement with Patheon, which is our sole supplier of Xyrem, extends until July 2016 and may be extended, at our option, for additional two-year terms with written notice at least twelve months before the end of the then current term. Either party has the right to terminate the agreement in the event of the other party's uncured material breach or insolvency.

Quotas from the U.S. Drug Enforcement Administration, or DEA, are required in order to manufacture and package sodium oxybate and Xyrem. DEA quotas are required for Siegfried to supply us with sodium oxybate and for Patheon to supply us with Xyrem. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for

Table of Contents

a quota request, obtaining a sufficient DEA quota can be a difficult and time-consuming process. The need for quota has prevented us in the past, and may prevent us in the future, from building significant inventories. For information related to this quota requirement by the DEA, see "Government Regulation—U.S. Regulations—Other Regulatory Requirements" in this Item 1.

Erwinaze is exclusively licensed to us, and manufactured for us, by PHE, which is our sole supplier for Erwinaze. The agreement with PHE expires in December 2020, subject to automatic extension for additional five-year periods unless terminated by either party in writing prior to a fixed date before the end of the then-current term. Either party has the right to terminate the agreement in the event of the other party's uncured material breach or insolvency. We provide periodic rolling forecasts to PHE, and a portion of each rolling forecast constitutes a firm purchase order. We are obligated to make tiered royalty payments to PHE based on worldwide net sales of Erwinaze and Erwinase. The BLA approving Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze by PHE. We have limited inventory of Erwinaze, and, during 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. In the past, we have experienced a disruption of supply of Erwinase in the European market due to manufacturing challenges, including shortages related to the failure of a batch to meet certain specifications in 2013, and we may experience similar or other manufacturing challenges in the future. If our continued efforts to avoid supply shortages are not successful, we could experience Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. In addition, while we continue to work with PHE to evaluate potential steps to increase the supply of Erwinaze over the longer term to address expected growing worldwide demand, our ability to increase sales of Erwinaze may be limited by our ability to obtain an increased supply of the product.

Furthermore, if PHE experiences a disruption in supply or capacity constraints as a result of increased demand, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach by PHE or the cessation of PHE's business. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinaze.

We manufacture the defibrotide drug substance at our manufacturing plant in Italy. We are our sole supplier of defibrotide and do not believe there is another producer of defibrotide currently available. There is an agreement in place with a single third party supplier based in Italy to process the defibrotide drug substance into its finished vial form for our commercial supply for the planned launch of Defitelio in the EU and for our future clinical supply.

We are in the process of changing our supplier for ziconotide, the active pharmaceutical ingredient in Prialt, and have commenced the transfer to the new supplier. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for finished product for a number of years, which we expect to be sufficient time to complete the transfer to the new supplier. In addition, our new manufacturer of finished product was approved by the FDA in December 2012 and started to supply us with Prialt finished product in January 2014.

For FazaClo HD, FazaClo LD and Versacloz, we have single sources of supply for both the active pharmaceutical ingredient and finished product, and should it become necessary to change suppliers, the process could take two years or longer.

We are in the process of identifying a supplier for JZP-110. In order to commence our planned Phase 3 clinical programs, we need to have sufficient quantity of JZP-110 manufactured. In addition, we rely on Concert to transfer its manufacturing methods to us and our contract manufacturers to produce sufficient quantity of JZP-386 required for our planned first study in humans. We believe that we will be able to obtain sufficient supplies of JZP-110 and JZP-386 before the commencement of the applicable planned clinical trials. Any delay in receiving sufficient supplies of JZP-110 or JZP-386 for our planned studies could negatively impact our development programs.

Our active pharmaceutical ingredient and finished product manufacturers may not be able to continue to meet our requirements for quality, quantity and timeliness. In addition, our manufacturers and suppliers are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and other rules and regulations

prescribed by non-U.S. regulatory authorities. We depend on our third party suppliers and manufacturers for continued compliance with these requirements, and they may not be able to do so.

Government Regulation

The research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of pharmaceutical products are subject to extensive regulation by the FDA, the European Commission and other regulatory authorities, and regulations differ from country to country. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, regulates the review, approval, manufacturing and marketing of pharmaceutical products. We are not permitted to market medicines in the

Table of Contents

United States or in the EU member states until we receive approval from the FDA, the European Commission or the competent authorities of the EU member states, respectively, generally of an NDA or a BLA, or their non-U.S. equivalent. The application must contain information demonstrating the quality, safety and efficacy of the pharmaceutical product, including data from preclinical and clinical trials, information pertaining to the preparation and manufacture of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and information concerning the stability of the drug or biologic.

Xyrem is also regulated as a controlled substance and is subject to additional regulation by the DEA under the Controlled Substances Act, or CSA, and its implementing regulations. Similarly, Xyrem is regulated as a controlled substance in accordance with the national laws of the EU member states and Canada.

Failure of us or any of our third party partners to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, withdrawal of product approval, notices of violation, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall or seizure, total or partial suspension of production or distribution, interruption of manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, civil penalties and/or criminal prosecution.

U.S. Regulations

Drug and Biologic Approval Process

To obtain FDA approval of a product candidate, an applicant, also called a sponsor, must, among other things, submit the results of preclinical and clinical trials with data supporting safety and efficacy, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling. The submission is in the form of an NDA or BLA, as applicable, and includes payment of a user fee.

The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The steps required before a drug or biologic may be approved for marketing in the United States generally include: preclinical laboratory tests and animal tests; submission to the FDA of an 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 or biologic for each indication; the submission to the FDA of a marketing application; 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 application; and FDA review and approval of the application.

The FDA reviews all applications submitted before it accepts them for filing and may request additional information rather than, or before, accepting an NDA or BLA for filing. For example, a prior NDA submission for defibrotide in the United States was voluntarily withdrawn from consideration in order to address issues raised by the FDA. We are currently assessing what we believe would be the optimal path for potential approval of defibrotide in the United States.

Once an NDA or BLA submission is accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has twelve months from submission in which to complete its initial review of a standard application and respond to the applicant, and eight months for a priority application. The FDA does not always meet its PDUFA goal dates, and in certain circumstances the PDUFA goal date may be extended. The FDA may not act quickly or favorably in reviewing applications, and we may encounter significant difficulties or costs in any efforts to obtain FDA approvals, which could delay or preclude us from marketing our product candidates.

If the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include, as part of the application or after approval, a proposed REMS, which may include a patient package insert or a medication guide to provide information to consumers about the product's risks and benefits, a plan for communication to healthcare providers, and restrictions on the product's distribution referred to as "elements to assure safe use," or ETASU. For example, Xyrem is required to have a REMS. Elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, are deemed to be an

approved REMS pursuant to the FDAAA. The Xyrem Risk Management Program, however, is not in the form that is now required for REMS documents. The FDAAA, which amended the FDCA, requires that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

Table of Contents

The FDA has notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiate dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we will initiate dispute resolution procedures with the FDA by the end of February 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem. See the discussion below regarding REMS in the context of potential generic competition under "The Hatch-Waxman Act" and in the risk factor in Item 1A entitled "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

FazaClo HD and FazaClo LD are sold under one risk management plan in the United States and Versacloz is sold under an approved REMS, each involving a patient registry. In 2012, the FDA notified us, along with other holders of applications for products containing clozapine, that a single shared system should be used to implement the REMS for this entire class of products. We are working with other manufacturers of clozapine products to address the FDA's requirements.

After the FDA evaluates a marketing application, including a REMS program when applicable, it also evaluates any manufacturing facilities for the proposed product. When the FDA's evaluation is complete, 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 application, 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 and has used various programs, including fast track, priority review, breakthrough therapy and accelerated approval (Subpart H and E), that are intended to expedite or simplify the process for reviewing certain applications and/or provide for approval on the basis of surrogate endpoints or restricted distribution. Generally, drugs and biologics may be eligible for one or more of these programs if they are intended for serious or life-threatening diseases or conditions, have potential to address unmet medical needs, or may provide meaningful benefit over existing treatments. In June 2013, the FDA granted Fast Track designation to the investigation of Asparec for ALL. Defibrotide has been granted Fast Track Designation by the FDA to treat severe VOD. We cannot be sure that any of our other product candidates will qualify for any of these programs, or that, if a product candidate does qualify, the review time will be shorter than a standard review.

Post-Approval Regulation

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, modifying a REMS, 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.

Often, even after a drug or biologic 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 and trials. If such post-approval conditions are not satisfied, the FDA may impose civil money penalties, declare the product misbranded or prohibit the introduction of the drug in interstate commerce. In addition, holders of an approved NDA or BLA 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. For example, the FDA's approval of the BLA

for Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze by us and the PHE. Also, the marketing authorization in the EU for Defitelio requires us to comply with a number of post-marketing obligations, including obligations relating to the establishment of a patient registry. Before we can launch Defitelio in the EU, we need to establish Defitelio's patient registry and open it for recruitment, which is subject to our receipt of a positive recommendation by the PRAC on the design of the patient registry.

We monitor adverse events resulting from the use of our commercial products, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The authorities review these events and reports, and if they determine that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing and/or require or conduct other actions. From time to time, the FDA issues drug safety communications on its adverse event reporting system based on its review of reported adverse events. In December 2012, the FDA issued a drug safety communication reminding physicians and patients that the use of Xyrem with alcohol or central nervous system

Table of Contents

depressants can impair consciousness and lead to severe breathing problems. At that time, we agreed with the FDA on a change to our label that included a new contraindication for the use of alcohol with Xyrem. See also the risk factor in Item 1A entitled "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third party manufacturers and our corporate partners are subject to cGMP, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the FDA, the EMA and other regulatory authorities. 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 product, 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 impose significant reporting and other burdens on the affected companies.

The Hatch-Waxman Act

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.

Alternatively, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which updated certain sections of the FDCA, establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of products already covered by an approved NDA. The first path, under Section 505(b)(2), is for the approval of a product that is similar, but not identical, to a previously-approved product. Under this path, the applicant is permitted to rely to some degree on the FDA's finding that the referenced drug is safe and effective, and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. 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.

The second path established under the Hatch-Waxman Act is for the approval of generic drugs. Section 505(j) of the FDCA permits the submission of an ANDA for a generic version of an approved, brand-name drug. Generally, an ANDA must contain data and information showing that the proposed generic product and the approved, brand-name drug, which is referred to as the "referenced drug," (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This data and information are provided instead of independently demonstrating the proposed generic product's safety and effectiveness, which are inferred from the fact that the generic product is the same as the referenced drug, which the FDA previously found to be safe and effective. Each of Roxane Laboratories, Inc., or Roxane, Amneal Pharmaceuticals, LLC, or Amneal, and Par Pharmaceutical, Inc., or Par, has filed an ANDA with the FDA requesting approval to market a generic version of Xyrem. ANDAs have been filed in the past seeking approval to market generic versions of certain of our other products, and additional ANDAs may be filed in the future seeking approval to market generic forms of Xyrem and/or other products.

To the extent that an ANDA or a Section 505(b)(2) NDA 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 publication "Approved Drug Products with Therapeutic Equivalence Evaluations," 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 referenced 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 ANDA or the Section 505(b)(2) NDA 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 ANDA or the Section 505(b)(2) NDA may also be subject to delay in review or approval based on applicable non-patent exclusivities, such as exclusivity that results from obtaining approval of a new chemical entity or of a new use of a previously approved active ingredient.

Table of Contents

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 ANDA or the Section 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 proposed generic product for infringing the patent. The filing of a patent infringement lawsuit within 45 days of receipt of a Paragraph IV Certification automatically prevents the FDA from approving the ANDA or the Section 505(b)(2) NDA until the earliest of 30 months after the NDA holder's receipt of the notice of the Paragraph IV Certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA sponsor. The 30-month stay period may also be shortened or lengthened upon order of the court in the infringement lawsuit. 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 reference drug NDA. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant will not be subject to the 30-month stay. The FDA may issue tentative approval of an ANDA if the generic applicant meets all conditions for approval but cannot receive effective approval because the 30-month stay or a period of statutory exclusivity has not expired.

We intend to submit for Orange Book listing all relevant patents for our products and product candidates, and to vigorously defend any patents for our approved products, including Orange Book-listed patents. In October 2010, December 2012 and November 2013, respectively, we received a Paragraph IV Certification from each of Roxane, Amneal and Par that each had filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the Orange-Book-listed patents relating to Xyrem. We have sued Roxane, Amneal and Par seeking to prevent them from introducing a generic version of Xyrem that would infringe our patents. For a description of these matters, please see Item 3. "Legal Proceedings." If an ANDA is approved after the 30-month stay and before conclusion of any relevant patent litigation at the district, and potentially appellate, court, a generic manufacturer could nonetheless choose to commercialize the generic product. In the event of such commercialization, the generic manufacturer generally would be liable to the NDA holder for damages if the NDA holder ultimately prevails in the patent litigation.

Section 505-1(i)(1) of the FDCA generally provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same or comparable elements as the referenced drug, such as a medication guide, a patient package insert and other ETASU, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and permit the ANDA holder to submit a separate but comparable REMS if the FDA either determines that the burden of creating a single shared system outweighs its benefit, or if the ANDA applicant certifies that it has been unable to obtain a license to any aspects of the REMS for the referenced drug product that are covered by a patent or a trade secret. The FDCA provides that the FDA may seek to negotiate a license between the ANDA sponsor and the sponsor of the listed product before granting a waiver of the single shared system requirement. The FDCA further states that a REMS shall not be used by an NDA holder to block or delay generic drugs from entering the market. Accordingly, we expect to face pressure to license or share our Xyrem Risk Management Program, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with regard to licensing or sharing our REMS program.

In the FDA's December 2012 response denying a Citizen Petition we filed in July 2012, the FDA stated that when an NDA holder has a deemed REMS, the FDA directs the ANDA applicant(s) to work with the NDA holder to create a single shared system to implement the ETASU that will be approved as a final REMS. More broadly, the FDA has stated that it expects the negotiation of a single shared REMS between an NDA holder and ANDA applicants to proceed concurrently with the FDA's review of ANDA applications. The FDA has further stated that it typically monitors the progress of industry working groups attempting to develop shared REMS systems, and that it has acted to help ensure that sponsors were cooperating and that there were no obstacles to developing a single shared system. In January 2014, the FDA held an initial meeting with us and current Xyrem ANDA applicants to facilitate the development of a single shared system REMS. We cannot predict the timing, outcome or impact on our business of

any discussions with the FDA and/or any ANDA applicant with respect to the potential creation of a single shared system REMS for Xyrem (sodium oxybate), including the impact of the ongoing process with respect to potential modifications to the Xyrem deemed REMS as discussed above, or the impact of single shared system REMS discussions on our ongoing litigation with each of the ANDA applicants. See the risk factor in Item 1A entitled “We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products.”

If we do not develop a single shared system REMS or license or share our REMS with a generic competitor within a time frame or on terms that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to allow the generic competitor to market a generic drug with a REMS that does not include the same elements that are in our deemed REMS or, when Xyrem REMS documents are approved, with a separate REMS that includes different, but comparable, ETASU.

It is also possible that the FDA may take the position that a potential generic competitor does not need a REMS that has the same ETASU as our Xyrem deemed REMS in order to obtain approval of its ANDA. In the denial of our Citizen Petition

Table of Contents

described above, the FDA stated that if the FDA determines that an ANDA may be ready for approval before final approval of the REMS of a sponsor holding a deemed REMS, the FDA will direct the ANDA applicant to submit a proposed risk management plan with ETASU that are comparable to the ETASU that are approved for the referenced drug to have adequate risk management elements in place for the ANDA until the final REMS is approved. The legal basis for this position is uncertain. However, it is possible that the FDA may rely on this position as a basis to grant approval of an ANDA with a risk management plan rather than a final REMS. The 30-month stay of FDA approval of Roxane's ANDA expired on April 18, 2013, and we have not yet received approval of final REMS documents for Xyrem. Accordingly, it is possible that, consistent with the position that the FDA articulated in its denial of our Citizen Petition, the FDA could approve Roxane's ANDA with a risk management plan that is separate from our Xyrem deemed REMS, rather than with a final REMS or a shared REMS for both the generic and Xyrem. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects. See the risk factor in this Item 1A entitled "We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products."

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 the FDA accepting for review an 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 litigation leading to a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA that could extend to 7.5 years after approval of the referenced drug. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another "full" NDA; however, the applicant would 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.

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 product or its use may be extended, and only if the regulatory review leads to the first commercial marketing of that drug, and the extension must be applied for prior to expiration of the patent. The USPTO, 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.

Orphan Drug and Other Exclusivities

Some jurisdictions, including the United States, may designate drugs or biologics for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs or biologics 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 the United States if there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product. In the United States, in order to obtain orphan drug designation, this 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 that 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 product for the same indication for a period of seven years from the time of FDA approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug 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 treatment of EDS and cataplexy in patients with narcolepsy, but those periods of orphan drug exclusivity have expired. Erwinaze has orphan drug exclusivity until November 2018, seven years from its FDA approval. Asparec and defibrotide have been granted orphan drug designation by the FDA for ALL and severe VOD, respectively.

Separately, Erwinaze, as a biologic product approved under a BLA, is subject to the BPCIA. The BPCIA establishes a period of twelve years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting

Table of Contents

data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a twelve-year period. The FDA is in the process of implementing the BPCIA and has not established final guidelines for administering the review and approval of applications for data exclusivity. We expect that Erwinaze would receive data exclusivity in the United States through 2023 under the BPCIA.

Products also may be eligible for six months of additional exclusivity and patent protection if the sponsor submits pediatric data that fairly respond to a written request from the FDA for this data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within statutory time limits, whatever statutory or regulatory periods of exclusivity or listed patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the period during which, because of regulatory exclusivity or listed patents, the FDA cannot approve an ANDA or 505(b)(2) NDA. We will consider seeking pediatric exclusivity if we meet the legal requirements and believe it will be commercially beneficial.

United States Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, together the Healthcare Reform Act, was adopted in the United States. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, the Healthcare Reform Act increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Healthcare Reform Act and subsequent legislation changed the definition of average manufacturer price. A final regulation regarding these changes to the Medicaid Drug Rebate program is expected in 2014. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Sales of orphan drugs are excluded from this fee as long as no non-orphan indications have been approved for such orphan drugs.

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 coverage gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. The Healthcare Reform Act also expanded the Public Health Service's 340B drug pricing discount program. 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 Healthcare Reform Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access

hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts “orphan drugs” - those designated under section 526 of the FDCA - from the ceiling price requirements for these newly-eligible entities. The Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation to implement the orphan drug exception in July 2013. The final regulation interprets the orphan drug exception narrowly. It exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. The newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. The final regulation, which became effective October 1, 2013, is subject to a pending lawsuit that seeks to block its implementation. The narrow scope of the orphan drug exception in HRSA’s final regulation will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations.

The Healthcare Reform Act also obligates the Secretary of the U.S. Department of Health and Human Services, or the

Table of Contents

HHS, to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. HRSA is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, the Supreme Court struck down a provision in the Healthcare Reform Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition.

Other Regulatory Requirements

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, or FTC, the U.S. Department of Commerce, the Office of Inspector General of the HHS and other regulatory bodies. In addition to the FDCA, other statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our partners, including our suppliers, manufacturers and distributors and the central pharmacy for Xyrem, are subject to many of the same requirements.

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition to quota requirements, the DEA imposes various registration, recordkeeping and reporting requirements, labeling and packaging requirements, importing, exporting, security controls and a restriction on prescription refills on certain pharmaceutical products under the CSA. The states also impose similar requirements for handling controlled substances. A principal factor in determining the particular requirements, if any, applicable to a 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. As a Schedule III drug, Xyrem is subject to limitations on prescription refills. 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. The DEA publishes an annual aggregate quota for the active pharmaceutical ingredient of Xyrem, and our supplier is required to request and justify allocation of sufficient annual manufacturing quota, as well as additional manufacturing quota if needed throughout the year. Until 2011, our active pharmaceutical ingredient supplier obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for each of 2012, 2013 and 2014, our supplier has been allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. Consequently, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota.

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 laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business, including recently enacted laws in all jurisdictions where we operate. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. In addition, we obtain patient health information from most healthcare providers who prescribe our products and

Table of Contents

research institutions we collaborate with, and they are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, pursuant to the Export Administration Regulations, we are required to obtain a license from the U.S. Department of Commerce prior to the exportation of certain materials and technical information related to Prialt, a synthesized conotoxin, which is a designated controlled biological toxin.

A discussion of the U.S. Foreign Corrupt Practices Act, or the FCPA, is included below.

Non-U.S. Regulations

We are also subject to a variety of regulations and oversight in countries outside of the United States governing medicinal products and medical devices, including with respect to pre- and post-authorization clinical studies, product manufacturing, advertising and promotion, distribution, and safety reporting. Outside of the United States, our ability to market a product generally 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 generally be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. In addition, many countries have adopted specific legal frameworks and procedures to enable the supply of unauthorized medicinal products in the context of named patient or compassionate use programs. These programs are subject to different requirements and subject to different rules in the countries where we operate.

Most of the countries where we market our products have product authorization and post-authorization regulatory processes. In the EU, marketing authorization for medicinal products can be obtained through several different procedures. The centralized procedure allows a company to submit a single application to the EMA which will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. A centralized marketing authorization, valid in all EU member states, can then be granted by the European Commission. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products, biologic products and certain other new products, and optional for certain other products. Unlike the centralized procedure, the national procedure requires a separate application to, and leads to separate approval by, each EU member state. The decentralized procedure allows applicants to file identical applications to several EU member states and receive national approvals based on the recognition by the EU member states concerned of an assessment by a reference member state. The mutual recognition procedure similarly is based on the acceptance by EU member states of the assessment and/or authorization of a medicinal product by a reference member state. The making available or placing on the EU market of unauthorized medicinal products is generally prohibited, but EU member states may exceptionally and temporarily allow the making available of such products to individual patients or a group of patients. Clinical studies must be conducted in accordance with the requirements of the EU Clinical Trials Directive and applicable good clinical practice standards, as implemented into national legislation by EU member states. The time needed to secure approval for medicinal products 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.

The initial marketing authorization granted in the EU is valid for five years, but once renewed is usually valid for an unlimited period. In addition, products for which the applicant can demonstrate that comprehensive data on the efficacy and safety under normal conditions of use cannot be provided as a result of certain specified reasons may be eligible for marketing authorization under exceptional circumstances. A marketing authorization granted under exceptional circumstances is also valid for five years, but is subject to an annual reassessment of the risk-benefit balance. In October 2013, the European Commission granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe VOD in adults and children undergoing HSCT therapy.

In the EU, orphan drug status is granted to products that can be used in the diagnosis, treatment or prevention of life-threatening diseases with an incidence of no more than 5 in 10,000. In order to receive orphan status, there must also be either no satisfactory method of diagnosis, prevention or treatment of the authorized condition, or if such a method exists, the medicine must potentially be of a significant benefit to those affected by the condition. Orphan status confers 10 years of marketing exclusivity in all EU member countries following approval and in addition a range of other benefits during the development and regulatory review process including scientific assistance for study protocols, access to the centralized review process covering all member countries and a reduction or elimination of registration and marketing authorization fees. Defibrotide has been granted orphan drug designation by the EMA both to treat severe VOD and to prevent VOD and for the prevention of GvHD. The Korean Ministry of Food and Drug Safety has granted defibrotide orphan drug designation both to

Table of Contents

treat severe VOD and to prevent VOD and the Commonwealth of Australia-Department of Health has granted defibrotide orphan drug designation for the treatment of severe VOD.

Irrespective of the different marketing authorization tracks, various additional requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the EU Medicinal Products Directive and EU Medicinal Products Regulation. These requirements include compliance with EU equivalent cGMP standards when manufacturing active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Similarly, the distribution of medicinal products into and within the EU is subject to compliance with EU requirements and guidelines.

The holder of an EU marketing authorization for a medicinal product must also comply with the EU's revised pharmacovigilance legislation adopted in 2010, which entered into force in mid-2012 and entails many new and revised requirements for conducting pharmacovigilance, as well as the codification of various existing requirements previously set out in guidance. EU regulators now can, for example, require post-authorization efficacy studies at the time of approval of a medicinal product or afterwards, and require additional monitoring of products placed on the EU market. Compliance with the pharmacovigilance requirements, as well as the requirements of the EU Paediatric Regulation, is subject to the EU Penalties Regulation, which enables the European Commission to impose financial penalties on central marketing authorization holders for violation of specific pharmacovigilance and paediatric requirements. National marketing authorization holders may be subject to civil, criminal or administrative sanctions in case of non-compliance with the EU requirements applicable to the manufacturing and marketing of medicinal products.

The EU legal framework applicable to medical devices currently does not provide for a marketing authorization. Instead, medical devices are classified in different risk categories, and different requirements apply based on the classification of a device. The current EU legal framework relies on self-certification and registration (generally for low-risk devices) or on a conformity assessment performed by so-called Notified Bodies (generally for higher-risk devices). Notified Bodies are private entities considered competent by the EU member states to perform conformity assessments. Manufacturers of medical devices must ensure that their products comply with specific requirements set out in the EU Medical Device Directive, the EU Active Implantable Medical Device Directive, or the EU In Vitro Diagnostic Directive, as implemented into national legislation by EU member states, before they place their products on the EU market. Manufacturers must also have appropriate medical device vigilance and quality assurance systems in place, in accordance with EU guidance documents and national requirements.

Enforcement of medical device related requirements remains the responsibility of the competent authorities of EU member states, and non-compliance may result in civil, criminal or administrative sanctions under national laws. Oversight and coordination between competent authorities of EU member states increased after an incident with medical devices manufactured by a French manufacturer became public early in 2012. In September 2012, the European Commission published proposals for two regulations intended to replace the current three EU medical device directives, which if adopted would likely lead to more stringent requirements related to the manufacturing and placing on the EU market of medical devices.

The United States and the EU member states are parties to the Convention on Psychotropic Substances (1971), or the 1971 Convention. In October 2012, the World Health Organization, or the WHO, sent a recommendation to the United Nations Commission on Narcotic Drugs, or the CND, to reschedule gamma-hydroxybutyrate, or GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. In March 2013, the CND voted to reschedule GHB from Schedule IV to Schedule II under the 1971 Convention. While the DEA imposes its own scheduling requirements in the United States under the CSA, the United States is obligated as a signatory to the 1971 Convention to ensure that drug scheduling in the United States is consistent with its obligations under the international treaties. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, the international rescheduling of GHB means that Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements in the EU and certain other

countries than the restrictions currently in place. In the United States, under DEA regulations, the Xyrem finished product is currently classified as a Schedule III controlled substance, with sodium oxybate, classified as a Schedule I controlled substance. Although the HHS has taken the position in the past that the United States would not be required to alter the domestic control of GHB should it be rescheduled to Schedule II under the 1971 Convention, we cannot guarantee that international rescheduling of GHB from Schedule IV to Schedule II will not impact restrictions on Xyrem in the United States. Failure by us or any of our partners, including suppliers, manufacturers and distributors, to comply with such requirements could result in, among other things, additional operating costs to us, delays in shipments outside or into the United States and adverse regulatory actions.

Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act of 2010, or the UK Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or

Table of Contents

decision, secure an improper advantage, or obtain or retain business. Excepted from the FCPA are payments to facilitate or expedite routine government action and bona fide, reasonable reimbursement of expenses. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The UK Bribery Act prohibits giving, offering, or promising bribes to any person, including non-UK government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies which carry on a business or part of a business in the UK may be held liable for bribes given, offered or promised to any person, including non-UK government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the UK Bribery Act there is no exception for facilitation payments. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers may be subject to the FCPA. Recently the Securities and Exchange Commission, or SEC, and the Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures, and internal controls. However, there is no certainty that all employees and third party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU member states may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, that are not considered by the European Commission to provide an adequate level of data protection, including the United States. There are also similar data transfer restrictions in Switzerland. However, there are a number of legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, including, among others, a voluntary U.S. - EU Safe Harbor Framework, a voluntary U.S. - Switzerland Safe Harbor Framework and the EU's set of standard form contractual clauses for the transfer of personal data outside of the EEA. Our United States subsidiary, Jazz Pharmaceuticals, Inc., has certified compliance with the U.S. - EU Safe Harbor Framework and the U.S. - Switzerland Safe Harbor Framework through the U.S. Department of Commerce. A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration and, if adopted, could lead to additional and stricter requirements and penalties in the event of non-compliance.

Additional requirements and restrictions regarding, among other things, the export and importation of products, intellectual property rights, the environment, taxation and work safety apply in individual countries, and

non-compliance with such requirements may result in civil, criminal or administrative sanctions.

Pharmaceutical Pricing and Reimbursement

Our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. In the United States, the federal government provides health insurance for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease through the Medicare program, and many prescription drugs, including some of our products, are covered under Medicare Part D. Medicaid, another program in the United States, is a health insurance program for low-income children, families, pregnant women, and people with disabilities that is jointly funded by the federal and state governments, but administered by the states. In general, state Medicaid programs are required to cover drugs and biologics of manufacturers that have entered into a Medicaid Drug Rebate Agreement, as discussed below, although such drugs and biologics may be subject to prior authorization or other utilization controls. Both Medicare and Medicaid are administered by the Centers for Medicare and Medicaid Services, or CMS.

Table of Contents

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. 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 other products, and third party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

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 impact our ability to sell our products profitably. We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. We anticipate that 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.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS, the federal agency that administers the Medicaid Drug Rebate program, has made draft National Average Drug Acquisition Cost, or NADAC, and draft National Average Retail Price, or NARP, data publicly available on at least a monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid supplemental rebate programs and other governmental pricing programs, and we have obligations to report ASP for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the CMS. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

Federal law also requires that a company that participates in the Medicaid rebate program report ASP information to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Changes affecting the calculation of ASP could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively

impact our results of operations.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, have been reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240. The Bipartisan Budget Act of 2013, Pub. L. No. 113-67, extended the 2% reduction to 2023. If Congress does not take action in the future to modify these sequestrations, Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment provisions, as described below, could have a similar effect.

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.

Table of Contents

These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies, we participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make our product available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, Public Health Service and Coast Guard, that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the Department of Veterans Affairs on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, established by Section 703 of the National Defense Authorization Act for FY 2008 and related regulations, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between Annual Non-FAMP and FCP.

Outside of the United States, political, economic and regulatory developments are also subjecting the healthcare industry to fundamental changes and challenges. Pressure by governments and other stakeholders on prices and reimbursement levels continue to exist. In various European countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. In the EU, our products are marketed through various channels and within different legal frameworks. In certain EU member states, reimbursement for unauthorized products is provided through national named patient or compassionate use programs. Such reimbursement may no longer be available if authorization for named patient or compassionate use programs expire or are terminated. In other EU member states, authorization and reimbursement policies may also delay commercialization of our products, or may adversely affect our ability to sell our products on a profitable basis. For example, we are currently engaged in pricing and reimbursement submissions in preparation for our planned launch of Defitelio in several EU countries in 2014. After initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced member states.

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 in the EU.

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 our business. We own a portfolio of United States and non-U.S. patents and patent applications and have licensed rights to a number of issued patents and patent applications. Our owned and licensed patents and patent applications cover certain 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. 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® (sodium oxybate) oral solution. Xyrem is covered by fourteen U.S. patents that expire at various times from December 2019 to June 2024. These patents relate to Xyrem's stable and microbially resistant formulation, its manufacturing process, and its method of use, including its restricted distribution system. Eleven of these fourteen patents are listed in the Orange Book. Of the patents listed in the Orange Book, three are formulation patents, two of which expire in December 2019 and one expires July 2020; six are method of use patents covering the distribution of Xyrem, three expire in June 2024 and three expire in December 2022; two are method of use patents covering Xyrem's use in narcolepsy, both of which expire in December 2019; and two are method of treatment patents expiring in December 2019. Two process patents for methods for making the formulation and a distribution system patent are not listed in the Orange Book also relate to Xyrem and expire in December 2019 and June 2024,

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Table of Contents

respectively. A Xyrem formulation patent has issued in multiple non-U.S. countries and will expire in December 2019. This formulation patent is currently pending in two additional countries. In addition to our issued patents, we have patent applications relating to Xyrem pending in the United States. The patent laws of non-U.S. countries differ from those in United States, and the degree of protection afforded by non-U.S. patents may be different from the protection offered by U.S. patents. Three companies have notified us that they have filed ANDAs with the FDA seeking FDA approval to market a generic version of Xyrem. We initiated lawsuits against each of these companies, and the litigation proceedings are ongoing. See the risk factor in Item 1A entitled "We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products."

- Defitelio® (defibrotide). We have a portfolio of U.S. and non-U.S. patents and patent applications relating to various compositions of defibrotide and methods of use, which will expire at various times between April 2017 and June 2032. One patent that issued in the United States and several other countries covers the method for determining the biological activity of defibrotide. This patent expires in November 2022 in most countries.
- Prialt® (ziconotide) intrathecal infusion. Prialt is covered by a portfolio of three U.S. patents for a formulation and methods of use. Two of these patents are listed in the Orange Book. These patents will expire from June 2015 to December 2016. Also, there are four non-U.S. patents that will expire in June 2016. There are also eight additional U.S. patents issued on a formulation containing Prialt and other active ingredients and methods for their use as well as some pending patent applications relating to methods of use that will expire in October 2024. One of the eight additional U.S. patents is listed in the Orange Book. We also have equivalent non-U.S. applications to these additional patents pending in Canada and Japan that, if issued, would expire in October 2024.
- FazaClo® HD (clozapine, USP) and FazaClo® LD (clozapine, USP) Orally Disintegrating Tablets. FazaClo HD and FazaClo LD are covered by three U.S. formulation patents. All are licensed by us, one from Ethypharm, expiring in December 2017, and the other two from CIMA, expiring in April 2018. The three patents are listed in the Orange Book. The patentability of the two patents licensed from CIMA was confirmed in re-examination proceedings at the USPTO. As part of its settlement with Teva in 2011, Azur Pharma granted a sublicense to an affiliate of Teva of its rights to have manufactured, market and sell a generic version of both FazaClo HD and FazaClo LD. The sublicenses for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events.
- Versacloz™ (clozapine) oral suspension. Versacloz is covered by a U.S. formulation patent and a pending U.S. patent application that we license from Douglas Pharmaceuticals. The patent expires in May 2028.
- Asparec™ (mPEG-r-crisantaspase) is not yet covered by any issued U.S. patents. We have rights to patent applications for Asparec pending in the United States and many other countries that, if issued, would expire in July 2030, subject to any patent term extension.
- JZP-110. JZP-110 and its associated uses are claimed in multiple U.S. and non-U.S. patents and applications. We acquired rights to JZP-110 from Aerial in January 2014, including rights to the patent portfolio, other than in certain jurisdictions in Asia where SK retains rights. The U.S. composition of matter patents begin to expire in September 2015 and the methods of use patents covering treatment for narcolepsy will expire in August 2027, subject to any patent term extension.
- Erwinaze® (asparaginase Erwinia chrysanthemi) has no patent protection, and we rely on trade secrets and other unpatented proprietary information to protect our commercial position, which we may be unable to do.

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.

As reflected above, generic manufacturers have challenged our patents covering Xyrem, FazaClo HD and FazaClo LD. Azur Pharma settled a suit against Teva relating to FazaClo LD and FazaClo HD. Other suits are ongoing. See Item 3. “Legal Proceedings.” We cannot assure you that our patents will not be further 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.

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

Table of Contents

patentable or infringes 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 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 have approximately 70 registered trademarks and service marks in the United States and over 300 registered trademarks and service marks in other jurisdictions. We also have 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. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Failure to obtain or maintain patent and trade secret protection, for any reason, could have a material adverse effect on our business.

Employees

As of February 19, 2014, we had approximately 810 employees worldwide. We consider our employee relations to be good.

Environment, Health and Safety

Our manufacturing of active pharmaceutical ingredients in Italy involves the controlled storage, use and disposal of chemicals and solvents. We are subject to Italian laws, which implement EU directives and regulations governing the use, transportation, treatment, storage, handling and disposal of solid and hazardous materials, wastewater discharges and air emissions. We have obtained certification under the UNI EN ISO 14001 Standard for our environmental management system and have an Eco-management and Audit Scheme (EMAS) for our plant in Italy. Our environmental policy is designed to comply with current regulations on environmental protection, to provide for continuous improvement of our manufacturing performance, to protect our employees' health, to protect the safety of people working at our location in Italy and to respect the safety of people living close to our plant and in the surrounding community.

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc is a public limited company formed under the laws of Ireland (registered number 399192) and is the ultimate parent company to the Jazz Pharmaceuticals group of companies. Jazz Pharmaceuticals plc was originally formed as a private limited liability company in March 2005 under the name Azur Pharma Limited, and was subsequently re-registered as a public limited company under the name Azur Pharma Public Limited Company in October 2011. On January 18, 2012, the business of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in the Azur Merger in connection with which Azur Pharma was re-named Jazz Pharmaceuticals plc and we became the parent company of and successor to Jazz Pharmaceuticals, Inc. Jazz Pharmaceuticals, Inc. was treated as the acquiring

company in the Azur Merger, for accounting purposes and the transaction was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations. Our predecessor, Jazz Pharmaceuticals, Inc., was originally incorporated in California in March 2003 and was reincorporated in Delaware in January 2004. In the Azur 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," as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger.

Our principal offices are located at One Burlington Road, Dublin 4, Ireland, and our telephone number is 353-1-634-7800. We have offices in Palo Alto, California and Philadelphia, Pennsylvania in the United States and non-U.S. offices in Oxford, United Kingdom, Lyon, France, Villa Guardia (Como), Italy, Zug, Switzerland and elsewhere in Europe.

Table of Contents

Our website address is 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 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 Exchange Act, electronically with the SEC. We make available on our website at 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.

Item 1A. Risk Factors

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

Risks Relating to Xyrem and the Significant Impact of Xyrem Sales

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

Xyrem® is our largest selling product and our financial results are significantly influenced by sales of Xyrem, which accounted for 65.8% of our net product sales for the year ended December 31, 2013 and 65.2% of our net product sales for the year ended December 31, 2012. Our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2011 to 2012 and from 2012 to 2013, we cannot assure you that we can maintain sales of Xyrem at or near current levels, or that Xyrem sales will continue to grow. We have periodically increased the price of Xyrem, most recently in February 2014, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

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

- the potential introduction of a generic version of Xyrem;
- changed or increased regulatory restrictions, including changes to our risk management program and the terms of the final REMS documents for Xyrem, and the pressure to develop a single shared system REMS with potential generic competitors, as discussed in more detail in the risk factors below;
- our manufacturing partners' ability to obtain sufficient quota from the DEA to satisfy our needs for Xyrem;
- any supply, manufacturing or distribution problems arising with any of our manufacturing and distribution partners, all of whom are sole source providers for us;
- the availability of reimbursement from third party payors;
- changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement and coverage by federal healthcare programs;
- continued acceptance of Xyrem as safe and effective by physicians and patients, even in the face of negative publicity that surfaces from time to time; and
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem.

These and the other risks described below related to Xyrem product sales and protection of our proprietary rights could have a material adverse effect on our ability to maintain or increase sales of Xyrem.

If sales of Xyrem were to decline significantly, we might need to reduce our operating expenses or to seek to raise additional funds, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects, or we might not be able to acquire, in-license or develop new products in the future to grow our business.

Table of Contents

If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected. Although Xyrem is covered by patents covering its formulation, distribution system and method of use, three third parties have filed ANDAs seeking FDA approval of generic versions of Xyrem, and additional third parties may also seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch generic competition to Xyrem at risk of potentially being held liable for damages for patent infringement.

In October 2010, December 2012 and November 2013 we received a Paragraph IV Certification from each of Roxane, Amneal and Par, respectively, that each had filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the Orange-Book-listed patents relating to Xyrem. We have sued Roxane, Amneal and Par seeking to prevent them from introducing a generic version of Xyrem that would infringe our patents, but we cannot assure you that any of the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. Additional ANDAs could also be filed requesting approval to market generic versions of Xyrem. If an ANDA is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Although no trial date has been set in any of the ANDA suits, we anticipate that trial in the Roxane case could occur as early as late in the fourth quarter of 2014. However, the actual timing of events may be significantly earlier or later than contemplated by current scheduling orders, and we cannot predict the timing or outcome of events in this or the other ANDA litigations. In accordance with the Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA had been stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification, but that stay has expired. We do not know the status of Roxane's ANDA and cannot predict what actions the FDA or Roxane may take with respect to Roxane's ANDA. With the expiration of the 30-month stay, if Roxane's ANDA is approved by the FDA, Roxane may seek to launch a generic version of Xyrem prior to a District Court, or potential appellate court, decision in our ongoing patent litigation. While, in the event of such commercialization, Roxane would be liable to us for damages in the event we ultimately prevail in the patent litigation, we expect that the introduction of generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects. See the next risk factor in this Item 1A entitled "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

A generic manufacturer would need to obtain quota from the DEA in order to manufacture both the active pharmaceutical ingredient and the finished product for a generic version of Xyrem. The DEA publishes an annual aggregate quota for the active pharmaceutical ingredient of Xyrem, and our supplier is required to request and justify allocation of sufficient annual manufacturing quota as well as additional manufacturing quota if needed throughout the year. Until 2011, our active pharmaceutical ingredient supplier obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for each of 2012, 2013 and 2014, our supplier was allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. Consequently, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In addition, our supplier was initially allocated only a portion of the quota it requested for 2013 to make the active pharmaceutical ingredient of Xyrem. Similarly, our finished product manufacturer for Xyrem was initially allocated only a portion of the quota it requested to make finished product. As a result, in 2013, both our active pharmaceutical ingredient supplier and our finished product manufacturer had to request and justify increased quotas from the DEA. For 2014, both our active pharmaceutical ingredient supplier and finished product manufacturer have been allocated most, but not all, of their respective requested quotas and may need to request and justify increased quotas from the DEA in 2014. If we and our supplier and manufacturer cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

After any introduction of a generic competitor, a significant percentage of the prescriptions written for Xyrem may be filled with the generic version, resulting in a loss in sales of Xyrem. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. We expect that generic competition for Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Table of Contents

The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management and controlled distribution system, which we refer to as the Xyrem Risk Management Program, that was implemented at the time Xyrem was approved, which includes parts of the Xyrem Success Program, to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. Our Xyrem Risk Management Program includes a number of elements including patient and physician education, a database of information so that we may track and report certain information, and the use of a single central pharmacy to distribute Xyrem. Elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA. The Xyrem Risk Management Program, however, is not in the form that is now required for REMS documents. The FDAAA requires that deemed REMS and related documents be updated to comply with the current requirements for REMS documents. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA has notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiate dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we will initiate dispute resolution procedures with the FDA by the end of February 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

Section 505-1(i)(1) of the FDCA generally provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same elements as the referenced drug, such as a medication guide, a patient package insert and other ETASU, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and permit the ANDA holder to submit separate but comparable REMS documents if the FDA either determines that the burden of creating a single shared system outweighs its benefit, or if the ANDA applicant certifies that it has been unable to obtain a license to any aspects of the REMS for the referenced drug product that are covered by a patent or a trade secret. The FDCA provides that the FDA may seek to negotiate a license between the ANDA sponsor and the sponsor of the listed product before granting a waiver of the single shared system requirement. Accordingly, we expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with respect to licensing or sharing our REMS, or the FDA's response to a certification that a third party has been unable to obtain a license.

In the FDA's December 2012 response denying a Citizen Petition that we filed in July 2012, the FDA stated that when an NDA holder has a deemed REMS, the FDA directs the ANDA applicant(s) to work with the NDA holder to create a single shared system to implement the ETASU that will be approved as a final REMS. More broadly, the FDA has stated that it expects the negotiation of a single shared REMS between an NDA holder and ANDA applicants to proceed concurrently with the FDA's review of ANDA applications. The FDA has further stated that it typically

monitors the progress of industry working groups attempting to develop shared REMS systems, and that it has acted to help ensure that sponsors were cooperating and that there were no obstacles to developing a single shared system. In January 2014, the FDA held an initial meeting with us and current Xyrem ANDA applicants to facilitate the development of a single shared system REMS. We cannot predict the timing, outcome or impact on our business of discussions with the FDA and/or any ANDA applicant with respect to the potential creation of a single shared system REMS for Xyrem (sodium oxybate), including the impact of the ongoing process with respect to potential modifications to the Xyrem deemed REMS as discussed above, or the impact of any single shared system REMS on our ongoing litigation with each of the ANDA applicants. See the risk factor in this Item 1A entitled “We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products.”

If we do not develop a single shared system REMS or license or share our REMS with a generic competitor within a time frame or on terms that the FDA considers acceptable, the FDA may assert that its waiver authority permits it to allow the generic competitor to market a generic drug with a REMS that does not include the same elements that are in our deemed

Table of Contents

REMS or, when Xyrem REMS documents are approved, with a separate REMS that includes different, but comparable, ETASU.

The FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular to whether REMS may be deliberately being used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner. The FDCA further states that a REMS shall not be used by an NDA holder to block or delay generic drugs from entering the market. Two of the ANDA applicants have asserted that our patents covering the distribution system for Xyrem should not have been listed in the Orange Book, and that the Xyrem REMS is blocking competition. We cannot predict the outcome of these claims in the ongoing litigation, or the impact of any similar claims that may be made in the future.

It is also possible that the FDA may take the position that a potential generic competitor does not need a REMS that has the same ETASU as our Xyrem deemed REMS in order to obtain approval of its ANDA. In the denial of our Citizen Petition described above, the FDA stated that if the FDA determines that an ANDA may be ready for approval before final approval of the REMS of a sponsor holding a deemed REMS, the FDA will direct the ANDA applicant to submit a proposed risk management plan with ETASU that are comparable to the ETASU that are approved for the referenced drug in order to have adequate risk management elements in place for the ANDA until the final REMS is approved. The legal basis for this position is uncertain. However, it is possible that the FDA may rely on this position as a basis to grant approval of an ANDA with a risk management plan rather than a final REMS. The 30-month stay of FDA approval of Roxane's ANDA expired on April 18, 2013, and we have not yet received approval of final REMS documents for Xyrem. Accordingly, it is possible that, consistent with the position that the FDA articulated in its denial of our Citizen Petition, the FDA could approve Roxane's ANDA with a risk management plan that is separate from our Xyrem deemed REMS, rather than with a final REMS or a shared REMS for both the generic and Xyrem. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects. See the risk factor in this Item 1A entitled "We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products."

Currently, our Xyrem deemed REMS requires that all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under our program is cumbersome. While we have an exclusive agreement with the central pharmacy for Xyrem, ESSDS, through June 2015, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem and our sales would be adversely affected. If we change our central pharmacy, new contracts might be required with government and other insurers who pay for Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA and would also need to implement the particular processes, procedures and activities necessary to distribute Xyrem under our Xyrem Risk Management Program or any REMS that we are subject to in the future. Transitioning to a new pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the United States, result in additional costs and expenses for us, and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

As required by the FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to the FDA and could result in the FDA requiring changes to the Xyrem label or taking or requiring us to take other actions that could have an adverse effect on Xyrem's commercial success. Our Xyrem deemed REMS includes unique features that provide more extensive information about adverse events, including deaths, than is generally available for other products that are not subject to similar risk management programs. For example, in April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us, as required. We reported these cases to the FDA when we discovered them, investigated the related data from ESSDS as well as additional data we gathered, and submitted an

analysis of the data to the FDA. In October 2011, we received a warning letter from the FDA regarding certain aspects of our adverse event reporting system for Xyrem and drug safety procedures related to the deaths that we discovered in April 2011 which had not been reported. We completed the actions and submitted the data required to address the observations in the 2011 warning letter and arising from a subsequent inspection. In August 2013, we received a close-out letter from the FDA. Although we believe that we have taken appropriate corrective action to address the issues that led to the failure to report certain patient deaths, and that the FDA will not require additional investigation or corrective action, there can be no assurance that, despite the close-out letter, the FDA will not require us to take additional actions with respect to adverse event reporting or other matters. Such actions may be costly or time consuming and/or negatively affect the commercial success of Xyrem.

Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the FDA's or any other regulatory authority's satisfaction could result in such regulatory authorities taking actions in the future, which could have a material and adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth

Table of Contents

prospects. See also the risk factor in this Item 1A entitled "We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products." The FDA has required that Xyrem's label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. In addition, Xyrem's FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. We cannot predict whether the FDA will require additional warnings, including boxed warnings, to be included on Xyrem's label. Warnings in the Xyrem label and any limitations on our ability to advertise and promote Xyrem may have affected, and could in the future negatively affect, Xyrem sales and therefore our business, financial condition, results of operations and growth prospects.

Risks Relating to Our Business

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

In addition to Xyrem, we are commercializing a portfolio of products, including our other key products Erwinaze® (asparaginase Erwinia chrysanthemi) (called Erwinase® in markets outside the United States) and Prialt® (ziconotide) intrathecal infusion, and we intend to launch Defitelio in selected countries in the EU during 2014. See the discussion regarding the planned launch of Defitelio in the risk factor in this Item 1A entitled "We may not be able to successfully launch and market Defitelio in the EU, or obtain marketing approval in other countries, including the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects."

Erwinaze, a biologic product, is used in conjunction with chemotherapy to treat patients with ALL with hypersensitivity to E. coli-derived asparaginase. Erwinaze is exclusively licensed to us, and manufactured for us, by PHE, and was approved by the FDA under a BLA and launched in the U.S. market in November 2011. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere.

Erwinaze represents an important part of our strategy to grow sales of our existing products. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of challenges, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to E. coli-derived asparaginase within that population, our ability to obtain approval for the intravenous administration of Erwinaze in the United States, our ability to obtain data on the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase, as well as our need to apply for and receive marketing authorizations, through the EU's mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries. Another significant challenge to maintenance of current sales level and continued growth is our need to ensure sufficient supply of Erwinaze on a timely basis. See the discussion regarding Erwinaze supply issues in the risk factor in this Item 1A entitled "We depend on single source suppliers and manufacturers for each of our products, product candidates and their active pharmaceutical ingredients. The loss of any of these suppliers or manufacturers, or delays or problems in the supply or manufacture of our products for commercial sale or our product candidates for use in our clinical trials, could materially and adversely affect our business, financial condition, results of operations and growth prospects."

We also face numerous other risks that may impact Erwinaze sales, including regulatory risks, the development of new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL, the development of new treatment protocols for ALL that may not include asparaginase-containing regimens, difficulties with obtaining and maintaining favorable pricing and reimbursement arrangements and potential competition from biosimilar products. In addition, if we fail to comply with our obligations under our agreement with PHE and lose exclusive rights to Erwinaze, or otherwise fail to maintain and grow sales of Erwinaze, our growth prospects could be negatively

affected.

Prialt, an intrathecally administered infusion of ziconotide, was approved by the FDA in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. We face many challenges in maintaining and growing sales of Prialt, including acceptance of intrathecal administration by patients and physicians and challenges for physicians with timely reimbursement for use of Prialt. In addition, the FDA has required that the label for Prialt include a boxed warning regarding the risk of psychiatric symptoms and neurological impairment. We cannot predict whether the FDA will require additional warnings, or place any additional limitations on our ability to advertise and promote Prialt, which could negatively impact Prialt sales. In May 2013, we completed the roll-out of the NAVIGATOR Reimbursement and Access Program™, a centralized program that provides a single point of access to Prialt, and transitioned to

Table of Contents

a centralized distribution system for Prialt through an exclusive distributor and pharmacy. In connection with the implementation of the new distribution system, we experienced some fluctuation in product sales.

Failure to maintain or increase prescriptions and revenue from sales of our products, including Erwinaze and Prialt, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may choose to increase the price of our products, and we cannot assure you that price adjustments will not negatively affect our sales volumes. In addition, sales of Erwinaze may fluctuate significantly from quarter to quarter, depending on the number of patients receiving treatment, the availability of supply to meet the demand for the product, the dosing requirements of treated patients and other factors. The market price of our ordinary shares may decline if the sales of our products do not continue or grow at the rates anticipated by financial analysts or investors. In addition, if we fail to obtain approvals for certain of our products in new indications or formulations, we will be unable to commercialize our products in new indications or formulations, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be able to successfully launch and market Defitelio in the EU, or obtain marketing approval in other countries, including the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We acquired Defitelio as a result of the Gentium Acquisition. In October 2013, the European Commission granted marketing authorization for Defitelio for the treatment of severe VOD in adults and children undergoing HSCT therapy. We plan to launch Defitelio in the EU during 2014, and expect to begin these efforts in selected countries in the first half of 2014 after Defitelio's patient registry has been established and is open for recruitment. Opening of the Defitelio patient registry is subject to the receipt of a positive recommendation by the PRAC on the patient registry design. We do not know whether we will receive positive recommendations or whether the PRAC will request additional information or require modifications to our proposed design. Any delay in receiving positive recommendations on Defitelio's patient registry design would negatively affect the timing of the launch of Defitelio and anticipated revenue from Defitelio in 2014 and could negatively affect our growth prospects.

We are also making pricing and reimbursement submissions with respect to Defitelio in those EU countries where pricing and reimbursement approvals are required for launch. We have not yet obtained pricing and reimbursement guidelines in any of those countries and therefore cannot predict the timing of Defitelio's launch in those countries. If we experience delays and unforeseen difficulties in obtaining pricing and reimbursement approvals for Defitelio in any of these countries, the planned launch would be delayed and our anticipated revenue from Defitelio in 2014 and our growth prospects could be negatively affected. We have developed estimates of anticipated pricing for these countries, which are based on our research and understanding of the product and target market. However, due to efforts to provide for containment of health care costs, one or more EU countries may not support our estimated level of governmental pricing and reimbursement for Defitelio, particularly in light of the budget crises faced by a number of countries in the EU, which would negatively impact anticipated revenue from Defitelio. In addition, until 2008, Gentium sold forms of defibrotide in Italy to treat vascular disease with risk of thrombosis at a price that was substantially lower than the anticipated commercial price for Defitelio. The regulators in Italy may use the price of the past sales by Gentium as a reference price for Defitelio, which may make it more difficult for us to justify our requested higher commercial price, which would also negatively impact anticipated revenue from Defitelio in Italy. Furthermore, after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced EU countries. If any of these events occurs, our anticipated revenue from Defitelio would be negatively affected.

We also cannot predict the level of sales of Defitelio in the EU after its planned launch. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from Defitelio would be negatively affected which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

address issues raised by the FDA. We are currently assessing what we believe would be the optimal path for potential approval of defibrotide in the United States, which may include filing a new application with existing clinical data or generating additional clinical data before a new application is ready for submission and FDA review. We are also assessing the potential for approval of defibrotide in other countries and for additional development of defibrotide in other indications. We cannot know when, if ever, defibrotide will be approved in the United States or in any other country or under what circumstances, and what, if any, additional clinical or other development activities will be required in order to potentially obtain such regulatory approval and the cost associated with any such activities. If we fail to obtain approval for defibrotide in other countries or for new indications, our anticipated revenue from defibrotide and our growth prospects would be negatively affected.

Table of Contents

While we have limited revenue from sales of defibrotide on a named patient basis, we cannot predict whether historical revenues from named patient programs will continue, whether we will be able to continue to distribute defibrotide on a named patient basis, or whether the planned launch of Defitelio in the EU will generate higher revenue in the applicable EU countries than revenues generated from sales on a named patient basis.

Defibrotide is currently available in approximately 40 countries on a named patient basis and is being distributed to patients diagnosed with severe VOD in the United States through an expanded access program pursuant to a treatment IND protocol. In certain EU countries, reimbursement for products that have not yet received marketing authorization is provided through national named patient or compassionate use programs. Such reimbursement may cease to be available if authorization for named patient or compassionate use programs expires or is terminated. While Gentium has generated and we continue to generate revenue on the distribution of defibrotide through named patient programs, we cannot predict whether historical revenues from these programs will continue, whether we will be able to continue to distribute defibrotide on a named patient basis in these countries, or whether the planned launch of Defitelio in the EU will generate higher revenue in the applicable EU countries than revenues historically generated from sales on a named patient basis. Any failure to maintain revenues from sales of defibrotide on a named patient basis and/or to generate higher revenues following the planned launched of Defitelio would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredient and the finished product in sufficient quantities that meet detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. If we or any of our third party suppliers or manufacturers encounter these or any other manufacturing, quality or compliance difficulties with respect to any of our products, we may be unable to meet the commercial demand for such products, which could adversely affect our business, financial condition, results of operations and growth prospects.

Other than the manufacturing plant in Italy where we produce some active pharmaceutical ingredients, including the defibrotide drug substance, we do not currently have our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. The availability of our products for commercial sale depends upon our ability to procure the ingredients, raw materials, packaging materials and finished products we need from third parties. In part due to the limited market size for our products and product candidates, we have entered into supply and manufacturing agreements with suppliers and manufacturers, each of which is currently our single source for each of our marketed products and for the active pharmaceutical ingredients used in some of these products.

We maintain limited inventories of certain of our products, including Xyrem and Erwinaze, as well as the ingredients or raw materials used to make our products. Our limited inventory puts us at significant risk of not being able to meet product demand. During 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. In the past, we have experienced a disruption of supply of Erwinase in the European market due to manufacturing challenges, including shortages related to the failure of a batch to meet certain specifications in 2013, and we may experience similar or other manufacturing challenges in the future. If our continued efforts to avoid supply shortages are not successful, we could experience Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. Other difficulties or delays in production, such as those described elsewhere in this risk factor, could also result in supply interruptions in the future. If, for any reason, our suppliers and manufacturers,

including any new suppliers, do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

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

Table of Contents

finished product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA or similar international regulatory body approval of a new supplier or manufacturer.

Our current supplier of sodium oxybate, Siegfried was approved by the FDA in late 2011 and became our sole supplier in 2012. We expect that Siegfried will continue to be our sole supplier of sodium oxybate for the foreseeable future, and we cannot assure you that Siegfried can or will continue to supply on a timely basis, or at all, sufficient quantities of active pharmaceutical ingredient to enable the manufacture of the quantities of Xyrem that we need.

Erwinaze is licensed to us, and manufactured for us, by PHE, which is our sole supplier for Erwinaze. The FDA's approval of the BLA for Erwinaze includes a number of post-marketing commitments related to the manufacture of Erwinaze by us and the PHE. Inability by PHE to comply with regulatory requirements, including follow through on manufacturing-related post-marketing commitments that are part of the BLA approval and monitored by the FDA, could adversely affect its ability to supply Erwinaze to us and could result in FDA approval being revoked or product recalls, either of which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. In addition, if the FDA or any non-U.S. regulatory authority mandates any changes to the specifications for Erwinaze, we may face challenges having product produced to meet such specifications, and PHE may charge us more to supply Erwinaze meeting such specifications, which may result in additional costs to us and may decrease any profit we would otherwise achieve with Erwinaze.

We cannot assure you that PHE will be able to continue to supply our ongoing commercial needs of Erwinaze in a timely manner, or at all, especially if our demand for product continues to increase. If PHE experiences a disruption in supply or capacity constraints as a result of increased demand or otherwise, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach by PHE or the cessation of PHE's business. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming, might not be successful and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinaze. While we continue to work with PHE to evaluate potential steps to increase the supply of Erwinaze over the longer term to address expected growing worldwide demand, our ability to increase sales of Erwinaze may be limited by our ability to obtain an increased supply of the product. Any inability of PHE to supply sufficient quantities of Erwinaze to meet commercial needs at historic levels or higher could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are in the process of changing our supplier for ziconotide, the active pharmaceutical ingredient in Prialt, and have commenced the transfer to the new supplier. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for finished product for a number of years, which we expect to be sufficient time to complete the transfer to the new supplier. In addition, our new manufacturer of finished product was approved by the FDA in December 2012 and started to supply us with Prialt finished product in January 2014. There can be no assurance that the new supplier of ziconotide will be approved by the FDA or non-U.S. regulatory authorities or that the new manufacturer of Prialt finished product will be able to meet our demand in the future. Any failure to obtain and maintain sufficient commercial supplies could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

For FazaClo HD, FazaClo LD and Versacloz, we have single sources of supply for both the active pharmaceutical ingredient and finished product, and should it become necessary to change suppliers, the process could take two years or longer.

We are in the process of identifying a supplier for JZP-110. In order to commence our planned Phase 3 clinical programs, we need to have sufficient quantity of JZP-110 manufactured. In addition, we rely on Concert to transfer its manufacturing methods to us and our contract manufacturers to produce sufficient quantity of JZP-386 required for our planned first study in humans. We believe that we will be able to obtain sufficient supplies of JZP-110 and JZP-386 before the commencement of the applicable planned clinical trials. Any delay in receiving sufficient supplies of JZP-110 or JZP-386 for our planned studies could negatively impact our development programs.

The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem, sodium oxybate, is a Schedule I controlled substance, our supplier of sodium oxybate, as well as our finished product manufacturer, must each obtain separate DEA quotas in order to supply us with sodium oxybate and Xyrem. Since the DEA typically grants quotas on an annual basis, our sodium oxybate supplier and Xyrem manufacturer are required to request and justify allocation of sufficient annual DEA quotas as well as additional DEA quotas if our commercial or clinical requirements exceed the allocated quotas throughout the year. In the past, we have had to engage in lengthy efforts to obtain the needed quotas after the original annual quotas had first been allocated. For example, in 2013, our supplier was initially allocated only a portion of the quota it requested to make the active pharmaceutical ingredient of Xyrem. Similarly, our finished product manufacturer for Xyrem was initially allocated only a portion of the quota it requested to make finished product. As a result, in 2013, both our active pharmaceutical ingredient supplier and our finished product manufacturer had to request and justify increased quotas from the

Table of Contents

DEA for 2013. For 2014, both our active pharmaceutical ingredient supplier and finished product manufacturer have been allocated most, but not all, of their respective requested quotas and may need to request and justify increased quotas from the DEA later in 2014. If we and our supplier and manufacturer cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

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

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products or ingredients to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA's current cGMP requirements. In complying with cGMP requirements, our suppliers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our products and product candidates meet applicable specifications and other requirements for product safety, efficacy and quality. DEA regulations also govern facilities where controlled substances such as sodium oxybate, Xyrem's active pharmaceutical ingredient, are manufactured. Manufacturing facilities of our suppliers have been and are subject to periodic unannounced inspection by the FDA, the DEA and other regulatory authorities, including state authorities and similar authorities in non-U.S. jurisdictions. For example, the FDA inspected the PHE facility where Erwinaze is manufactured in 2013 and will do so again in the future. Failure to comply with applicable legal requirements subjects the suppliers to possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need.

Our ability to develop and deliver products in a timely and competitive manner depends on our third party suppliers and manufacturers being able to continue to meet our ongoing commercial needs. Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products, or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects.

We may not realize the anticipated financial and strategic benefits from the recent Gentium Acquisition or be able to successfully integrate the acquired business.

After the close of the tender offer, we have acquired approximately 98% of the outstanding voting securities of Gentium for an aggregate acquisition cost of approximately $993 million. The Gentium Acquisition creates numerous uncertainties and risks, and has required, and will continue to require, significant efforts and expenditures, including with respect to integrating the acquired business with our historical business. We may encounter unexpected difficulties, or incur unexpected costs, in connection with our transition activities and integration efforts, which include:

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

- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures;
- any unanticipated liabilities for activities of or related to Gentium or its operations, products or product candidates; and
- the challenges and risks associated with Gentium not being our wholly owned subsidiary, including needing to consider the rights of, and duties owed to, the minority shareholders of Gentium under Italian law when making future decisions that might impact Gentium, its business or operations.

Table of Contents

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

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

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

We are headquartered in Dublin, Ireland and have multiple offices in the United States, the United Kingdom, Italy and other countries in Europe. Our headcount has grown from approximately 260 employees at the end of 2011 to approximately 810 in February 2014. This includes employees in fourteen countries in North America and Europe, a European commercial presence, and a complex distribution network for products in Europe and additional territories. In addition, we may expand our international operations into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations and financial condition, including, among other things:

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

Failure to effectively manage these risks could have a material adverse effect on our business. For example, although the European Commission granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe VOD in adults and children undergoing HSCT therapy in October 2013, before launching Defitelio in certain EU countries, country-specific pricing and reimbursement approvals must be obtained. If we experience delays or unforeseen difficulties in obtaining pricing and reimbursement for Defitelio in any of these countries, the planned launch would be delayed and our anticipated revenue from Defitelio in 2014 could be negatively affected.

In recent years, the global economy has been impacted by the effects of an ongoing global financial crisis, including the European sovereign debt crisis, which has caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. In addition, we expect to continue to grow our product sales in Europe, including through our planned launch of Defitelio. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe and the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, has led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively

impact our revenues and profitability.

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

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

- 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;

Table of Contents

- the prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and
- the availability of adequate reimbursement by third parties.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies, including generic versions of our products, could materially and adversely affect our business, financial condition, results of operations and growth prospects. For example, from time to time, there is negative publicity about illicit GHB and its effects, including with respect to illegal use, overdoses, serious injury and death. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Patients, physicians and regulators may therefore view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of its connection to GHB. Xyrem's label includes information about adverse events from GHB.

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

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

We have made significant investments into expanding our product development pipeline and expect to substantially increase our research and development organization to pursue targeted development activities in 2014 and beyond. Significant clinical, development and financial resources will be required to progress product candidates to obtain necessary regulatory approvals and to develop them into commercially viable products. We have a number of product candidates under development, including JZP-110 and JZP-386 in the sleep area and Asparec and Leukotac in the hematology and oncology area. As a condition to regulatory approval, each drug product candidate must undergo extensive and expensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. Clinical testing can take many years to complete and failure can occur any time during the clinical trial process. If a product candidate fails at any stage of development, it will not receive regulatory approval, we will not be able to commercialize it, and we will not receive any return on our investment from that product candidate.

Our development pipeline projects include not only new product candidates, but also projects involving line extensions for existing products and the generation of additional clinical data for existing products. Specifically, in the hematology and oncology therapeutic area, we have ongoing projects involving Erwinaze and are evaluating potential development of defibrotide in indications in addition to the treatment of severe VOD in adults and children undergoing HSCT therapy. These development efforts may not be successful, and any adverse events or other information generated during the course of our studies related to existing products could result in action by the FDA or any non-U.S. regulatory agency, which may restrict our ability to sell, or sales of, currently marketed products, or such events or other information could otherwise have a material adverse effect on a related commercial product. Any failure or delay in completing clinical trials for line extensions or the generation of additional clinical data could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

Although Defitelio has been approved in Europe, a prior NDA submission by Gentium for defibrotide in the United States was voluntarily withdrawn from consideration before an FDA decision on accepting the application for filing,

based on issues raised by the FDA. We are currently assessing what we believe would be the optimal path for potential approval of defibrotide in the United States, which may include filing a new application with existing clinical data or generating additional clinical data before a new application is ready for submission and FDA review. We cannot know when, if ever, defibrotide will be approved in the United States or under what circumstances, and what, if any, additional clinical or other development activities will be required in order to potentially obtain regulatory approval in the United States and the cost associated with

Table of Contents

any such activities. These development efforts may not be successful, which could adversely affect our potential future revenue from defibrotide and our growth prospects.

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

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

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

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

We are currently undertaking a Phase 1 clinical trial of Asparec in Europe. Under our license agreement with Alizé, under which we obtained rights to develop and commercialize Asparec, we are subject to contractual obligations to meet certain development milestones within the applicable timeframes provided under the license agreement. Our ability to meet some of these milestones is uncertain, and depends upon a number of factors, including our ability to obtain clinical material, to recruit study centers with appropriate expertise and patient populations and to develop a clinical program meeting the development requirements of both the FDA and European regulatory authorities in a timely fashion. If our development activities are delayed and we fail to meet our licensing obligations to Alizé, we may lose our rights to develop and commercialize Asparec. We submitted an IND to conduct studies relating to Asparec to the FDA in November 2012, and received FDA confirmation in December 2012 that we may proceed with the initial clinical study. We are working with investigators to initiate our first study of Asparec in children.

In June 2013, the FDA granted Fast Track designation to the investigation of Asparec for ALL. Defibrotide has also been granted Fast Track designation by the FDA to treat severe VOD. The Fast Track program is designed to enable more frequent interactions with the FDA during drug development and to expedite new drug candidate review. Although we have obtained Fast Track designation from the FDA for Asparec and defibrotide, receipt of Fast Track designation may not result in a faster development process, review or approval compared to drugs considered for

approval under conventional FDA procedures, and Fast Track designation may be withdrawn by the FDA at any time. In addition, Fast Track designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that either Asparec or defibrotide will receive any regulatory approvals.

Table of Contents

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

We rely on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as a high priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and non-U.S. regulatory agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the United States. Our failure, or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

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

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

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

We cannot assure you that we will be able to successfully manage these risks or other anticipated and unanticipated problems in connection with an acquisition or in-licensing. We may not be able to realize the anticipated benefits of any acquisition or in-licensing for a variety of reasons, including the possibility that a product candidate proves not to be safe or effective in later clinical trials, a product fails to reach its forecasted commercial potential or the integration of a product or product candidate gives rise to unforeseen difficulties and expenditures. Any failure in identifying and managing these risks and uncertainties effectively would have a material adverse effect on our business.

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

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

Table of Contents

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

In 2012 we added Erwinaze, as well as other smaller products in the oncology supportive care market, to our product portfolio. We are further expanding our hematology and oncology product offering with the planned launch of Defitelio in Europe. We compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in the oncology and oncology supportive care markets, and our failure to compete effectively in this area could negatively affect our sales of Erwinaze, Defitelio and other products.

We also face competition, and may in the future face additional competition, from manufacturers of generic drugs. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. See the risk factor in this Item 1A entitled “If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.”

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

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

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

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

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

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of

confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology

Table of Contents

systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Related to Our Intellectual Property

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

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

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. Although Xyrem is covered by patents covering its formulation, distribution system and method of use, third parties are seeking to introduce generic versions of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents, if it is determined that our patents are invalid or unenforceable, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch generic versions of Xyrem at risk of potentially being held liable for damages for patent infringement.

In October 2010, December 2012 and November 2013, we received a Paragraph IV Certification from each of Roxane, Amneal and Par, respectively, that each had filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the Orange-Book-listed patents relating to Xyrem. If any one of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Additional ANDAs could also be filed requesting approval to market generic versions of Xyrem; if those applications for generics were approved and the generics were launched, sales of Xyrem would decrease. We have sued Roxane, Amneal and Par seeking to prevent them from introducing a generic version of Xyrem that would infringe our patents, but we cannot assure you that the lawsuits will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. See the risk factor in this Item 1A entitled “If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.”

Azur Pharma received Paragraph IV certifications from three generic manufacturers, two in 2008 and one in 2010, relating to generic versions of FazaClo LD. Azur Pharma and CIMA, our licensor and whose drug-delivery technology is incorporated into FazaClo LD, filed lawsuits in response to each certification. In July 2011, Azur Pharma, CIMA, Barr Laboratories (one of the three generic manufacturers) and Teva, which had acquired Barr Laboratories, entered into an agreement settling the patent litigation and granting an affiliate of Teva a license of our rights to have manufactured, market and sell a generic version of FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicenses for FazaClo LD commenced in July 2012; the sublicense for FazaClo HD will commence in May 2015 or earlier upon the occurrence of certain events. In August 2011, Azur Pharma received a Paragraph IV certification notice from Teva advising that Teva had filed an ANDA with the FDA seeking approval to market a generic version of FazaClo HD. As noted above, FazaClo HD was covered under the July 2011 settlement agreement with Teva. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product at the end of August 2012, which is having a negative impact on our sales of FazaClo LD and, to some extent, FazaClo HD and is expected to continue to do so.

The two formulation patents covering FazaClo HD and FazaClo LD that we license from CIMA were under reexamination by the USPTO, and both of the reexamination proceedings proceeded to appeal at the USPTO. The ANDA lawsuits with the other two generic manufacturers had been stayed pending the outcome of these

reexamination proceedings. In September 2013 and January 2014, reexamination certificates were issued for the two patents, with the claims of the patents confirmed and the parties have requested the stay of litigation be lifted. We cannot predict the timing or outcome of the patent litigation, or the impact on the entry of additional generic competitors for FazaClo HD or FazaClo LD.

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

Table of Contents

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed and prosecuted and may also affect patent litigation. The final substantive provisions of the Leahy-Smith Act, including the first to file system, became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to invent or file, as appropriate, subject matters covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- our issued patents and the issued patents of our licensors or partners may be vulnerable to legal challenges as a result of changes in applicable law;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets and other unpatented proprietary information to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures.

If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. For example, Erwinaze has no patent protection, and we rely on trade secrets and other unpatented proprietary information to protect our commercial position, which we may be unable to do. Another method of protection is regulatory exclusivity. Erwinaze, as a biologic product approved under a BLA, is subject to the BPCIA. The BPCIA establishes a period of twelve years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a twelve-year period. The FDA is in the process of implementing the BPCIA and has not established final guidelines for administering the review and approval of applications for data exclusivity. Although we expect that Erwinaze would receive data exclusivity in the United States through 2023 under the BPCIA, we cannot provide assurance that it will receive this exclusivity. While Erwinaze has orphan drug marketing exclusivity for a seven-year period from its FDA approval in the United States until November 2018, and is expected to receive data exclusivity in the United States through 2023 under the BPCIA, it is possible that a potential competitor might obtain earlier approval from the FDA based upon an approval application that does not rely on or refer to data in our BLA for Erwinaze. In the EU, the

regulatory data protection and thus regulatory exclusivity period for Erwinaze has lapsed. This also means that any new marketing authorizations for Erwinaze in other EU member states will not receive any regulatory data protection. If a biosimilar product to Erwinaze is approved in the future in the United States or in other countries where it is sold, a significant percentage of the prescriptions written for Erwinaze may be filled with the biosimilar version, resulting in a loss in sales of Erwinaze, and there may be a decrease in the price at which Erwinaze can be sold. Competition from a biosimilar product to Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, although there are patent applications for Asparec pending in the United States and many other countries, it is not

Table of Contents

yet covered by any U.S. patents. Asparec was granted orphan drug designation in Europe and the United States subject to certain conditions. In addition, the FDA has not yet clarified whether Asparec is eligible to receive data exclusivity under the BPCIA. Defibrotide has been granted orphan drug designation by the FDA, by the EMA and by the Korean Ministry of Food and Drug Safety, both to treat and to prevent VOD, and by the Commonwealth of Australia-Department of Health for the treatment of VOD. If we fail to obtain orphan drug marketing exclusivity and/or data exclusivity, and if we also fail to successfully execute on other strategies to protect our intellectual property with respect to Asparec, including protection by one or more issued patents, Asparec would be subject to competition from a biosimilar product, which could have a material adverse effect on our ability to recognize any return on our investment in the development of this product as well as on our future growth prospects.

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

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

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

If we choose to go to court to stop a third party from infringing our patents, our licensed patents or our partners' patents, that third party has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that a court will decide that these patents are not valid or infringed and that we do not have the right to stop the other party from using the patented subject matter. There is also the risk that, even if the validity of these patents is upheld and infringement of these patents found, the court will refuse to stop the other party on the grounds that it is in the public interest to permit the infringing activity. We are prosecuting lawsuits against the generic manufacturers who delivered Paragraph IV certifications to us with respect to Xyrem, FazaClo HD and FazaClo LD. See Item 3 "Legal Proceedings." We cannot assure you that these, or other lawsuits we may file in the future, will be successful in stopping the infringement of our patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for us.

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

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

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many non-U.S. jurisdictions are typically not published until 18 months after their

Table of Contents

priority date, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors' or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Patent interferences are limited or unavailable for applications filed after March 16, 2013.

Some of our competitors may be able to sustain the costs of complex patent and other intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We own patents that cover the formulation and method of use covering the administration for Xyrem, as well as method of use patents and trade secrets that cover elements of the Xyrem deemed REMS, including patents that cover the use of a single central pharmacy to distribute Xyrem. We are engaged in ongoing communications with the FDA with respect to our REMS documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA has notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiate dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we will initiate dispute resolution procedures with the FDA by the end of February 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. See the risk factor in this Item 1A entitled "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem. In particular, depending on the extent to which certain provisions of our Xyrem deemed REMS which are currently protected by our method of use patents covering the distribution of Xyrem are changed, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced. Certain claims of our patents may not provide as much protection in the context of a modified REMS structure. In addition, the extent of protection provided by our method of use patents covering the distribution of Xyrem depends on the nature of the distribution system that may be used by any generic competitor, including whether the distribution system is as restricted as the distribution system set forth in our current Xyrem deemed REMS. If a generic competitor is able to obtain ANDA approval for a generic version of Xyrem based on a risk management plan or REMS that does not fall within the scope of any of the claims of our distribution patents, those patents will not be a barrier to the generic version's entry into the market. We cannot be certain whether our existing distribution patents or patents that may be granted in the future will be construed to cover any generic

REMS or risk management plan that might be approved by the FDA. The interpretation of intellectual property protections and the effect of these protections are extremely complex, and we cannot predict the impact of any changes to our REMS documents on our business.

Risks Related to Our Industry

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

The research, testing, manufacturing, labeling, advertising and promotion, distributing and exporting of pharmaceutical products are subject to extensive regulation, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. For example, we are not permitted to market

Table of Contents

our product candidates in the United States or in the EU member states until we receive approval from the FDA, the European Commission, or the competent authorities of the EU member states, respectively, generally of an NDA, a BLA or a marketing authorization application. The application must contain information demonstrating the quality, safety and efficacy of the medicinal product, including data from the preclinical and clinical trials, information pertaining to the preparation and manufacture of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and information concerning the stability of the medicinal product. Submission of an application for marketing authorization does not assure approval for marketing in any jurisdiction, and we may encounter significant difficulties or costs in our efforts to obtain approval to market products. If we are unable to obtain regulatory approval of our product candidates, we will not be able to commercialize them and recoup our research and development costs. Any delay or failure in obtaining approval of a drug candidate, or receiving approval for narrower conditions of use than sought, can have a negative impact on our financial performance.

If the FDA, the European Commission or the competent authorities of the EU member states determine that a REMS or the imposition of post-marketing obligations is necessary to ensure that the benefits of the drug outweigh the risks, we may be required to include a proposed REMS as part of an NDA or to propose post-marketing obligations to be included in the marketing authorization for our products in the EU. We may also be required to include a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide information to consumers about the drug's risks and benefits. For example, the FDA requires a REMS for Xyrem, discussed in detail under the risk factor "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem" above, and other products that we sell are or may become subject to a REMS specific to our product or shared with other products in the same class of drug. We cannot predict the impact that any new REMS requirements applicable to any of our products would have on our business.

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

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

In March 2010, the U.S. President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Healthcare Reform Act. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program and expanded the Public Health Service's 340B drug pricing discount program. Details of these changes are discussed under the risk factor "If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and

growth prospects."

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

In 2012, the Supreme Court of the United States heard challenges to the constitutionality of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act; however, the Supreme Court struck down a provision in the Healthcare Reform Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal

Table of Contents

poverty limit. As a result of the Supreme Court's ruling, some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Healthcare Reform Act, including the employer mandate. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

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

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third party payors to keep healthcare costs down while expanding individual healthcare benefits. Likewise, in the countries in the EU, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to health care cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices we will be able to charge for our products and any approved product candidates or the amounts of reimbursement available for these products from governmental agencies or third-party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Further, an increasing number of EU member states and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU member states, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU member states, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem free product voucher program and co-pay coupon programs for certain products. The co-pay coupon programs of other pharmaceutical manufacturers are the subject of ongoing class action lawsuits, first filed in 2012, challenging their legality under a variety of federal and state laws, and our co-pay coupon programs could become the target of similar lawsuits. In addition, co-pay coupon programs, including our program for Xyrem, have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives. It has also come to our attention that at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain drugs the insurer identified. In addition, in November 2013 CMS issued guidance to the issuers of qualified health plans sold through the Healthcare Reform Act's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. It is possible that the outcome of the pending litigation against other manufacturers, changes in insurer policies regarding co-pay coupons, and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these programs, which could result in fewer patients using affected products, which could include Xyrem, and therefore could have a material adverse effect on our sales, business and financial condition.

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

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

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of our products are, and any of our product candidates that may be approved by the FDA, the European Commission, the competent authorities of the EU member states and other non-U.S. regulatory authorities will be, subject to extensive and ongoing regulatory requirements. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. Failure by us or any of our third party partners, including suppliers, manufacturers and distributors and our respective central pharmacies for Xyrem and for Prialt, to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, withdrawal, suspension or

Table of Contents

variation of product approval, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall, withdrawal or seizure, total or partial suspension of production or distribution, interruption of manufacturing or clinical trials, operating restrictions, injunctions; suspension of licenses, civil penalties and/or criminal prosecution, any of which could have a significant impact on our sales, business and financial condition.

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

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

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

We have not obtained marketing authorizations and/or may not currently have updated the marketing authorization approval dossiers for Erwinaze and several other medicinal products in every international market in which those products are being sold. For example, in some EU countries where we do not have a marketing authorization, Erwinaze is being provided to patients on the basis of government-approved named patient programs or temporary use authorizations. In addition, Defitelio has been provided to patients in some EU countries on a named patient basis and in certain of these countries, reimbursement is provided for unauthorized products provided through national named patient or compassionate use programs. Such reimbursement may no longer be available if authorization for named patient or compassionate use programs expire or are terminated. While we believe we have satisfied the regulations regarding our communications and medical affairs activities in those countries, if any such country's regulatory authorities determine that we are promoting Erwinaze or Defitelio without a marketing authorization in place, we could be found to be in violation of pharmaceutical advertising law or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties.

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

In addition, certain of our products are currently marketed as medical devices in individual EU member states. If a competent authority in the EU were to determine that the products concerned are incorrectly classified as a medical device, we may be subject to administrative action or other enforcement measures, such as the suspension of the marketing or the withdrawal from the market of the product concerned.

The FDA requires advertising and promotional labeling to be truthful and not misleading, and products to be marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA routinely provides its interpretations of that authority in informal communications and also in more formal communications such as untitled letters or warning letters, and although such communications may not be considered final agency decisions, companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful. For example, in September 2012, we received a warning letter from the FDA related to a direct-to-consumer patient brochure for FazaClo. We were no longer using the allegedly violative promotional materials at the time we received the letter, but reviewed all of our other promotional materials for FazaClo in accordance with the letter. We agreed with the FDA on plans for correcting the promotional materials and disseminating the corrective messages to healthcare providers, patients and consumers and began implementation of the corrective actions in accordance with the agreed-upon

Table of Contents

plans in February 2013. We believe that we have taken necessary actions required to fully address the agency's concerns. However, there can be no assurance that the FDA will agree with our assessment. The FDA could take further action, could require us to take further action, with respect to our FazaClo promotional materials, or could otherwise conclude we have not taken all appropriate corrective actions with respect to the warning letter. The FDA or other regulatory authorities may disagree with our response to the warning letter or challenge other of our promotional materials or activities in the future, through additional enforcement action, which may have a negative impact on our sales and/or may subject us to financial or other penalties.

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

Various U.S. state agencies traditionally oversee pharmaceutical compounding activities. Compounded drugs are made by certain pharmacies, typically by combining, mixing or altering ingredients of a drug to make a formulation that is not readily available to patients and/or approved by the FDA. A number of problems have been associated with the making and use of compounded drugs, including product contamination, product toxicity, product instability and impaired performance of medical devices used to deliver drugs. Improperly compounded products can pose serious public health issues, as evidenced by the October 2012 fungal meningitis outbreak in the United States which was traced to compounded drugs from the New England Compounding Center. Pharmaceutical products administered intrathecally, such as Prialt, are frequently compounded with other products by pharmacies, a process over which we have no control. If any of our products are used in compounded drugs, we may have exposure to claims by patients treated with compounded formulations containing our products and to regulatory action by relevant government agencies. Any such claims or regulatory actions could result in harm to our reputation and have a negative effect on our business. In addition, since late 2012, there have been increased legislative and enforcement activities on the federal level and new legislation was passed in November 2013 which gives the FDA increased authority over compounding operations. We cannot predict the impact of any new legislation on our business.

Other Regulatory Authorities

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

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition to quota requirements, the DEA imposes various registration, importing, exporting, recordkeeping and reporting requirements, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the CSA. The states also impose similar requirements for handling controlled substances. The United States and the EU member states are parties to the 1971 Convention. In October 2012, the WHO sent a recommendation to the CND to reschedule GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. In March 2013, the CND voted to reschedule GHB from Schedule IV to Schedule II under the 1971 Convention. While the DEA imposes its own scheduling requirements in the United States under the CSA, the United States is obligated as a signatory to the 1971 Convention to ensure that drug scheduling in the United States is consistent with its obligations under the international treaties. Because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, the international rescheduling of GHB means that Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements in the EU and certain other countries than the

Table of Contents

restrictions currently in place. In the United States, under DEA regulations, the Xyrem finished product is currently classified as a Schedule III controlled substance, with sodium oxybate, classified as a Schedule I controlled substance. Although the HHS, has taken the position in the past that the United States would not be required to alter the domestic control of GHB should it be rescheduled to Schedule II under the 1971 Convention, we cannot guarantee that international rescheduling of GHB from Schedule IV to Schedule II will not impact restrictions on Xyrem in the United States. Failure by us or any of our partners, including suppliers, manufacturers and distributors, to comply with such requirements could result in, among other things, additional operating costs to us, delays in shipments outside or into the United States and adverse regulatory actions.

In addition, pursuant to the Export Administration Regulations, we are required to obtain a license from the U.S. Department of Commerce prior to the exportation of certain materials and technical information related to Prialt, a synthesized conotoxin, which is a designated controlled biological toxin.

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

The U.S. Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment of federal funds, or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company’s products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, in recent years the government has pursued False Claims Act cases against a number of pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

In addition, the Physician Payment Sunshine provisions of the Healthcare Reform Act require extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. CMS has issued a final rule implementing the Physician Payment Sunshine provisions and clarifying the scope of the reporting obligations. The final rule also provided that manufacturers begin tracking on August 1, 2013 and begin reporting payment data to CMS by March 31, 2014. It is widely anticipated that public reporting under the Sunshine Act will result in increased scrutiny of the financial relationships between industry, teaching hospitals and physicians, and such scrutiny may negatively impact our ability to engage with physicians on matters of importance to us.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities. Still other states require the posting of information relating to clinical studies and their

outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Additional states are considering or recently have considered similar proposals. Non-U.S. governments often have similar regulations which we also will be subject to in those countries where we market and sell products.

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

Table of Contents

consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

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

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The UK Bribery Act prohibits giving, offering, or promising bribes to any person, including non-UK government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies which carry on a business or part of a business in the UK may be held liable for bribes given, offered or promised to any person, including non-UK government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the UK Bribery Act there is no exception for facilitation payments. As described above, our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the SEC and the Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures, and internal controls. However, there is no certainty that all employees and third party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

We are also subject to laws and regulations covering data privacy and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business, including recently enacted laws in all jurisdictions where we operate. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. In addition, we obtain patient health information from most healthcare providers who prescribe our products and research institutions we collaborate with, and they are subject to privacy and security requirements under the HIPAA, as amended by the HITECH Act. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Moreover, EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data,

Table of Contents

including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU member states may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, including the U.S. There are also similar data transfer restrictions in Switzerland. However, there are a number of legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, including, among others, a voluntary U.S. - EU Safe Harbor Framework, a voluntary U.S. - Switzerland Safe Harbor Framework and the EU's set of standard form contractual clauses for the transfer of personal data outside of EEA. Our U.S. subsidiary, Jazz Pharmaceuticals, Inc., has certified compliance with the U.S. - EU Safe Harbor Framework through the U.S. Department of Commerce. A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration. The EU Data Protection Regulation is expected to introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules. If the draft EU Data Protection Regulation is adopted in its current form it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

The number and complexity of both federal and state laws continue to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government's ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, and amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Compliance with the various EU, national, and federal and state laws that apply to pharmaceutical manufacturers is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and, in some cases, the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. For example, the FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular to whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner. The FDCA further states that a REMS shall not be used by an NDA holder to block or delay generic drugs from entering the market. Two of the ANDA applicants have asserted that our patents covering the distribution system for Xyrem should not have been listed in the Orange Book, and that the Xyrem REMS is blocking competition. Such a challenge or any other challenge that we or our business partners have failed to comply with applicable laws and regulations could have a material adverse effect on our business, financial condition, results of operations and growth prospects. If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also

generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

We manufacture certain active pharmaceutical ingredients, including the defibrotide drug substance, at our manufacturing facility in Italy. In addition, we have engaged a third party manufacturer to process defibrotide into the finished product at its Italian manufacturing plant. These facilities are subject to continuing regulation by the Italian Health Authority and other Italian regulatory authorities with respect to the manufacturing of active pharmaceutical ingredients, including the defibrotide drug substance or its finished form. These facilities are also subject to inspection and regulation by the FDA and the EMA with respect to the manufacturing of the defibrotide drug substance and its finished form. Also, part of the process to obtain FDA and EMA approval for defibrotide is to obtain certification from those authorities that these facilities are in compliance with cGMP. Following initial approval, if any, the FDA or the EMA will continue to inspect our manufacturing facilities, in some cases, unannounced, to confirm ongoing compliance with cGMP. These regulators may deny approval to manufacture our active pharmaceutical ingredients or otherwise require us to stop manufacturing our active pharmaceutical ingredients if they determine that either our facility or our third party manufacturer’s facility in Italy does not meet the standards of compliance

Table of Contents

required under applicable regulations. In addition, these regulators may require us to complete costly alterations to our facilities.

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

We participate in the Medicaid Drug Rebate program, established by the Omnibus Budget Reconciliation Act of 1990 and amended by the Veterans Health Care Act of 1992 as well as subsequent legislation. We also participate in and have certain price reporting obligations to several state Medicaid supplemental rebate and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price at which the drug is made available to any commercial purchaser or payor, net of rebates and other price concessions. Such data previously have not been submitted for our two radiopharmaceutical products, ProstaScint® (capromab pendetide) and Quadramet® (samarium sm 153 lexidronam injection). We have been engaged in interactions with CMS and a trade group, the Council on Radionuclides and Radiopharmaceuticals, or CORAR, regarding the reporting of Medicaid pricing data and paying Medicaid rebates for radiopharmaceutical products. For ProstaScint, we plan to begin making any required reports when CMS provides guidance on this requirement and reporting methodology, which is currently expected in 2014. We sold Quadramet to a third party in December 2013, but have retained any liabilities related to sales of the product during prior periods. In addition to the discussions with CMS as part of CORAR, we have had separate discussions with CMS directly regarding Quadramet. We are currently unable to predict whether price reporting and rebates will be required for ProstaScint and Quadramet and if so, for what period they will be required. We are currently unable to reasonably estimate an amount or range of a potential contingent loss related to the payment of rebates for Quadramet or ProstaScint. Any material liability resulting from radiopharmaceutical price reporting and rebates would negatively impact our financial results.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebate liability expanded from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. With regard to the amount of the rebates owed, the Healthcare Reform Act increased the minimum Medicaid rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11.0% to 13.0% for non-innovator products; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the Healthcare Reform Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Sales of orphan drugs are excluded from this fee as long as no non-orphan indications have been approved for such orphan drugs.

In 2012, the CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming,

and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of

Table of Contents

operations. The initiation of any reporting of Medicaid pricing data for ProstaScint and Quadramet could result in retroactive 340B ceiling price liability for these two products as well as prospective 340B ceiling price obligations for ProstaScint. We are currently unable to reasonably estimate an amount or range of a contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results.

The Healthcare Reform Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts “orphan drugs” - those designated under section 526 of the FDCA - from the ceiling price requirements for these newly-eligible entities. The HRSA, which administers the 340B program, issued a final regulation to implement the orphan drug exception in July 2013. The final regulation interprets the orphan drug exception narrowly. It exempts orphan drugs from the ceiling price requirements for the newly-eligible entities only when the orphan drug is used for its orphan indication. The newly-eligible entities are entitled to purchase orphan drugs at the ceiling price when the orphan drug is not used for its orphan indication. The final regulation, which became effective October 1, 2013, is subject to a pending lawsuit that seeks to block its implementation. The narrow scope of the orphan drug exception in HRSA’s final regulation will increase the complexity of compliance, will make compliance more time-consuming, and could negatively impact our results of operations.

The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. HRSA is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report ASP information to CMS for certain categories of drugs that are paid under Part B of the Medicare program. Manufacturers calculate ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Statutory or regulatory changes or CMS binding guidance could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

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

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, average sales price, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. Our failure to submit monthly/quarterly average manufacturer price, average sales price, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per

day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

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

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies, it also must participate in the VA FSS

Table of Contents

pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies - the VA, the Department of Defense, or DoD, the Public Health Service, and the Coast Guard - at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the VHCA. The FCP is based on a weighted average Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed "tracking customer." Further, in addition to the "Big Four" agencies, all other federal agencies and some non-federal entities are authorized to access FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies "negotiated pricing" for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor's commercial "most favored customer" pricing. We offer one single FCP-based FSS contract price to all FSS purchasers for all products.

In addition, pursuant to regulations issued by the DoD TRICARE Management Activity, or TMA, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs is listed on a Section 703 Agreement with TMA under which we have agreed to pay rebates on covered drug prescriptions dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. Companies are required to list their innovator products on Section 703 Agreements in order for those products to be eligible for DoD formulary inclusion. The formula for determining the rebate is established in the regulations and our Section 703 Agreement and is based on the difference between the Annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

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

Price approvals and reimbursement may not be available for our products, which could diminish our sales or affect our ability to sell our products profitably.

In both U.S. and non-U.S. markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. In many countries, price approvals must be obtained before products can be placed on the market or submitted for reimbursement. Third party payors, including government payors, decide which drugs can be reimbursed and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. We may need to conduct expensive pharmacoeconomic and/or clinical studies in order to demonstrate the cost-effectiveness of our products. Even with such studies, our products may be considered less safe, less effective or less cost-effective than other products, and third party payors may not provide and maintain price approvals, coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part. In addition, third party payors' reimbursement practices may affect the price levels for our products, including Xyrem, or the availability of reimbursement for Xyrem. Our business could be materially harmed if the Medicaid program, Medicare program or other third party payors were to deny reimbursement for our

products or provide reimbursement only on unfavorable terms. This risk is particularly significant with respect to Xyrem, in part due to payor sensitivity to the price of Xyrem. Our business could also be harmed if the Medicaid program, Medicare program or other reimbursing bodies or payors limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances than we believe is appropriate.

In addition, third party payors draw on diagnostic criteria to establish reimbursement guidelines. Meaningful changes to the diagnostic criteria for narcolepsy are included in the recently published fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and are expected to be included in the third edition of International Classification of Sleep Disorders (ICSD-3), which is expected to be published in 2014. As a result, third party payors may make changes to the coverage and reimbursement for our products, which may have a negative impact on revenues from Xyrem.

Table of Contents

In many countries, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing approval. We have not yet obtained pricing and reimbursement with respect to Defitelio in any of the EU countries where pricing and reimbursement approvals are required for launch. If we fail to obtain such pricing and reimbursement for Defitelio in any of EU countries in which we intend to market Defitelio or if we experience delays in obtaining such pricing and reimbursement, our growth prospects could be negatively affected. See the discussion regarding the planned launch of Defitelio in the risk factor in this Item 1A entitled "We may not be able to successfully launch and market Defitelio in the EU, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects."

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

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

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. For example, much attention has been paid to legislation proposing federal rebates on Medicare Part D and Medicare Advantage utilization for drugs issued to certain groups of lower income beneficiaries and the desire to change the provisions that treat these dual-eligible patients differently from traditional Medicare patients. Any such changes could have a negative impact on revenues from sales of our products.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS has made draft NADAC and draft NARP data publicly available on at least a

monthly basis. In July 2013, CMS suspended the publication of draft NARP data, pending funding decisions. In November 2013, CMS moved to publishing final rather than draft NADAC data and has since made updated NADAC data publicly available on a weekly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover products appropriately under our DoD pricing agreements, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the Federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In various EU member states we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of

Table of Contents

reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. We have periodically increased the price of Xyrem, most recently in February 2014, and we have made and may in the future make similar price increases on our other products. We cannot assure you that such price adjustments will not negatively affect our ability to secure and maintain reimbursement coverage for our products, which could negatively impact our sales volumes.

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

Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologicals, have been reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240. The Bipartisan Budget Act of 2013, Pub. L. No. 113-67, extended the 2% reduction to 2023. If Congress does not take action in the future to modify these sequestrations, Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment provisions, as described below, could have a similar effect. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products are associated with significant risks of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could exacerbate a patient’s condition, or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Some of our products, including Xyrem, have boxed warnings in their labels. In many countries, including in EU member states, national laws provide for strict (no-fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party.

Product liability claims may be brought by individuals seeking relief for themselves, or by groups seeking to represent a class of injured patients. Further, third party payors, either individually or as a putative class, may bring actions seeking to recover monies spent on one of products. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. The risk of product liability claims may also increase if a company receives a warning letter from a regulatory agency. We cannot predict the frequency, outcome or cost to defend any such claims.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, if at all. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. In addition, we may not continue to be able to obtain insurance on satisfactory terms or in adequate amounts.

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

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

A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by the FDA, the EMA, or the competent authorities of the EU member states. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension, variation, or withdrawal of approval. Similarly, any such regulatory action by the FDA, the EMA or the competent authorities of the EU member states could lead to product liability lawsuits as well. Similar investigations and risks can occur in other countries outside the United States.

Table of Contents

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

Our manufacturing of active pharmaceutical ingredients in Italy involves the controlled storage, use and disposal of chemicals and solvents. We are subject to Italian laws, which implement EU directives and regulations governing the use, transportation, treatment, storage, handling and disposal of solid and hazardous materials, wastewater discharges and air emissions. We have obtained certification under the UNI EN ISO 14001 Standard for our environmental management system and have an Eco-management and Audit Scheme (EMAS) for our plant in Italy. Our environmental policy is designed to comply with current regulations on environmental protection, to provide for continuous improvement of our manufacturing performance, to protect our employees' health, to protect the safety of people working at our location in Italy and to respect the safety of people living close to our plant and in the surrounding community. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by these laws and regulations, we cannot completely eliminate the risk of contamination or injury from hazardous materials. If an accident occurs, an injured party could seek to hold us liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs to comply with current or future environmental laws and regulations.

Risks Relating to Our Financial Condition

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

As of December 31, 2013, we had approximately $554.4 million in secured debt outstanding. In connection with the Gentium Acquisition, we incurred an additional $650.0 million in secured debt, including $350.0 million of incremental term loans and $300.0 million of revolving loans. All of our secured debt was incurred pursuant to a credit agreement that we entered into in connection with our acquisition of EUSA Pharma Inc., or the EUSA Acquisition, in June 2012 and subsequently amended in June 2013 and in January 2014, which is referred to in this report as our credit agreement. Our debt may:

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

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

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

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

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable preferred stock;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including acquisitions of exclusive licenses) and capital expenditures;

- enter into agreements that restrict distributions from our subsidiaries;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and

Table of Contents

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

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

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

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

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

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

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

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

our cost of financing and have an adverse effect on the market price of our securities.

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

We are incorporated in Ireland and maintain subsidiaries in North America, a number of other European jurisdictions and Bermuda. Azur Pharma was able to achieve a low average tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland and Bermuda, together with intra-group service and transfer

Table of Contents

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

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

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Internal Revenue Code of 1986, as amended, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. Because we indirectly acquired all of Jazz Pharmaceuticals, Inc.'s assets through the acquisition of the shares of Jazz Pharmaceuticals, Inc. common stock in the Azur Merger, the IRS could assert that we should be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874. For us to be treated as a foreign corporation for U.S. federal tax purposes under Section 7874 of the Code, either (1) the former stockholders of Jazz Pharmaceuticals, Inc. must have owned (within the meaning of Section 7874 of the Code) less than 80% (by both vote and value) of our ordinary shares by reason of holding shares in Jazz Pharmaceuticals, Inc. (the "ownership test"), or (2) we must have substantial business activities in Ireland after the Azur Merger (taking into account the activities of our expanded affiliated group). The Jazz Pharmaceuticals, Inc. stockholders owned less than 80% of our share capital immediately after the Azur Merger by reason of their ownership of shares of Jazz Pharmaceuticals, Inc. common stock. As a result, we believe that we should be treated as a foreign corporation for U.S. federal tax purposes. It is possible that the IRS could disagree with the position that the ownership test is satisfied and assert that Section 7874 of the Code applies to treat us as a U.S. corporation following the Azur Merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. The IRS continues to scrutinize transactions that are potentially subject to Section 7874, and issued new final and temporary regulations under Section 7874 in June 2012 and in January 2014. We do not expect these regulations to affect the U.S. tax consequences of the Azur Merger. Nevertheless, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have retroactive application to us, Jazz Pharmaceuticals, Inc., our respective shareholders, and/or the Azur Merger.

Section 7874 of the Code limits Jazz Pharmaceuticals, Inc. and its U.S. affiliates' ability to utilize their U.S. tax attributes to offset certain U.S. taxable income, if any, generated by certain taxable transactions.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code can limit the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, this limitation applies to us. As a result, after the Azur Merger, Jazz Pharmaceuticals, Inc. or its U.S. affiliates have not been able and will continue to be unable, for a period of time, to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions. Notwithstanding this limitation, we plan to fully utilize Jazz Pharmaceuticals, Inc.'s U.S. net operating losses, or NOLs, prior to their expiration. As a result of this limitation, however, it may take Jazz Pharmaceuticals, Inc. longer to use its NOLs. Moreover, contrary to these plans,

it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Jazz Pharmaceuticals, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Jazz Pharmaceuticals, Inc. does not generate sufficient taxable income.

Our U.S. affiliates' ability to use their net operating losses to offset potential taxable income and related income taxes that would otherwise be due could be subject to further limitations if we do not generate taxable income in a timely manner or if the "ownership change" provisions of Sections 382 and 383 of the Code result in further annual limitations.

Our U.S. affiliates have a significant amount of NOLs. Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, our U.S. affiliates will generate sufficient taxable income to use all of the NOLs. In addition, realization of NOLs to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of Sections 382 and 383 of the Code and similar state provisions, which may result in the expiration of additional NOLs before

Table of Contents

future utilization. In general, an "ownership change" occurs if, during a three-year rolling period, there is a change of 50% or more in the percentage ownership of a company by 5% shareholders (and certain persons treated as 5% shareholders), as defined in the Code and Treasury Regulations. In this regard, we currently estimate that, as a result of these ownership change provisions, we have an annual limitation on the utilization of certain NOLs of $28.6 million for each of the years 2014 to 2016, $11.9 million for 2017, and a combined total of $3.3 million for 2018 to 2026. However, Sections 382 and 383 of the Code are extremely complex provisions with respect to which there are many uncertainties, and we have not requested a ruling from the IRS to confirm our analysis of the ownership change limitations related to the NOLs generated by our U.S. affiliates. Therefore, we have not established whether the IRS would agree with our analysis regarding the application of Sections 382 and 383 of the Code. If the IRS were to disagree with our analysis, or if our U.S. affiliates were to experience additional ownership changes in the future, our U.S. affiliates could be subject to further annual limitations on the use of the NOLs to offset potential taxable income and related income taxes that would otherwise be due.

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

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

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

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

As of December 31, 2013, we had recorded $1.3 billion of intangible assets and goodwill related to our past acquisitions. Intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

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

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

We have significant operations in Europe as well as in the United States, but we report revenues, costs and earnings in U.S. dollars. Our primary currency translation exposures relate to our subsidiaries that have functional currencies denominated in the Euro and the British Pound. Exchange rates between the U.S. dollar and each of the Euro and British Pound are likely to fluctuate from period to period. Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the functional currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. As we continue to expand our international operations, including with the Gentium Acquisition, we will conduct more transactions in currencies other than the U.S. dollar. To the extent that revenue and expense transactions are not denominated in the functional currency, we are also subject to the risk of transaction losses. Given the volatility of exchange rates, there is no assurance that we will be able to effectively manage currency transaction and/or conversion risks. We have not entered into derivative instruments to offset the impact of foreign exchange fluctuations. Fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations and financial condition.

Risks Relating to Our Ordinary Shares

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

Investors who hold our ordinary shares may not be able to sell their shares at or above the price at which they purchased their ordinary shares (or the price at which they purchased their shares of Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger). The price of our ordinary shares has fluctuated significantly from time to time since the completion of the Azur Merger in January 2012, and the price of Jazz Pharmaceuticals, Inc.'s common stock historically fluctuated significantly. The risk factors described above relating to our business and products could cause the price of our ordinary shares to continue to

Table of Contents

fluctuate significantly. In addition, the stock market in general, including the market for life sciences companies, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our ordinary shares, regardless of our operating performance.

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

In addition, the market price of our ordinary shares may decline if the effects of the Gentium Acquisition and/or potential future acquisitions on the financial results of our company are not consistent with the expectations of financial analysts or investors.

Future sales of our ordinary shares in the public market could cause our share price to fall.

Sales of a substantial number of our ordinary shares in the public market, including sales by members of our management or board of directors, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity or equity-related securities. As of February 19, 2014, we had 58,068,360 ordinary shares outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144.

In addition, we have in the past and may in the future grant rights to some of our shareholders that require us to register the resale of our ordinary shares on behalf of these shareholders and/or facilitate offerings of ordinary shares held by these shareholders, including in connection with potential future acquisitions of additional products, product candidates, or companies. For example, consistent with our obligations under existing registration rights agreements, we entered into underwriting agreements with certain underwriters and selling shareholders pursuant to which selling shareholders sold an aggregate of approximately 13 million ordinary shares in two separate registered public offerings in March 2012 and in March 2013. If current or potential future holders of registration rights, by exercising their registration rights or otherwise, sell a large number of shares, the sale could adversely affect the market price of our ordinary shares. We have also filed registration statements to register the sale of our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and intend to file additional registration statements to register any shares automatically added each year to the share reserves under these plans.

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

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

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

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

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

- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes;

Table of Contents

- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association; and
- permit our board of directors to issue one or more series of preferred shares with rights and preferences, as our shareholders may determine by ordinary resolution.

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

These provisions may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions could also discourage proxy contests and make it more difficult for you and other shareholders to elect directors other than the candidates nominated by our board.

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

Other than funds we have allocated for the purposes of supporting our share repurchase program announced in May 2013, we anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs, acquire or in-license additional products and product candidates, and pursue other opportunities. If we propose to pay dividends in the future, we must do so in accordance with Irish law, which provides that distributions including dividend payments, share repurchases and redemptions be funded from "distributable reserves." In addition, our ability to pay cash dividends on or repurchase our ordinary shares is restricted under the terms of our credit agreement. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our credit agreement and other factors our board of directors deems relevant. Accordingly, holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future.

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

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

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

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to our shareholders. Shareholders that are resident in the United States, EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of

shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

Table of Contents

Our auditor, like other independent registered public accounting firms operating in Ireland and a number of other European countries, is not currently permitted to be subject to inspection by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, our investors currently do not have the benefits of PCAOB oversight. As an auditor of companies that are publicly-traded in the United States and as a firm registered with the PCAOB, our independent registered public accounting firm is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and the professional standards of the PCAOB. However, because our auditor is located in Ireland, a jurisdiction where the PCAOB is currently unable to conduct inspections, our auditor is not currently inspected by the PCAOB. Inspections of other auditors conducted by the PCAOB outside of Ireland have at times identified deficiencies in those auditor's audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections in Ireland prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. In addition, the inability of the PCAOB to conduct auditor inspections in Ireland makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors located outside of Ireland that are subject to regular PCAOB inspections. As a result, our investors are deprived of the benefits of PCAOB inspections, and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

Item 1B. Unresolved Staff Comments

There are no material unresolved written comments that were received from the SEC staff 180 days or more before the end of our 2013 fiscal year relating to our periodic or current reports under the Exchange Act.

Item 2. Properties

Our corporate headquarters are located in Dublin, Ireland and our United States operations are located in Palo Alto, California and Philadelphia, Pennsylvania.

We occupy approximately 12,000 square feet of office space in Dublin, Ireland under a lease which expires in May 2022. We have an option to terminate this lease in May 2017, with no less than six months' prior written notice and the payment of a termination fee. In Palo Alto, California, we occupy a total of approximately 100,000 square feet of office space, 44,000 square feet of which is occupied under a lease, or the Palo Alto Lease, that expires in August 2017, 17,000 square feet of which is occupied under a sublease that expires in July 2017 and 39,000 square feet of which is occupied under a sublease that expires in April 2016. We have the right to extend the term of the Palo Alto Lease for up to an additional two years. We also occupy approximately 19,000 square feet of office space in Philadelphia, Pennsylvania under a lease that expires in February 2018.

In addition, we have offices in Oxford, United Kingdom, Lyon, France, Villa Guardia (Como), Italy and elsewhere in Europe. We occupy approximately 5,000 square feet of office space in Oxford, United Kingdom under a lease that expires in March 2015. We also occupy approximately 9,000 square feet of office space in Lyon, France under a lease that expires January 2019. We have an option to terminate this lease in December 2015. We own a manufacturing facility in Villa Guardia (Como), Italy which is subject to a mortgage securing repayment of an aggregate of approximately €1.1 million ($1.5 million) of debt owed to Banca Nazionale del Lavoro. The manufacturing facility is 25,295 square feet in size. We also lease approximately 51,667 square feet of office and laboratory space and 1,076 square feet of laboratory and manufacturing space in Villa Guardia (Como), Italy under leases that expire in December 2017.

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

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

Xyrem ANDA Matters: On October 18, 2010, we received a Paragraph IV Certification notice from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleged that all five patents then listed for Xyrem in the Orange Book on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States

District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. Additional patents covering Xyrem have issued since the original suit was filed, and cases involving these patents have been consolidated with the original action. In December 2013, the District Court permitted Roxane to amend its Answer in the consolidated case to allege additional equitable defenses, and the parties have been given additional time for discovery on those new defenses. Although no trial date for the consolidated case has been scheduled, based on the current scheduling order, we anticipate that trial in the consolidated case could occur as early as late in the fourth quarter of 2014. However, the actual timing of events in this litigation may be significantly earlier or later than contemplated by the scheduling order, and we cannot predict the timing or outcome of events in this litigation. In accordance with the Hatch-

Table of Contents

Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA had been stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification notice, but that stay has expired. We cannot predict the timing or outcome of this matter.

On December 10, 2012, we received a Paragraph IV Certification notice from Amneal that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Amneal's Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal's proposed generic product. Amneal's Paragraph IV Certification further alleged that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification notice alleging that a ninth patent listed in the Orange Book for Xyrem is invalid. On January 18, 2013, we filed a lawsuit against Amneal in response to Amneal's Paragraph IV Certifications in the District Court. An additional patent covering Xyrem issued since the original suit was filed and the case involving this patent has been consolidated with the original case. We are seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Amneal, FDA approval of Amneal's ANDA will be stayed until the earlier of (i) June 10, 2015, which is 30 months after our receipt of Amneal's Paragraph IV Certification notice on December 10, 2012, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of this matter.

On November 21, 2013, we received a Paragraph IV Certification notice from Par that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Par's Paragraph IV Certification alleged that ten patents listed in the Orange Book for Xyrem are invalid, unenforceable, and/or will not be infringed by Par's proposed generic product. On December 27, 2013, we filed a lawsuit against Par in the United States District Court, in response to Par's Paragraph IV Certification. We are seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Par, FDA approval of Par's ANDA will be stayed until the earlier of (i) May 21, 2016, which is 30 months after our receipt of Par's Paragraph IV Certification notice on November 21, 2013, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of this matter.

FazaClo ANDA Matters: Azur Pharma received Paragraph IV Certification notices from three generics manufacturers, Barr Laboratories, Inc., or Barr, Novel Laboratories, Inc., or Novel, and Mylan Pharmaceuticals, Inc., or Mylan, indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo LD. Azur Pharma and CIMA, a subsidiary of Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification against Barr on August 21, 2008, against Novel on November 25, 2008 and against Mylan on July 23, 2010. Each case was filed in the United States District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product at the end of August 2012. The Novel and Mylan matters have been stayed pending reexamination of the patents in the lawsuits. In September 2013 and January 2014, reexamination certificates were issued for the two patents-in-suit, with the claims of the patents confirmed, and the parties have requested that the stay of litigation be lifted. We cannot predict the timing or outcome of this litigation.

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir in the California Superior Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as

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

Shareholder Litigation Matter: In January 2014, we became aware of a purported class action lawsuit filed in the Southern District of New York in connection with the Gentium Acquisition. The lawsuit, captioned Xavion Jyles, Individually and on Behalf of All Others Similarly Situated v. Gentium S.P.A. et al., names Gentium, each of the Gentium's directors, us and our Italian subsidiary as defendants. The lawsuit alleges, among other things, that Gentium's directors breached their fiduciary duties to Gentium's shareholders in connection with a tender offer agreement that Gentium entered into with us and our Italian subsidiary valuing Gentium ordinary shares and ADSs at $57 per share, and that we and our Italian subsidiary violated

Table of Contents

Sections 14(e) and 20(a) of the Exchange Act by allegedly overseeing Gentium's preparation of an allegedly false and misleading Section 14D-9 Solicitation/Recommendation Statement. The lawsuit seeks, among other relief, class action status, rescission, and unspecified costs, attorneys' fees and other expenses. We cannot predict the timing or outcome of this matter.

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

Item 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

Our ordinary shares began trading on The NASDAQ Global Select Market under the trading symbol "JAZZ" on January 18, 2012. From June 1, 2007 until January 17, 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) also under the trading symbol "JAZZ." The following table sets forth the high and low intraday sales prices of our ordinary shares (and for periods prior to January 18, 2012, the common stock of Jazz Pharmaceuticals, Inc.) on The NASDAQ Global Select Market (or The NASDAQ Global Market prior to January 3, 2012) for the periods indicated.

	High	Low
Calendar Quarter—2012		
First Quarter	$53.10	$37.90
Second Quarter	$54.50	$40.38
Third Quarter	$58.94	$43.38
Fourth Quarter	$60.00	$47.37
Calendar Quarter—2013		
First Quarter	$60.79	$53.52
Second Quarter	$72.00	$50.76
Third Quarter	$93.84	$69.00
Fourth Quarter	$128.49	$80.40

On February 19, 2014, the last reported sales price per share of our ordinary shares was $170.28 per share.

Holders of Ordinary Shares

As of February 19, 2014, there were three holders of record of our ordinary shares. Because substantially all 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

No cash dividends have ever been declared or paid on the common equity to date by Jazz Pharmaceuticals, Inc. or us, and we do not currently 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." In addition, the terms of our credit agreement restrict our ability to make certain restricted payments, including dividends and other distributions by us in respect of our ordinary shares, subject to a general exception for dividends and other restricted payments up to $30 million and another exception for restricted payments, so long as there is no default or event of default under our credit agreement and our total leverage ratio (as defined in our amended credit agreement) exceeds 2:1 after giving pro forma effect to the dividend or distribution, permits dividends and other restricted payments up to $100 million plus a formula-based amount that tied our consolidated net income. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our credit agreement and other factors our board of directors deems relevant.

Unregistered Sales of Equity Securities

Except as previously reported in our quarterly reports on Form 10-Q filed with the SEC during the year ended December 31, 2013, there were no unregistered sales of equity securities by us during the year ended December 31, 2013.

Irish Law Matters

As we are an Irish incorporated company, the following matters of Irish law are relevant to the holders of our ordinary shares.

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-

Table of Contents

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, or EU. 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, Republic of Guinea-Bissau, Myanmar/Burma, 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 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 (outside of DTC) will not be subject to DWT provided that the shareholder has completed the appropriate Irish DWT form and this form remains valid. Such shareholders must provide the appropriate Irish DWT form to our transfer agent at least seven business days before the record date for the first dividend payment to which they are entitled.

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.

While the United States/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 United States resident shareholder to rely on the treaty provisions.

Income Tax on Dividends. A shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us unless that shareholder holds our ordinary shares through a branch or agency in Ireland through which a trade is carried on.

A shareholder who is neither resident nor ordinarily resident in Ireland and who is not entitled to an exemption from DWT generally has no additional liability to Irish income tax or to the universal social charge on a dividend from us. The DWT deducted by us discharges the liability to Irish income tax and to the universal social charge. This however is not the case where the shareholder holds the ordinary shares through a branch or agency in Ireland through which a trade is carried on.

Irish Tax on Capital Gains. A shareholder who is neither resident nor ordinarily resident in Ireland and does not hold our ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency should not be within the charge to Irish tax on capital gains on a disposal of our ordinary shares.

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 33% 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

Table of Contents

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 shareholder return on the last day of each year of an investment of $100 in cash as if made on December 31, 2008 in (i) our ordinary shares; (ii) the NASDAQ Composite Index; and (iii) the NASDAQ Biotechnology Index through December 31, 2013. Information set forth in the graph below represents the performance of the Jazz Pharmaceuticals, Inc. common stock from December 31, 2008 until January 17, 2012, the day before the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, or the Azur Merger; and the performance of our ordinary shares from January 18, 2012 through December 31, 2013. Our ordinary shares trade on the same exchange, the NASDAQ Global Select Market (or The NASDAQ Global Market prior to January 3, 2012), and under the same trading symbol, "JAZZ," as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however, we did not declare or pay any dividends on our common stock or ordinary shares during the comparison period. The shareholder 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 shareholder returns.

COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURN(2)

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(1) This section is not "soliciting material", is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Exchange Act, 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

Issuer Purchases of Equity Securities

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our "affiliated purchasers" as defined in Rule 10b-18(a)(3) under the Exchange Act during each fiscal month during the three-month period ended December 31, 2013:

	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (3)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (4)
October 1 - 31, 2013	267,518	$87.85	267,518	$74,136,183
November 1 - 30, 2013	110,855	$95.49	110,855	$63,552,629
December 1 - 31, 2013	—	$—	—	$63,552,629
Total	378,373	$90.09	378,373	

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

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

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

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

Item 6. Selected Financial Data

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. Our historical results are not necessarily indicative of our future results.

We derived the consolidated statements of operations data for the years ended December 31, 2013, 2012 and 2011 and the consolidated balance sheet data as of December 31, 2013 and 2012 from the 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, 2010 and 2009, and the selected consolidated balance sheet data as of December 31, 2011, 2010 and 2009 are derived from audited consolidated financial statements not included in this Annual Report on Form 10-K. The selected consolidated financial data for periods prior to the year ended December 31, 2012 is that of Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries, our predecessor, while the selected consolidated financial data for periods after and including the year ended December 31, 2012 is that of Jazz Pharmaceuticals plc and its consolidated subsidiaries.

Table of Contents

	Year Ended December 31,				
	2013	2012(1)	2011	2010	2009
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net	$865,398	$580,527	$266,518	$170,006	$115,108
Royalties and contract revenues	7,025	5,452	5,759	3,775	13,341
Total revenues	872,423	585,979	272,277	173,781	128,449
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technologies)	102,146	78,425	13,942	13,559	9,638
Selling, general and administrative	304,303	223,882	108,936	68,996	58,652
Research and development	46,620	20,477	14,120	25,612	36,561
Intangible asset amortization	79,042	65,351	7,448	7,825	7,668
Total operating expenses	532,111	388,135	144,446	115,992	112,519
Income from operations	340,312	197,844	127,831	57,789	15,930
Interest expense, net (including $570 and $1,183 for the years ended December 31, 2010 and 2009, respectively, pertaining to a related party)	(26,916)	(16,869)	(1,600)	(12,724)	(22,766)
Foreign currency loss	(1,697)	(3,620)	—	—	—
Loss on extinguishment and modification of debt (including $701 for the year ended December 31, 2010 pertaining to a related party)	(3,749)	—	(1,247)	(12,287)	—
Income (loss) from continuing operations before income tax provision (benefit)	307,950	177,355	124,984	32,778	(6,836)
Income tax provision (benefit)	91,638	(83,794)	—	—	—
Income (loss) from continuing operations	216,312	261,149	124,984	32,778	(6,836)
Income from discontinued operations, net of taxes	—	27,437	—	—	—
Net income (loss)	$216,312	$288,586	$124,984	$32,778	$(6,836)
Basic income (loss) per ordinary share: (2)					
Income (loss) from continuing operations	$3.71	$4.61	$3.01	$0.90	$(0.23)
Income from discontinued operations	—	0.48	—	—	—
Net income (loss)	$3.71	$5.09	$3.01	$0.90	$(0.23)
Diluted income (loss) per ordinary share: (2)					
Income (loss) from continuing operations	$3.51	$4.34	$2.67	$0.83	$(0.23)
Income from discontinued operations	—	0.45	—	—	—
Net income (loss)	$3.51	$4.79	$2.67	$0.83	$(0.23)
Weighted-average number of ordinary shares outstanding: (2)					
Basic	58,298	56,643	41,499	36,343	30,018
Diluted	61,569	60,195	46,798	39,411	30,018

73

Table of Contents

	As of December 31,				
	2013	2012 (1)	2011	2010	2009
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$636,504	$387,196	$157,898	$44,794	$15,595
Working capital (deficit)	660,589	360,034	146,261	14,522	(22,287)
Total assets	2,238,221	1,966,493	253,573	135,729	107,396
Long-term debt, current and non-current (including $6,552 as of December 31, 2009 held by a related party)	549,976	456,761	—	40,693	114,866
Retained earnings (accumulated deficit)	18,532	(61,296)	(349,882)	(474,866)	(507,644)
Total shareholders' equity (deficit)	1,295,534	1,121,292	192,788	30,551	(72,830)

(1) On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in the Azur Merger pursuant to which 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. Jazz Pharmaceuticals, Inc. was treated as the acquiring company in the Azur Merger for accounting purposes, and as a result, the historical consolidated financial statements of Jazz Pharmaceuticals, Inc. became our consolidated financial statements. On June 12, 2012, we completed our acquisition of EUSA Pharma Inc., or the EUSA Acquisition. At the closing of the EUSA Acquisition, we paid $678.4 million in cash, and agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze achieved net sales in the United States of $124.5 million or more in 2013. In 2013, net sales of Erwinaze in the United States exceeded $124.5 million and as a result, we are obligated to make this payment in the first quarter of 2014. The results of operations of the acquired Azur Pharma and EUSA Pharma businesses, along with the estimated fair values of the assets acquired and liabilities assumed in each transaction, are included in our consolidated financial statements since the effective dates of the Azur Merger and the EUSA Acquisition, respectively. We financed the EUSA Acquisition, in part, by entering into our credit agreement, which at the time provided for $475.0 million principal amount of term loans and a $100.0 million revolving credit facility. We used all of the proceeds of those term loans, together with cash on hand, for the EUSA Acquisition.

(2) All references to "ordinary shares" refer to Jazz Pharmaceuticals, Inc.'s common stock with respect to periods prior to the year ended December 31, 2012 and to our ordinary shares with respect to periods after and including the year ended December 31, 2012. Our earnings per share in the periods prior to the year ended December 31, 2012 were not impacted by the Azur Merger since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and converted into the right to receive one ordinary share upon the consummation of the Azur Merger.

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.

Overview

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

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

In 2013 and to date in 2014, we have made substantial progress in the execution of our strategy. Our strong revenue growth continued, primarily from the sales of our lead marketed products, Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in markets outside of the United States. We acquired the product Defitelio® (defibrotide) as a result of our acquisition pursuant to a tender offer of approximately 98% of the outstanding and fully diluted voting securities of Gentium S.p.A., or Gentium, as of February 21, 2014, for an aggregate acquisition cost of approximately $993 million, which we refer to as the Gentium Acquisition. In October 2013, the European Commission granted marketing authorization for Defitelio for the treatment of severe hepatic veno-occlusive disease, or VOD, in adults and children undergoing hematopoietic stem cell transplantation, or HSCT, therapy. We plan to launch Defitelio in selected EU countries during 2014, and expect to begin these efforts in the first half of 2014 after Defitelio's patient registry has been established and is open for recruitment, subject to the receipt of a positive recommendation by the Pharmacovigilance Risk Assessment Committee, or PRAC, at the European Medicines Agency, or EMA, on the patient registry design. We are engaged in pricing and reimbursement submissions in applicable EU countries in preparation for planned launches in these countries. We intend eventually to promote Defitelio in all EU markets where it has marketing authorization. In February 2014, we launched Versacloz™ (clozapine) oral suspension in the United States for treatment-resistant schizophrenia and for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorders.

As a result, going into 2014, we have a portfolio of approved products that address medical needs in the following therapeutic areas, including:

Narcolepsy: Xyrem, the only product approved by the United States Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy;

Hematology/Oncology: Erwinaze, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to E. coli-derived asparaginase, and Defitelio, for the treatment of severe VOD in adults and children undergoing HSCT therapy;

Pain: Prialt® (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for the management of severe chronic pain for patients who are intolerant of or refractory to other treatments; and

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

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

In addition, we made significant progress and investment in expanding our product development pipeline. In February 2013, we licensed rights to JZP-386, an early-stage investigational compound being developed for potential use in

narcolepsy, from Concert Pharmaceuticals, Inc., or Concert. In January 2014, we acquired rights to JZP-110 (formerly known as ADX-N05), a late-stage investigational compound being developed for potential treatment of excessive daytime sleepiness, or EDS, in patients with narcolepsy from Aerial BioPharma LLC, or Aerial, with an upfront payment totaling $125 million. We also intend to pursue development of JZP-110 for EDS in patients with obstructive sleep apnea, or

Table of Contents

OSA. In addition to its existing approved indication in the EU, Defitelio has the potential to be developed for approval in other indications, and for approval in countries outside the EU, including the United States. We are currently assessing what we believe would be the optimal path for potential approval of defibrotide in the United States. Finally, we are conducting ongoing trials involving Asparec™ (mPEG-r-crisantaspase), a pegylated recombinant Erwinia asparaginase for the treatment of patients with ALL with E. coli asparaginase hypersensitivity, and Leukotac™ (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft versus host disease, or GvHD.

Our development pipeline projects also include line extensions for existing products and the generation of additional clinical data for existing products. We plan to conduct a clinical trial to further evaluate the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase.

For 2014 and beyond, we expect that our research and development expenses will increase substantially from historical levels, particularly as we initiate our various planned clinical trials and development work.

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

The Gentium Acquisition was carried out pursuant to a tender offer agreement that we entered into with a wholly-owned subsidiary of ours, as purchaser, and Gentium. On December 23, 2013, we launched a tender offer for all of Gentium's ordinary shares and American Depositary Shares, or ADSs, at a purchase price of $57.00 per share, net to the holders in cash, without interest on the purchase price, less any required withholding taxes. The initial tender offer period expired on January 22, 2014, and we accepted and purchased all of the Gentium ordinary shares and ADSs properly tendered at that time, which represented approximately 69% of the then fully diluted number of Gentium ordinary shares and ADSs. Following the expiration of the tender offer, and in accordance with the terms of the tender offer agreement, we commenced a subsequent offering period of the tender offer to acquire all remaining untendered ordinary shares and ADSs. The subsequent offering period expired on February 20, 2014 and we accepted and purchased an additional approximately 29% of the fully diluted Gentium ordinary shares and ADSs properly tendered during the subsequent offering period, resulting in total purchases pursuant to the tender offer of approximately 98% of the fully diluted number of Gentium ordinary shares and ADSs as of February 21, 2014. The acquisition cost of the total number of Gentium ordinary shares and ADSs we purchased pursuant to the tender offer was approximately $993 million. We intend to cause Gentium to seek the voluntary delisting of Gentium ADSs from the NASDAQ Stock Market, or NASDAQ, and the deregistration of Gentium ordinary shares and ADSs under the Securities and Exchange Act of 1934, as amended, or the Exchange Act. We expect that there will not be an active trading market for outstanding ADSs following the delisting.

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

In 2013, we initiated purchases under a share repurchase program for up to $200 million of our ordinary shares. We spent a total of $136.5 million, including commission, to repurchase our ordinary shares under this program in 2013. We suspended our share repurchase program in November 2013 to preserve cash for future business development opportunities, and subject to market conditions and alternative uses of cash, we plan to resume the program in 2014.

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

We anticipate that we will continue to face a number of challenges and risks to our business and our ability to execute our strategy in 2014. For example, while we now have a more diversified product portfolio than in the past, our financial results remain significantly influenced by sales of Xyrem, which accounted for 65.8% of our net product sales for 2013. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its

Table of Contents

approved indications, while remaining focused on ensuring the safe and effective use of the product. We are also focusing on the lifecycle management of Xyrem, including seeking to enhance and enforce our intellectual property rights.

Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, including those discussed in Part I, Item 1A of this Annual Report on Form 10-K. In particular, there are three abbreviated new drug applications, or ANDAs, submitted to the FDA by third parties seeking to market generic versions of Xyrem. We initiated lawsuits against all three third parties, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. Although no trial date for the consolidated case with the first ANDA filer, Roxane Laboratories, Inc., or Roxane, has been scheduled, we anticipate that trial in that case could occur as early as late in the fourth quarter of 2014. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are continuing our efforts on various regulatory matters, including working with the FDA on updated documents that we have submitted to the FDA on our risk management and controlled distribution system for Xyrem, which we refer to as the Xyrem Risk Management Program. We are engaged in ongoing communications with the FDA with respect to our risk evaluation and mitigation strategies, or REMS, documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA has notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiate dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we will initiate dispute resolution procedures with the FDA by the end of February 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

In January 2014, the FDA held an initial meeting with us and current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). We also expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared system REMS for Xyrem (sodium oxybate), licensing or sharing our REMS, or the FDA's response to a certification that a third party had been unable to obtain a license.

Our financial results are increasingly influenced by sales of our second largest product, Erwinaze/Erwinase, which have continued to grow. Sales of Erwinaze/Erwinase accounted for 20.1% of our net product sales in 2013. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing research and development activities. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of risks and uncertainties, including those discussed in Part I, Item 1A of this Annual Report on Form 10-K. In particular, a key challenge to our ability to maintain the current sales level and continue to increase sales is our need to assure sufficient supply of Erwinaze on a timely basis. We have limited inventory of Erwinaze, and, during 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. In the past, we have experienced a disruption of supply of Erwinase in the European market due to manufacturing challenges, including shortages related to the failure of a batch to meet certain specifications in 2013, and we may experience similar or other manufacturing challenges in the future. If our continued efforts to avoid supply shortages are not

successful, we could experience Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and limit our potential future maintenance and growth of the market for this product. In addition, while we continue to work with the manufacturer of Erwinaze to evaluate potential steps to increase the supply of Erwinaze over the longer term to address expected growing worldwide demand, our ability to increase sales of Erwinaze may be limited by our ability to obtain an increased supply of the product.

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

- the challenges of protecting our intellectual property rights;

Table of Contents

- delays or problems in the supply or manufacture of our products, particularly because we maintain limited inventories of certain products, including products for which our supply demands are growing, and we are dependent on single source suppliers to continue to meet our ongoing commercial needs;
- the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to health care cost containment and other austerity measures in the United States and worldwide, and in particular the need to maintain reimbursement for Xyrem in the United States and obtain appropriate pricing approvals in order to launch Defitelio in certain EU countries which represent a significant market opportunity for Defitelio;
- the ongoing regulation and oversight by the FDA, the U.S. Drug Enforcement Administration, or DEA, and non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, adverse event reporting and product recalls or withdrawals;
- the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors, and in particular the successful commercial launch of Defitelio in the EU throughout 2014;
- the challenges inherent in the integration of the business of Gentium with our historic business, including the increase in geographic dispersion among our centers of operation and taking on the operation of a manufacturing plant;
- the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval, especially as we continue to undertake increased activities, and make growing investment in, our product pipeline development projects;
- our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business; and
- possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations, which have increased significantly as a result of, among other things, the Gentium Acquisition and the acquisition of JZP-110.

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

Results of Operations

The following discussions of our results of continuing operations exclude the results related to the women's health business sold in 2012 (see "Income from Discontinued Operations, Net of Taxes" below for more information). This business has been segregated from continuing operations and reflected as a discontinued operation for the 2012 period. The following table presents revenues and expenses from continuing operations for the years ended December 31, 2013, 2012 and 2011 (amounts in thousands):

	2013	Change	2012 (1)	Change	2011
Product sales, net	$865,398	49 %	$580,527	118 %	$266,518
Royalties and contract revenues	7,025	29 %	5,452	(5)%	5,759
Cost of product sales (excluding amortization of acquired developed technologies)	102,146	30 %	78,425	463 %	13,942
Selling, general and administrative	304,303	36 %	223,882	106 %	108,936
Research and development	46,620	128 %	20,477	45 %	14,120
Intangible asset amortization	79,042	21 %	65,351	777 %	7,448
Interest expense, net	26,916	60 %	16,869	954 %	1,600
Foreign currency loss	1,697	(53)%	3,620	N/A(2)	—
Loss on extinguishment and modification of debt	3,749	N/A(2)	—	N/A(2)	1,247
Income tax provision (benefit)	91,638	N/A(2)	(83,794)	N/A(2)	—

(1) Our financial results include the financial results of the historic Azur Pharma and EUSA Pharma businesses since the completion of the Azur Merger on January 18, 2012 and the EUSA Acquisition on June 12, 2012.
(2) Comparison to prior period is not meaningful.

Table of Contents

Revenues

The following table presents product sales, royalties and contract revenues, and total revenues for the years ended December 31, 2013, 2012 and 2011 (amounts in thousands):

	2013	Change		2012	Change		2011
Xyrem	$569,113	50	%	$378,663	62	%	$233,348
Erwinaze/Erwinase	174,251	142	%	72,083	N/A(1)		—
Prialt	27,103	3	%	26,360	N/A(1)		—
Psychiatry	49,226	(36	)%	76,489	131	%	33,170
Other	45,705	70	%	26,932	N/A(1)		—
Product sales, net	865,398	49	%	580,527	118	%	266,518
Royalties and contract revenues	7,025	29	%	5,452	(5	%)	5,759
Total revenues	$872,423	49	%	$585,979	115	%	$272,277

(1)Comparison to prior period is not meaningful.

Product Sales, Net

Xyrem product sales increased in 2013 and 2012 compared to the immediately preceding years, primarily due to higher average net selling prices in the 2013 and 2012 periods and, to a lesser extent, increases in sales volume. Price increases in 2013 and 2012 were based on market analysis. Xyrem product sales volumes increased by 12% and 11% in 2013 and 2012, respectively, compared to the immediately preceding years. The sales volume increases in both periods were driven by an increase in the average number of patients on Xyrem and by a greater number of Xyrem patients who refilled their Xyrem prescriptions on schedule and who remained on therapy, which we believe resulted from our efforts to increase physician knowledge about Xyrem and to improve patient support services. Recently, we have seen higher growth in sales volume from new or previously infrequent physician prescribers who treat narcolepsy. The sales volume increase in the 2012 period was also impacted by the deployment of a dedicated Xyrem sales force to increase physician awareness of narcolepsy and its diagnosis. We acquired Erwinaze/Erwinase in the EUSA Acquisition in June 2012. Erwinaze/Erwinase product sales increased in 2013 compared to 2012 primarily due to the inclusion of product sales for the full reporting period in 2013. On a pro forma basis, Erwinaze/Erwinase product sales increased by 32% in 2013 compared to 2012, primarily due to an increase in sales volume and to a lesser extent, a price increase in January 2013. The sales volume increase was driven primarily by a growth in new treatment sites prescribing Erwinaze as well as existing treatment sites identifying additional ALL patients with hypersensitivity to E. coli-derived asparaginase. Prialt product sales increased by 3% in 2013 compared to 2012. Psychiatry product sales decreased in 2013 compared to 2012 due to the launch of a generic version of Luvox CR® (fluvoxamine maleate) in 2013 and, to a lesser extent, the continued impact of the sale of the authorized generic product for FazaClo LD. Psychiatry product sales increased in 2012 compared to 2011, primarily due to the acquisition of FazaClo LD and FazaClo HD in January 2012 and, to a lesser extent, an increase in Luvox CR product sales. Luvox CR product sales increased in 2012 compared to 2011 due to price increases, partially offset by a decrease in sales volumes of 3%. We expect total product sales will increase in 2014 over 2013, primarily due to growth in sales of Xyrem and Erwinaze/Erwinase and the inclusion of product sales resulting from the Gentium Acquisition, partially offset by decreases in sales of certain other products.

Royalties and Contract Revenues

Royalties and contract revenues increased in 2013 compared to 2012 due to royalties from the acquired EUSA Pharma business. We expect royalties and contract revenues in 2014 to be consistent with 2013.

Cost of Product Sales

Cost of product sales increased in 2013 compared to 2012, primarily due to increased sales, partially offset by a decrease in acquisition accounting inventory fair value step-up adjustments. Cost of product sales increased in 2012 compared to 2011, primarily due to cost of product sales in relation to products acquired in the Azur Merger and the EUSA Acquisition, including acquisition accounting inventory fair value step-up adjustments of $16.8 million in 2012. Gross margins as a percentage of net product sales were 88.2%, 86.5% and 94.8% in 2013, 2012 and 2011,

respectively. The increase in our gross margin percentage in 2013 as compared to 2012 was primarily due to a decrease in acquisition accounting inventory fair value step-up adjustments of $13.0 million in 2013 compared to 2012. The decrease in our gross margin percentage in 2012 as compared to 2011 was primarily due to the acquisition accounting inventory fair value step-up adjustments and also due to the impact of our product mix in 2012. The gross margins on products acquired during 2012 were lower than the gross margins earned on our legacy

Table of Contents

products. We expect our gross margin percentage to increase slightly in 2014 compared to 2013, primarily driven by a change in product mix.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in 2013 compared to 2012, primarily due to an increase in salary and benefit related expenses (including share-based compensation expense) of $47.8 million, driven in most part by the expansion of our business; an increase in the change in fair value of the contingent consideration payable of $15.5 million; an increase in sales and promotional expenses of $10.8 million; and an increase in facility and maintenance expenses of $7.2 million; partially offset by decreases in transaction, integration and restructuring expenses of $13.9 million. Selling, general and administrative expenses were higher in 2012 compared to 2011 primarily due to an increase in salary and benefit related headcount expenses (including share-based compensation) of $49.0 million driven primarily by increased headcount following the Azur Merger in January 2012 and the EUSA Acquisition in June 2012; an increase in sales and promotional expenses of $12.8 million; an increase in transaction, integration and restructuring expenses of $10.4 million; an increase in professional and service fees of $15.2 million; and an increase in travel, facility and maintenance expenses of $15.5 million. We expect that selling, general and administrative expenses will be higher in 2014 than in 2013 due to increased headcount to support our larger, global organization, an increase in direct marketing spend on key products and the inclusion of expenses resulting from the Gentium Acquisition.

Research and Development Expenses

Research and development expenses consist primarily of personnel expenses, costs related to clinical studies and outside services, and other research and development costs. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Clinical study and outside services costs relate primarily to clinical studies performed by clinical research organizations, materials and supplies, and other third party fees. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. We do not track fully-burdened research and development expenses on a project-by-project basis. We manage our research and development expenses by identifying the research and development activities that we anticipate will be performed during a given period and then prioritizing efforts based on our assessment of what development activities are important to our business and have a reasonable probability of success, and by dynamically allocating resources accordingly. We also continually review our development pipeline projects and the status of their development and, as necessary, reallocate resources among our development pipeline projects that we believe will best support the future growth of our business.

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

	Year Ended December 31,		
	2013	2012	2011
Personnel expenses	$22,019	$10,432	10,581
Clinical studies and outside services	21,373	8,566	2,145
Other	3,228	1,479	1,394
Total	$46,620	$20,477	$14,120

Research and development expenses increased by $26.1 million in 2013 compared to 2012 primarily due to increased clinical studies and outside services costs of $12.8 million and increased personnel expenses of $11.6 million due to a 40% increase in headcount. Clinical studies and outside services expenses in 2013 included upfront license fees of $5.0 million, primarily in connection with our licensing of JZP-386 from Concert, with no similar expense in 2012. Clinical studies and outside services costs increased in 2013 compared to 2012, primarily due to an increase in costs incurred to develop new product candidates that we acquired in the EUSA Acquisition, in addition to an increase in costs related to the development of line extensions for existing products and the generation of additional clinical data. Research and development expenses increased by $6.4 million in 2012 compared to 2011, primarily due to increased clinical studies and outside services costs related to the generation of additional clinical data and the development of line extensions for existing products, and to a lesser extent, costs incurred to develop new product candidates that we

acquired in the EUSA Acquisition and the Azur Merger. Personnel expenses and other research and development expenses in 2012 were consistent with 2011.

Table of Contents

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

Intangible Asset Amortization

We acquired finite-lived intangible assets in connection with the Azur Merger and the EUSA Acquisition that are expected to be amortized over their useful economic lives of two to 15 years. The increase in amortization expense in 2013 compared to 2012 was primarily due to the inclusion of a full year of amortization expense relating to the intangible assets acquired in the EUSA Acquisition. The amortization of the intangible assets acquired in the Azur Merger and the EUSA Acquisition accounted for all of the increase in amortization expense in 2012 compared to 2011. During 2011, our intangible assets consisted primarily of developed technology related to Xyrem and Luvox CR. As a result of the Gentium Acquisition, we expect to record significant intangible assets and accordingly we expect intangible asset amortization to increase significantly in 2014.

Interest Expense, Net

Interest expense, net increased by $10.0 million in 2013 compared to 2012 primarily due to a larger debt balance, with the inclusion of interest expense on the term loans we obtained under our credit agreement in June 2012 and on the term loans we obtained in connection with the amendment of our credit agreement in June 2013. As of December 31, 2013, $554.4 million principal amount of term loans was outstanding and the interest rate on these term loans was 3.5%. Interest expense, net increased in 2012 compared to 2011 primarily due to a larger debt balance. In July 2011, we fully repaid a term loan outstanding at that time. In January 2014, in connection with the Gentium Acquisition, we incurred an additional $650.0 million in secured debt, including $350.0 million of incremental term loans and $300.0 million of revolving loans. Accordingly, we expect interest expense will be higher in 2014 compared to 2013 due to the increase in our debt balance.

Foreign Currency Loss

The foreign currency loss in 2013 and 2012 related to the translation of foreign currency monetary assets and liabilities, including intercompany balances.

Loss on Extinguishment and Modification of Debt

We recorded a loss of $3.7 million in 2013 in connection with the June 2013 refinancing of the term loans under our credit agreement. This was comprised of $2.7 million related to the expensing of unamortized deferred financing costs and unamortized original issue discount associated with extinguished debt and $1.0 million related to new third party fees associated with modified debt. In 2011, as a result of the repayment of a prior term loan and the termination of a prior 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.

Income Tax Provision (Benefit)

During 2013, we recognized an income tax provision of $91.6 million. Our 2013 effective tax rate from continuing operations was 29.8%. During 2012, we recognized an income tax benefit of $83.8 million relating to the United States, Ireland and other foreign jurisdictions. This tax benefit included a deferred tax benefit of $113.9 million, offset by an income tax provision of $30.1 million. The deferred tax benefit included a benefit of $104.2 million, primarily attributable to the release of a valuation allowance against substantially all of our U.S. federal and state deferred tax assets. Management determined that it was more likely than not that these deferred tax assets would be recoverable and the related valuation allowance was no longer needed based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2012, including an evaluation of cumulative income in recent years, future sources of taxable income, and significant risks and uncertainties related to our business. The 2013 effective tax rate was higher than the Irish statutory rate of 12.5%, primarily due to income taxable at a rate higher than the Irish statutory rate, certain uncertain tax positions, current year losses in some jurisdictions for which no tax benefit is available and various expenses not deductible for tax purposes, partially offset by benefits from certain

originating income tax credits. The 2012 effective income tax rate on continuing activities before utilization of our U.S. federal net operating loss carryforwards, or NOLs, and tax credit carryforwards and release in valuation allowance in 2012 of 42.5% was higher than the Irish statutory rate of 12.5% due to a number of factors, including income taxable at a rate higher than the Irish statutory rate, losses in certain tax jurisdictions for which no tax benefit is available and

Table of Contents

various expenses not deductible for tax purposes. The decrease in the effective tax rate in 2013 compared to 2012 was primarily due to changes in income mix among the various jurisdictions in which we operate, as well as higher taxes in 2012 relating to acquisition restructuring.

During 2011, we had operations only in the United States and made no provision for income taxes due to our utilization of our NOLs to offset both regular taxable income and alternative minimum taxable income and to our utilization of deferred state tax benefits.

Income from Discontinued Operations, Net of Taxes

In 2012, we sold our women's health business to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl, or collectively, Meda, for $97.6 million, including $2.6 million for certain inventory transferred to Meda upon the closing of the sale, less transaction costs of $3.7 million. As part of the transaction, Meda purchased six women's health products from us. As part of the sale, approximately 60 employees who directly supported the women's health business became Meda employees. We recorded a non-recurring gain on the sale of $35.2 million.

Net revenue and income from discontinued operations were as follows (in thousands):

	Year Ended December 31, 2012
Product sales, net	$20,873
Loss from discontinued operations before income taxes (1)	$(5,787)
Income tax expense (1)	(2,020)
Loss from discontinued operations, net of taxes	(7,807)
Gain on sale of discontinued operations (2)	35,244
Income from discontinued operations, net of taxes	$27,437

(1) The income tax expense relates to profits generated by the women's health business in 2012 which are attributable to the United States.

(2) The gain on sale of discontinued operations was not impacted by income taxes as the value attributable to the women's health business was held in a non-taxable jurisdiction.

Non-GAAP Financial Measures

To supplement our financial results presented on a U.S. generally accepted accounting principles, or GAAP, basis, we use certain non-GAAP, also referred to as adjusted or non-GAAP adjusted, financial measures as shown in the table and footnotes below. We believe that each of these non-GAAP financial measures is helpful in understanding our past financial performance and potential future results, particularly in light of the effect of various acquisition and divestiture transactions effected by the company. They are not meant to be considered in isolation or as a substitute for comparable GAAP measures, and should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP. Our management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate our business and make operating decisions. Compensation of our executives is based in part on the performance of our business based on certain of these non-GAAP financial measures. In addition, we believe that the presentation of these non-GAAP financial measures is useful to investors because it enhances the ability of investors to compare our results from period to period and allows for greater transparency with respect to key financial metrics we use in making operating decisions, and also because our investors and analysts regularly use them to model and track our financial performance. Investors should note that these non-GAAP financial measures are not prepared under any comprehensive set of accounting rules or principles and do not reflect all of the amounts associated with our results of operations as determined in accordance with GAAP. Investors should also note that these non-GAAP financial measures have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. In addition, from time to time in the future there

may be other items that we may exclude for the purposes of our non-GAAP financial measures; likewise, we may in the future cease to exclude items that we have historically excluded for the purpose of our non-GAAP financial measures. Because of the non-standardized definitions, the non-GAAP financial measures used in this Annual Report on Form 10-K may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by our competitors and other companies. Adjusted net income measures exclude from GAAP income from continuing operations, as applicable, intangible asset amortization, share-based compensation expense, acquisition accounting inventory fair value step-up adjustments, transaction and integration costs, restructuring charges, change in fair value of contingent consideration, upfront license fees, depreciation expense, loss on extinguishment and modification of debt and other non-cash expense (income), and adjust the income tax provision to the estimated amount of taxes payable in cash.

Table of Contents

A reconciliation of GAAP reported income from continuing operations to adjusted net income, a non-GAAP financial measure, and related per share amounts is as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2013	2012	2011
GAAP reported income from continuing operations	$216,312	$261,149	$124,984
Intangible asset amortization	79,042	65,351	7,448
Share-based compensation expense	44,551	23,006	20,704
Acquisition accounting inventory fair value step-up adjustments	3,826	16,794	—
Transaction and integration costs	6,240	18,821	11,245
Restructuring charges	1,457	2,789	—
Change in fair value of contingent consideration	15,200	(300)	—
Upfront license fees	4,988	—	—
Depreciation	3,048	—	—
Loss on extinguishment and modification of debt	3,749	—	1,247
Other non-cash expense	4,591	2,860	(744)
Income tax adjustments (1)	5,253	4,171	—
Valuation allowance release (2)	—	(104,247)	—
Non-GAAP adjusted net income (3)	$388,257	$290,394	$164,884
GAAP reported income from continuing operations per diluted share	$3.51	$4.34	$2.67
Non-GAAP adjusted net income per diluted share (3)	$6.31	$4.82	$3.52
Shares used in computing GAAP reported income from continuing operations and non-GAAP adjusted net income per diluted share amounts (4)	61,569	60,195	46,798

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

(2) Reversal of valuation allowance against deferred tax assets, primarily in the United States.

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

(4) All references to “share” or “shares” in this table refer to Jazz Pharmaceuticals plc’s ordinary shares with respect to 2013 and 2012 and to Jazz Pharmaceuticals, Inc.’s common stock with respect to 2011. GAAP reported income from continuing operations per diluted share and adjusted net income per diluted share in 2011 were not impacted by the Azur Merger in 2012 since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and automatically converted into and became the right to receive one ordinary share upon the consummation of the Azur Merger.

Liquidity and Capital Resources

As of December 31, 2013, we had cash and cash equivalents of $636.5 million, borrowing availability under a $200.0 million revolving credit facility and $554.4 million principal amount of term loans outstanding. During 2013, 2012 and 2011 we generated cash flows from operations of $283.6 million, $249.8 million and $151.6 million, respectively, and we expect to continue to generate positive cash flow from operations. In January 2014, we made an upfront payment totaling $125.0 million to Aerial under an asset purchase agreement to acquire the worldwide development, manufacturing and commercial rights to JZP-110 (other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights). In January 2014, we amended our credit agreement to provide for $350.0 million of incremental term loans, a tranche of term loans that refinanced the approximately $554.4 million aggregate principal amount of term loans previously outstanding, and a $425.0 million revolving credit facility that replaced our $200.0 million revolving credit facility. We used the proceeds from the incremental term loans and loans

under the revolving credit facility, together with cash on hand, to purchase approximately 98% of the outstanding and fully diluted Gentium ordinary shares and ADSs properly tendered and accepted as of February 21, 2014, for an acquisition cost of approximately $993 million.

We believe that our existing cash balances, cash we expect to generate from operations and funds remaining available under our revolving credit facility will be sufficient to fund our operations, to fund our share repurchase program and to meet our existing obligations for the foreseeable future, including our obligations under our current credit agreement, which include

Table of Contents

$904.4 million aggregate principal amount of term loans and $300.0 million of loans currently outstanding under the revolving credit facility, and our obligation to make a contingent consideration payment of $50.0 million in connection with the EUSA Acquisition as a result of Erwinaze achieving U.S. net sales of greater than $124.5 million in 2013. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses, as well as the other factors set forth in Part I, Item 1A of this Annual Report on Form 10-K under the headings "Xyrem is our largest selling product, and our inability to maintain or increase sales of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects," "If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected," "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to those restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem," and "To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business." Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we will need to commit substantial resources to one or more of product acquisition and in-licensing, product development and clinical trials of product candidates, and expansion of our commercial, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue new operations or the expansion of our existing operations. For example, in February 2014, we announced that we had commenced construction of a manufacturing and development facility in Ireland, and we expect to invest approximately €45 to €50 million ($61 to $68 million) to build and open the facility. Accordingly, we may again seek to raise additional funds to license or acquire additional products, product candidates or companies, to expand our operations or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders, and the consent of the lenders under our current credit agreement could be required for certain potential financings.

In May 2013, our board of directors authorized a share repurchase program pursuant to which we may repurchase a number of ordinary shares having an aggregate repurchase price of up to $200 million, exclusive of any brokerage commissions. The authorization became effective immediately and has no set expiration date. Under this authorization, we may repurchase our ordinary shares through open market purchases, privately negotiated purchases or a combination of these transactions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the current credit agreement, corporate and regulatory requirements and market conditions. Share repurchases may be suspended or discontinued at any time without prior notice. We initiated purchases under this program in May 2013. In 2013, we spent a total of $136.5 million to repurchase 1.8 million of our ordinary shares at an average total purchase price, including commissions, of $74.67 per share. All ordinary shares repurchased by the company were canceled. As of December 31, 2013, the remaining amount authorized under the share repurchase program was $63.6 million. We suspended our share repurchase program in November 2013 to preserve cash for future business development opportunities, and subject to market conditions and alternative uses of cash, we plan to resume the program in 2014.

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

	Year Ended December 31,		
	2013	2012	2011
Net cash provided by operating activities	$283,616	$249,752	$151,596

Net cash used in investing activities	(11,276)	(395,294)	(81,232)
Net cash provided by (used in) financing activities	(24,029)	448,530	(33,082)
Effect of exchange rates on cash and cash equivalents	997	2,132	—
Net increase in cash and cash equivalents	$249,308	$305,120	$37,282

Net cash provided by operating activities of $283.6 million in 2013 related to net income of $216.3 million, adjusted for non-cash items of $148.3 million primarily related to intangible asset amortization, share-based compensation expense and the change in fair value of contingent consideration. This was partially offset by $81.0 million of net cash outflow related to changes in operating assets and liabilities which included an increase in accounts receivable of $48.8 million primarily related to a pre-negotiated change in payment terms under a long-term contract with one large customer in connection with the

Table of Contents

elimination of a prompt pay discount as well as the impact of income tax payments. The revised payment terms will continue to result in higher accounts receivable balances in future periods that will reduce net cash from operating activities in those periods. However, we do not anticipate that the change in payment terms will result in potential collectability difficulties nor do we expect that the change will materially impact our liquidity. Net cash provided by operating activities of $249.8 million in 2012 related to net income of $288.6 million, offset by non-cash items of $33.7 million primarily related to deferred income taxes, and by a net cash outflow of $5.2 million related to changes in operating assets and liabilities. Net cash provided by operating activities of $151.6 million in 2011 related to net income of $125.0 million, adjusted for non-cash items of $30.3 million primarily related to share-based compensation expense. This was partially offset by $3.7 million of net cash outflow related to changes in operating assets and liabilities.

Net cash used in investing activities in 2013 related to purchases of property and equipment and acquisition of intangible assets. Net cash used in investing activities in 2012 primarily related to funding the EUSA Acquisition, partially offset by net proceeds of $93.9 million from the sale of our women's health business and net proceeds from the sales and maturities of investments of $75.8 million. 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 financing activities in 2013 primarily related to repayments totaling $465.9 million primarily for the full principal amount outstanding under the original term loans, $136.5 million used to repurchase our ordinary shares under our share repurchase program and payments totaling $5.6 million of income tax withholdings on behalf of employees related to the net share settlement of vested RSUs, partially offset by net proceeds of $553.4 million from our term loans under the June 2013 amended credit agreement and proceeds of $30.7 million from employee equity incentive and purchase plans and exercise of warrants. Net cash provided by financing activities in 2012 primarily related to net proceeds of $450.9 million from the original term loans and proceeds of $25.0 million from employee equity incentive and purchase plans and exercise of warrants, partially offset by payments totaling $25.3 million of income tax withholdings on behalf of certain employees related to the net share settlement of exercised share options in connection with the Azur Merger. 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 equity incentive and purchase plans and exercise of warrants.

Credit Agreement

As discussed above, we entered into our credit agreement in July 2012 in connection with the EUSA Acquisition, and we subsequently amended the credit agreement in July 2013 and January 2014. As of December 31, 2013, $554.4 million principal amount of term loans was outstanding under the credit agreement. After giving effect to the January 2014 amendment, the credit agreement provided for $904.4 million principal amount of term loans and a $425.0 million revolving credit facility. The term loans under the credit agreement have the same June 12, 2018 maturity date that was applicable to the refinanced term loans and the loans under the revolving credit facility have the same June 12, 2017 maturity date that was applicable to the prior revolving credit facility.

The term loans bear interest, at our option, at a rate equal to either the London Interbank Offered Rate (LIBOR), plus an applicable margin of 2.50% per annum (subject to a 0.75% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 1.50% per annum (subject to a 1.75% prime rate floor). Borrowings under the revolving credit facility bear interest, at our option, at a rate equal to either LIBOR, plus an applicable margin of 2.50% per annum, or the prime lending rate, plus an applicable margin equal to 1.50% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio.

As a result of the June 2013 amendment, the interest rate margins on the term loans and the revolving loans were reduced by 150 basis points, and as a result of the January 2014 amendment, the interest rate margins on the terms loans were reduced by a further 25 basis points. As of February 19, 2014, the interest rates on the outstanding term

loans was 3.25% and on our borrowings under the revolving credit facility was 2.66%. The interest rates on the term loans and loans under the revolving credit facility are subject to fluctuation based on LIBOR or the prime lending rate, as applicable.

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

We may make voluntary prepayments of principal at any time without payment of a premium except that a 1% premium

Table of Contents

would apply to any repricing of the term loans effected on or prior to July 23, 2014. We are required to make mandatory prepayments of the term loans (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), (3) beginning with the fiscal year ending December 31, 2014, 50% of our excess cash flow as defined in the current credit agreement (subject to decrease to 25% if our secured leverage ratio is equal to or less than 2.25 to 1.00 and greater than 1.25 to 1.00 or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.00), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the term loans are due quarterly beginning in March 2014 and are equal to 1.0% per annum of the original principal amount of $904.4 million with any remaining balance payable on the final maturity date.

Our credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to us and our restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement also contains a financial covenant that requires Jazz Pharmaceuticals plc and its restricted subsidiaries to maintain a maximum secured leverage ratio. We were, as of December 31, 2013, and are currently in compliance with this financial covenant.

Contractual Obligations

The table below presents a summary of our contractual obligations as of December 31, 2013 (in thousands):

	Payments due by period				
Contractual Obligations(1)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Term loan - principal	$554,402	$5,572	$11,144	$537,686	$—
Term loan - interest (2)	85,685	19,599	38,658	27,428	—
Purchase obligations (3)	54,456	52,046	850	400	1,160
Operating lease obligations (4)	29,309	9,760	15,546	3,873	130
Revolving credit facility (5)	2,623	760	1,523	340	—
Contingent consideration obligation (6)	50,000	50,000	—	—	—
Total	$776,475	$137,737	$67,721	$569,727	$1,290

(1) This table does not include potential future milestone payment or royalty obligations to third parties under asset purchase, product development and license agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable. On January 13, 2014, we signed a definitive agreement with Aerial under which we acquired rights to JZP-110, a novel compound in clinical development for the treatment of EDS in patients with narcolepsy. Under the agreement, we acquired worldwide development, manufacturing and commercial rights to JZP-110 (other than in certain countries in Asia where SK retains rights). Under the agreement, Aerial received an upfront payment of $125.0 million in January 2014. Aerial and SK are eligible to receive milestone payments up to an aggregate of $272.0 million based on development, regulatory and sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales of JZP-110. Potential future milestone payments to other third parties under other agreements could be up to an aggregate of $286.0 million, of which up to $120.0 million will become due and payable to Perrigo Company plc (formally Elan Pharmaceuticals, Inc.) in tiered contingent payments, with the first such payment becoming due if net sales of Prialt of at least $75.0 million are achieved in a calendar year. The remainder would become due and payable to other third parties upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones, the timing and likelihood of which are not known. We are also obligated under these agreements to pay royalties on net sales of certain products at specified rates, which royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.

(2) The interest rate was 3.5% at December 31, 2013, which we used to estimate interest owed on the term loans outstanding as of December 31, 2013 until the final maturity date in June 2018.

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

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

(5) Our revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.375% and assumed undrawn amounts of $200.0 million to estimate commitment fees owed. No amount was borrowed under the revolving credit facility as of December 31, 2013.

Table of Contents

(6) In 2013, Erwinaze U.S. net sales were greater than $124.5 million and, as a result, we are obligated to make a contingent consideration payment of $50.0 million in the first quarter of 2014.

The table above does not reflect the additional $650.0 million in debt we incurred under our credit agreement in connection with the Gentium Acquisition or the related interest rate adjustment. The table also does not include a fee of $5.0 million we are required to pay our investment banker as a result of the completion of the Gentium Acquisition. In February 2014, we agreed to pay a third party up to approximately €4.2 million ($5.7 million) to carry out the site preparation work needed to initiate construction of a manufacturing facility in Ireland, which is not included in the table above.

No provision for income tax in Ireland has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. Cumulative unremitted earnings of our foreign subsidiaries totaled approximately $664.3 million at December 31, 2013. In the event of the distribution of those earnings in the form of dividends or otherwise, we may be liable for income taxes, subject to an adjustment, if any, for foreign tax credits and foreign withholding taxes payable to certain foreign tax authorities. As of December 31, 2013, it is not practicable to determine the amount of the income tax liability related to these undistributed earnings due to a variety of factors.

As of December 31, 2013, our liability for unrecognized tax benefits amounted to $21.6 million (including interest and penalties). Due to the nature and timing of the ultimate outcome of these uncertain tax positions, we cannot make a reasonably reliable estimate of the amount and period of related future payments, if any. Therefore, our liability has been excluded from the above contractual obligations table. We do not expect a significant tax payment related to these obligations within the next year.

Critical Accounting Policies and Significant Estimates

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 2 of the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K, 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

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

A significant portion of our net product revenues are derived from sales of Xyrem. 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 2013, sales of Xyrem to Express Scripts accounted for 65.5% 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 eight years, product returns to Express Scripts from patients are rare; during 2013, we issued credits totaling less than $0.2 million to Express Scripts for returned product.

Items Deducted from Gross Product Sales. Revenues from sales of products are recorded net of government rebates and rebates under managed care plans, estimated allowances for sales returns, government chargebacks, prompt payment discounts, patient coupon programs, and specialty distributor and wholesaler fees. 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 applicable regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and channel inventory data. We review the adequacy of our provisions for sales deductions on a quarterly basis. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. Because we derive a significant portion 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

Table of Contents

we sold the product through the normal pharmaceutical wholesaler channel as we do with most of our other products. The most significant items deducted from gross product sales where we exercise judgment are rebates, sales returns and chargebacks.

The following table presents the activity and ending balances for our sales-related accruals and allowances (in thousands):

	Rebates payable	Sales Returns Reserve	Chargebacks	Discounts and Distributor Fees	Total
Balance at December 31, 2010	$6,620	$3,539	$12	$1,582	$11,753
Provision	21,742	2,250	451	16,178	40,621
Payments/credits	(17,585)	(1,487)	(443)	(15,993)	(35,508)
Balance at December 31, 2011	10,777	4,302	20	1,767	16,866
Additions relating to acquisitions	8,809	18,833	—	911	28,553
Provision (1)	52,603	9,733	13,072	35,161	110,569
Payments/credits	(46,942)	(6,483)	(10,556)	(34,193)	(98,174)
Balance at December 31, 2012 (2)	25,247	26,385	2,536	3,646	57,814
Provision	66,895	2,836	21,777	51,432	142,940
Payments/credits	(60,584)	(8,111)	(19,903)	(49,188)	(137,786)
Balance at December 31, 2013 (2)	$31,558	$21,110	$4,410	$5,890	$62,968

(1) The 2012 provision includes rebates, sales returns, chargebacks, and discounts and distributor fees related to our discontinued women's health business of $1.2 million, $3.8 million, $0.8 million and $2.4 million, respectively. The women's health business was acquired and disposed of in 2012.
(2) Includes both continuing operations and discontinued operations to date of disposal.

Total items deducted from gross product sales from continuing operations were $142.9 million, $102.4 million and $40.6 million, or 14.2%, 15.0% and 13.2% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2013, 2012 and 2011, respectively. Included in these amounts are immaterial adjustments related to prior-year sales due to changes in estimates. Such amounts represented less than 1% of net product sales for the years ended December 31, 2013, 2012 and 2011.

Rebates

We are subject to rebates on sales made under governmental and managed-care pricing programs in the United States. The largest of these rebates is associated with sales covered by Medicaid. We participate in state government-managed Medicaid programs as well as certain other qualifying federal and state government programs under the terms of which discounts and rebates are provided to participating government entities. We offer rebates and discounts to managed health care organizations in the United States. In estimating our provisions for rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers and group purchasing organizations. We estimate the rebate provision based on historical utilization rates, historical payment experience, new information regarding changes in regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and channel inventory data obtained from our major U.S. wholesalers in accordance with our inventory management agreements. Estimating these rebates is complex, in part due to the time delay between the date of sale and the actual settlement of the liability. We believe that the methodology we use to estimate rebates on product sales made under governmental and managed-care pricing programs is reasonable and appropriate given current facts and circumstances. However, estimates may vary from actual experience.

Rebates from continuing operations were $66.9 million, $51.4 million and $21.7 million, or 6.6%, 7.5% and 7.1% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2013, 2012 and 2011, respectively. Rebates as a percentage of gross product sales decreased in 2013 compared to 2012 primarily due to our exiting certain programs for certain products and the impact of generics on per-unit rebate amounts. Rebates as a percentage of gross product sales increased in 2012 compared to 2011 primarily due to the acquisition of products as part of the Azur Merger which had higher levels of rebates than the products we sold prior to the Azur Merger. We expect that rebates will continue to significantly impact our reported net sales. However, rebates as a percentage of gross product sales are not expected to change materially in 2014 compared to 2013.

Table of Contents

Sales returns

For certain products, we allow customers to return product within a specified period before and after the applicable expiration date and issue credits which may be applied against existing or future invoices. We account for sales returns as a reduction in net revenue at the time a sale is recognized by establishing an accrual in an amount equal to the estimated value of products expected to be returned. The sales return accrual is estimated principally based on historical experience, the level and estimated shelf life of inventory in the distribution channel, our return policy and expected future market events including generic competition.

Sales returns from continuing operations were $2.8 million, $5.9 million and $2.3 million, or 0.3%, 0.9% and 0.7% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2013, 2012 and 2011, respectively. Sales returns as a percentage of gross product sales in 2013 were lower compared to 2012 primarily due to a reduction in the sales returns reserve rate for certain products as a result of lower than anticipated product returns and decreased sales of products for which we have historically experienced higher levels of sales returns. Sales returns as a percentage of gross product sales in 2012 were relatively consistent with 2011. While sales returns will continue to impact our reported net product sales, sales returns as a percentage of gross product sales in 2014 are expected to remain consistent with 2013.

Chargebacks

We participate in chargeback programs with a number of entities, principally the U.S. Department of Defense, the U.S. Department of Veterans Affairs and other public parties, under which pricing on products below wholesalers' list prices is provided to participating entities. These entities purchase product through wholesalers at the lower negotiated price and the wholesalers charge back to us the difference between their acquisition cost and the lower negotiated price. We record the difference as allowances against accounts receivable. We determine our estimate of the chargebacks provision primarily based on historical experience on a product and program basis, current contract prices under the chargeback programs and channel inventory data.

Chargebacks from continuing operations were $21.8 million, $12.3 million and $0.5 million, or 2.2%, 1.8% and 0.1% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2013, 2012 and 2011, respectively. Chargebacks as a percentage of gross product sales increased in 2013 compared to 2012 primarily due to products acquired as part of the EUSA Acquisition being included for the full year. Chargebacks as a percentage of gross product sales increased in 2012 compared to 2011 primarily due to the acquisition of products as part of the EUSA Acquisition that have significantly higher levels of chargebacks. Prior to the EUSA Acquisition in June 2012, chargebacks were minimal. As a result of the products we acquired in the EUSA Acquisition, particularly Erwinaze, chargebacks are expected to continue to significantly impact our reported net product sales. Chargebacks as a percentage of gross product sales are not expected to change materially in 2014 compared to 2013.

Discounts and distributor fees

Discounts and distributor fees comprise prompt payment discounts, patient coupon programs and specialty distributor and wholesaler fees. We offer customers a cash discount on gross product sales as an incentive for prompt payment. We estimate provisions for prompt pay discounts based on contractual sales terms with customers and historical payment experience. To help patients afford our products, we have various programs to assist them, including patient assistance programs, a free product voucher program and co-pay coupon programs for certain products. We estimate provisions for these programs primarily based on expected program utilization, adjusted as necessary to reflect our actual experience on a product and program basis. Specialty distributor and wholesaler fees comprise fees for distribution of our products. We estimate provisions for distributor and wholesaler fees primarily based on sales

volumes and contractual terms with our distributors.

Discounts and distributor fees from continuing operations were $51.4 million, $32.8 million and $16.2 million, or 5.1%, 4.8% and 5.3% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2013, 2012 and 2011, respectively. Discounts and distributor fees as a percentage of gross product sales increased in 2013 compared to 2012 primarily due to increased patient coupon programs partially offset by decreased wholesaler dispensing fees and prompt payment discounts. Discounts and distributor fees as a percentage of gross product sales decreased in 2012 compared to 2011 primarily due to increased revenues from products for which distributor and wholesaler fees are either fixed or variable based on factors other than the level of gross product sales, which was partially offset by increased patient coupon programs. We expect that discounts and distributor fees as a whole will continue to significantly impact our reported net

Table of Contents

product sales. In this regard, discounts and distributor fees as a percentage of gross product sales are expected to increase slightly in 2014 compared to 2013 due primarily to an increase in patient coupon programs.

Goodwill and Intangible Assets

Goodwill

Goodwill represents the excess of the acquisition consideration 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. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then in the second step, the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. We have determined the fair value of our single reporting unit to be equal to our market capitalization, as determined by our traded share price, plus a control premium. The control premium used was based on a review of such premiums identified in recent acquisitions of companies of similar size and in similar industries. We performed our annual goodwill impairment test in October 2013 and concluded that goodwill was not impaired as the fair value of the reporting unit significantly exceeded its carrying amount, including goodwill. As of December 31, 2013, we had $450.5 million of goodwill primarily resulting from the Azur Merger on January 18, 2012 and the EUSA Acquisition on June 12, 2012.

Intangible Assets

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

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;
- estimating future cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates and probability rates by project.

We believe the fair values that we assign to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates. No assurance can be given, however, that the underlying assumptions used to estimate expected cash flows will transpire as estimated. In addition, we are required to estimate the period of time over which to amortize the intangible assets, which requires significant judgment.

Our finite-lived intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from two to 15 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. Intangible assets with finite lives are reviewed for impairment whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a product in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. 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.

IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. If the carrying value of the assets is not expected to be recovered,

the assets are written down to their estimated fair values.

As of December 31, 2013, we had $778.1 million of finite-lived intangible assets and $34.3 million of IPR&D assets primarily related to the marketed products and the IPR&D projects that we acquired in the Azur Merger and the EUSA Acquisition. We did not recognize an impairment charge related to our intangible assets during 2013, 2012 or 2011. Please refer to the footnotes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further

Table of Contents

information about our intangible assets and the remaining useful lives of our finite-lived intangible assets as of December 31, 2013.

Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis 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. We provide a valuation allowance when it is more-likely-than-not that deferred tax assets will not be realized.

Our most significant tax jurisdictions are Ireland, the United States and France. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations and the likelihood of settlement related to tax audit issues. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, the impact of accounting for share-based compensation, changes in our international organization, likelihood of settlement, and changes in overall levels of income before taxes.

Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence, including cumulative income in recent fiscal years, our forecast of future taxable income exclusive of reversing temporary differences and significant risks and uncertainties related to our business. In determining future taxable income, we are responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage our underlying business. Based on available objective evidence at December 31, 2012, we reversed the valuation allowance recorded against substantially all of our deferred tax assets in the United States, resulting in a tax benefit of $104.2 million. Management determined that a valuation allowance was no longer needed on these deferred tax assets based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2012, including an evaluation of cumulative income in recent years, our forecast of future sources of taxable income exclusive of reversing temporary differences, and significant risks and uncertainties related to our business. We continue to maintain a valuation allowance against certain other deferred tax assets where realizability is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowances to the extent we believe a portion will not be realized. This determination depends on a variety of factors, some of which are subjective, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. If we determine that the deferred tax assets are not realizable in a future period, we would record material changes to income tax expense in that period.

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. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate uncertain tax positions on a quarterly basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the more-likely-than-not threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews. We also accrue for potential interest and

penalties related to unrecognized tax benefits in income tax provision (benefit).

Contingent Consideration

As part of the EUSA Acquisition, we agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze achieved U.S. net sales of $124.5 million or greater in 2013. Contingent consideration is initially recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings. In 2012, the estimate of fair value contained uncertainties as it involved assumptions about the probability of 2013 U.S. net sales of Erwinaze equaling or exceeding the $124.5 million threshold and the discount rate. As of December 31, 2013, the fair value of this contingent

Table of Contents

consideration liability was $50.0 million, reflecting the achievement of the Erwinaze U.S. net sales milestone in the fourth quarter of 2013. We expect to pay this contingent consideration in the first quarter of 2014.

Share-Based Compensation

We have elected to use the Black-Scholes option pricing model to calculate the fair value of share 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 share options was estimated using the following assumptions:

	Year Ended December 31,		
	2013	2012	2011
Volatility	58%	64%	72%
Expected term (years)	4.4	4.6	5.2
Range of risk-free rates	0.5-1.4%	0.5-1.1%	0.0-2.7%
Expected dividend yield	— %	— %	— %

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 share option grants represents the weighted-average period the awards are expected to remain outstanding. We estimated the weighted-average expected term based on historical exercise data.

Since 2012, we rely only on a blend of the historical and implied volatilities of our own ordinary shares to determine expected volatility for share option grants because our trading history exceeds the expected term of the share options. In addition, we use a single volatility estimate for each share option grant. The weighted average volatility is determined by calculating the weighted average of volatilities for all share options granted in a given year. Prior to 2012, we used a blend of the historical volatility and implied volatility of our ordinary shares, as well as the historical volatility of a peer group, to determine expected volatility for share option grants, and we used the implied volatility of our ordinary shares for grants under our ESPP. We included consideration of the historical volatility of a peer group to estimate expected volatility for share option grants since the trading history of our ordinary shares was less than the expected term of the share options.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2013-11, “Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists”, or ASU No. 2013-11, which concludes that, under certain circumstances, unrecognized tax benefits should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. ASU No. 2013-11 is effective for us beginning January 1, 2014. We do not anticipate that the adoption of this standard will have a material impact on our financial position.

In March 2013, the FASB issued ASU No. 2013-05, “Parent’s Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity”, or ASU No. 2013-05. The objective of ASU No. 2013-05 is to resolve the diversity in practice regarding the release into net income of the cumulative translation adjustment upon derecognition of a subsidiary or group of assets within a foreign entity. ASU No. 2013-05 is effective for us beginning January 1, 2014. We do not anticipate that the adoption of this standard will have a material impact on our results of operations or financial position, absent any material transactions involving the derecognition of subsidiaries or groups of assets within a foreign entity.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Related Parties

In 2013, we entered into an underwriting agreement with an underwriter and certain selling shareholders, pursuant to which the selling shareholders sold to the underwriter 5.4 million of our ordinary shares, resulting in aggregate gross proceeds to the selling shareholders of approximately $314.4 million, before deducting underwriting discounts, commissions and other offering expenses. The selling shareholders included entities affiliated with certain members of our board of directors and one of our directors. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering and, consistent with our obligations under existing registration rights agreements with those shareholders, we paid expenses of approximately $0.5 million in connection with the offering. In 2012, in connection with the Azur Merger, we assumed a lease for office space in Dublin, Ireland. The lease agreement was with Seamus Mulligan, the former Chief Executive Officer of Azur Pharma, who is a member of our board of directors.

Table of Contents

Rentals paid on this lease amounted to $0.3 million in 2012. In November 2012, we terminated this lease at a cost of $1.2 million, which was the carrying value of our above market lease liability. There was no resulting gain or loss on the lease termination.

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

In 2011, Azur Pharma entered into an agreement with Circ Pharma Limited/Circ Pharma Research and Development Limited, or Circ, companies controlled by Seamus Mulligan, whereby Azur Pharma obtained an option to license certain rights and assets in relation to Tramadol (a chronotherapeutic formulation) and to conduct certain development activities. Azur Pharma paid Circ $0.3 million for this option in 2011. In 2012, we terminated the agreement at no cost.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. The primary objectives of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including United States federal government and federal agency securities, corporate bonds or commercial paper issued by United States corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, and tax-exempt obligations of states, agencies and municipalities in the United States. Our cash equivalents as of December 31, 2013 consisted of time deposits which are not subject to significant interest rate risk.

We are exposed to risks associated with changes in interest rates in connection with our term loans and borrowings under our revolving credit facility. Our indebtedness under our term loans is subject to LIBOR or base rate floors of 0.75% and 1.75%, respectively. We have elected to have the terms loans and borrowings under the revolving credit facility bear interest based on LIBOR (as opposed to the prime lending rate). Currently LIBOR is below the floor of 0.75%, and therefore an increase in interest rates would only impact our net interest expense on our term loans to the extent LIBOR exceeds the floor. Based on indebtedness under our term loans of $904.4 million as of February 19, 2014, a 1.0% change in interest rates, above the LIBOR floor, would increase net interest expense on our term loans for 2014 by approximately $8.6 million. Borrowings under our revolving credit facility are not subject to a LIBOR floor. Based on indebtedness under our revolving credit facility of $300.0 million as of February 19, 2014, a 1.0% change in interest rates would increase net interest expense on our revolving loan borrowings for 2014 by approximately $2.9 million.

Foreign Exchange Risk. We have significant operations in Europe as well as in the United States. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive income in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposures are related to our subsidiaries that have functional currencies denominated in the Euro and the British Pound. A 10% strengthening/(weakening) in the rates used to translate the results of our

foreign subsidiaries would have increased/(decreased) net income for the year ended December 31, 2013 by approximately $2.5 million.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in the foreign currency loss in the consolidated statements of income. At December 31, 2013, our primary exposure to transaction risk related to British Pound net monetary assets held by subsidiaries with a Euro functional currency. At December 31, 2013, a 10% strengthening/(weakening) in the British Pound against the Euro would have increased/(decreased) net income by approximately $2.0 million.

Table of Contents

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements as listed below are included in this Annual Report on Form 10-K as pages F-1 through F-40.

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 our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) 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 our disclosure controls and procedures were effective as of December 31, 2013.
Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.
Changes in Internal Control over Financial Reporting. During the quarter ended December 31, 2013, there were no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.
Management's Report on Internal Control over Financial Reporting. The following report is provided by management in respect of our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act):

1. Our management is responsible for establishing and maintaining adequate internal control over financial reporting.
2. Our management used the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO framework (1992), 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 our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our 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 our internal control over financial reporting as of December 31, 2013 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. KPMG, our independent registered public accounting firm, has audited the consolidated financial statements of Jazz Pharmaceuticals plc as of and for the year ended December 31, 2013, included herein, and has issued an audit report on our internal control over financial reporting which is included below.

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Jazz Pharmaceuticals plc

We have audited Jazz Pharmaceuticals plc's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Jazz Pharmaceuticals plc'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, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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 plc maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Jazz Pharmaceuticals plc and subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2013, and the related financial statement schedule, and our report dated February 25, 2014 expressed an unqualified opinion on those consolidated financial statements and the related financial statement schedule.

/s/ KPMG
Dublin, Ireland
February 25, 2014

Table of Contents

Item 9B. Other Information
Not applicable.

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 2014 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 included in the section entitled "Proposal 1—Election of Directors" in the proxy statement for our 2014 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 included in the section entitled "Executive Officers" in the proxy statement for our 2014 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 is to be included in the section entitled "Corporate Governance and Board Matters" in the proxy statement for our 2014 annual general meeting of shareholders. Such information is incorporated herein by reference. Information regarding compliance with Section 16(a) of the Exchange Act is to be included in the section entitled "Section 16(a) Beneficial Ownership Reporting Compliance" in our proxy statement for our 2014 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. The Code of Conduct is available on our website at 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, Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland. We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Conduct by posting such information on our website at the website address and location specified above.

Item 11. Executive Compensation
The information required by this item is to be included in our proxy statement for our 2014 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 2014 annual general meeting of shareholders under the section entitled "Equity Compensation Plan Information" and is incorporated herein by reference. The information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our proxy statement for our 2014 annual general meeting of shareholders under the section entitled "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by reference.

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 2014 annual general meeting of shareholders under the sections entitled “Certain Relationships and Related Transactions” and “Corporate Governance and Board Matters—Independence of the Board of Directors” and is incorporated herein by reference.

Table of Contents

Item 14. Principal Accountant Fees and Services

The information required by this item is to be included in our proxy statement for our 2014 annual general meeting of shareholders under the section entitled "Proposal 2-Approval of Appointment of Independent Auditors and Authorize the Audit Committee to Determine their 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 plc is filed as part of this Annual Report on Form 10-K on page F-40 and should be read in conjunction with the consolidated financial statements of Jazz Pharmaceuticals plc.

Schedule II: Valuation and Qualifying Accounts

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:

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500) filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
2.5	Asset Purchase Agreement, dated as of September 5, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals International II Limited, Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 15, 2012).
2.6	Tender Offer Agreement, dated December 19, 2013, by and among Jazz Pharmaceuticals Public Limited Company, Jazz Pharmaceuticals Italy S.r.l. and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K/A (File No. 001-33500), as filed with the SEC on December 20, 2013).
2.7†	

	Asset Purchase Agreement, dated January 13, 2014, by and among Jazz Pharmaceuticals International III Limited, Aerial BioPharma, LLC and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 13, 2014).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).

Table of Contents

4.1	Reference is made to Exhibit 3.1.
4.2A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500), for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008).
4.2D	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. on July 7, 2009 (incorporated herein by reference to Exhibit 4.6 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.5A	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).
4.5B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1†	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).
10.2†	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).
10.3†	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).
10.4	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).

Table of Contents

10.5†	Royalty Bearing License Agreement and Supply Agreement Re Erwinia-Derived Asparaginase, dated July 22, 2005, between the Health Protection Agency and EUSA Pharma SAS (formerly OPi, S.A.), as amended on each of December 22, 2009, March 23, 2012 and August 8, 2012 (incorporated herein by reference to Exhibit 10.11 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q/A (File No. 001-33500), as filed with the SEC on August 9, 2012).
10.6	Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., the Lenders and Barclays Bank PLC, as Administrative Agent, Collateral Agent, Swing Line Lender and L/C Issuer (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
10.7	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).
10.8	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).
10.9	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 (incorporated herein by reference to Exhibit 10.31 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.10	Lease, dated May 8, 2012, by and between John Ronan and Castle Cove Property Developments Limited and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.11+	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).
10.12+	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).
10.13+	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).
10.14+	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).
10.15+	Offer Letter from Jazz Pharmaceuticals, Inc. to Suzanne Sawochka Hooper (incorporated herein by reference to Exhibit 10.19 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on May 8, 2012).
10.16+	Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.17+	Amendment to Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).

10.18+	Noncompetition Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.19A+	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).
10.19B+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.3B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
10.19C+	Form of Notice of Grant of Stock Options and Form of Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27C in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).

Table of Contents

10.19D+	Form of Notice of Grant of Stock Options and Form of Option Agreement (Irish) under Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27D in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.19E+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27E in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.19F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27F in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.19G+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.19H+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.20A+	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).
10.20B+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.39B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
10.20C+	Form of Option Grant Notice and Form of Stock Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.20D+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.20E+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.28E in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.20F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.20G+	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 (incorporated herein by reference to Exhibit 10.10 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).

10.20H+	Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.28H in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.20I+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of U.S. Option Grant Notice and Form of U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.20J+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of U.S. Restricted Stock Unit Award Grant Notice and Form of U.S. Restricted Stock Unit Award Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.20K+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
101	

Table of Contents

10.20L+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.21+	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).
10.22A+	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).
10.22B+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.30B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.22C+	Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved August 1, 2013) (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.23A+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 10.31A in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.23B+	Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Sub-Plan Governing Purchase Rights to Participants in the Republic of Ireland (incorporated by reference herein to Exhibit 10.4C in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2012, as filed with the SEC on August 7, 2012).
10.24A+	Jazz Pharmaceuticals plc Cash Bonus Plan, (incorporated herein by reference to Exhibit 10.33 in the annual report on Form 10-K/A (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.24B+	Jazz Pharmaceuticals plc Cash Bonus Plan for U.S. Affiliates (incorporated herein by reference to Exhibit 10.32B in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.24C+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2013) (incorporated herein by reference to Exhibit 10.32C in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.24D+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2014).
10.25A+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (incorporated herein by reference to Exhibit 10.34 in the annual report on Form 10-K/A (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on April 27, 2012).
10.25B+	Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.26+	Jazz Pharmaceuticals plc 2012 Non-Employee Director Compensation Arrangements (incorporated herein by reference to Exhibit 10.32 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).

10.27+	Jazz Pharmaceuticals plc 2012 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.28+	Jazz Pharmaceuticals plc 2013 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2013, as filed with the SEC on May 7, 2013).
10.29	Amendment No. 1, dated as of June 13, 2013, to the Original Credit Agreement and related Guaranty, by and among Jazz Pharmaceuticals, Inc., Jazz Financing I Limited and Jazz Pharmaceuticals Ireland Limited, as borrowers, Jazz Pharmaceuticals plc, as guarantor, the Lenders thereto and Barclays Bank PLC, as Administrative Agent, Collateral Agent, L/C Issuer and Swing Line Lender (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 13, 2013).

Table of Contents

10.30+	Jazz Pharmaceuticals plc Non-Employee Director Compensation Policy (approved August 1, 2013 (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.31	Amended and Restated Commitment Letter, dated as of January 6, 2014, by and between Jazz Pharmaceuticals plc, Barclays Bank PLC, J.P. Morgan Securities LLC, JPMorgan Chase Bank, N.A., Merrill Lynch Pierce, Fenner & Smith Incorporated, Bank of America, N.A., Citigroup Global Markets Inc., Morgan Stanley Senior Funding, Inc., Royal Bank of Canada, DNB Bank ASA and DNB Capital Markets, Inc. (incorporated herein by reference to Exhibit 99.(B)(1) in Jazz Pharmaceuticals plc's tender offer statement on Schedule TO, as amended, as filed with the SEC on January 7, 2014).
10.32#	Amendment No. 2, dated as of January 23, 2014, to the Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Financing I Limited and Jazz Pharmaceuticals Ireland Limited, as borrowers, Jazz Pharmaceuticals Public Limited Company, as guarantor, the Lenders thereto and Barclays Bank PLC, as Administrative Agent, Collateral Agent, L/C Issuer and Swing Line Lender.
21.1	Subsidiaries of Jazz Pharmaceuticals plc.
23.1	Consent of KPMG, Independent Registered Public Accounting Firm.
23.2	Consent of Ernst & Young LLP, 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.

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

This exhibit replaces the exhibit previously filed as 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 24, 2014.

* 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.

Table of Contents

SIGNATURES

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

Date: February 25, 2014

Jazz Pharmaceuticals Public Limited Company
(Registrant)
/s/ BRUCE C. COZADD
Bruce C. Cozadd
Chairman and Chief Executive Officer and Director
(Principal Executive Officer)

/s/ KATHRYN E. FALBERG
Kathryn E. Falberg
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

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

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, Suzanne Sawochka Hooper 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 Bruce C. Cozadd	Chairman, Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2014
/s/ KATHRYN E. FALBERG Kathryn E. Falberg	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 25, 2014
/s/ KAREN J. WILSON Karen J. Wilson	Senior Vice President, Finance (Principal Accounting Officer)	February 25, 2014
/s/ PAUL L. BERNS Paul L. Berns	Director	February 25, 2014
/s/ PATRICK G. ENRIGHT Patrick G. Enright	Director	February 25, 2014
/s/ PETER GRAY Peter Gray	Director	February 25, 2014
/s/ HEATHER ANN MCSHARRY Heather Ann McSharry	Director	February 25, 2014
/s/ SEAMUS C. MULLIGAN Seamus C. Mulligan	Director	February 25, 2014
/s/ KENNETH W. O'KEEFE Kenneth W. O'Keefe	Director	February 25, 2014
/s/ NORBERT G. RIEDEL, PH.D. Norbert G. Riedel, Ph.D.	Director	February 25, 2014
/s/ CATHERINE A. SOHN, PHARM.D. Catherine A. Sohn, Pharm.D.	Director	February 25, 2014
/s/ RICK E WINNINGHAM Rick E Winningham	Director	February 25, 2014

Table of Contents

Report of KPMG, Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Jazz Pharmaceuticals plc

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals plc and subsidiaries (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2013. In connection with our audit of the consolidated financial statements, we also have audited the financial statement schedule at Item 15(a)2 for the years ended December 31, 2013 and 2012. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Jazz Pharmaceuticals plc and subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for the years ended December 31, 2013 and 2012, when considered in relation to the basic consolidated 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 plc's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 25, 2014 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG
Dublin, Ireland
February 25, 2014

Table of Contents

Report of Ernst & Young LLP, 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 statements of operations, comprehensive income, stockholders' equity and cash flows of Jazz Pharmaceuticals, Inc. for the year ended December 31, 2011. Our audit also included the financial statement schedule for 2011 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 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 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of its operations and its cash flows for the year 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.

/s/ Ernst & Young LLP
Redwood City, California
February 28, 2012

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	December 31, 2013	2012
ASSETS		
Current assets:		
Cash and cash equivalents	$636,504	$387,196
Accounts receivable, net of allowances of $3,680 and $3,779 at December 31, 2013 and 2012, respectively	124,805	75,480
Inventories	28,669	26,525
Prepaid expenses	7,183	7,445
Deferred tax assets, net	33,613	35,813
Other current assets	33,843	19,113
Total current assets	864,617	551,572
Property and equipment, net	14,246	7,281
Intangible assets, net	812,396	869,952
Goodwill	450,456	442,600
Deferred tax assets, net, non-current	74,597	74,850
Deferred financing costs	14,605	16,576
Other non-current assets	7,304	3,662
Total assets	$2,238,221	$1,966,493
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$21,005	$15,887
Accrued liabilities	119,718	104,666
Current portion of long-term debt	5,572	29,688
Income taxes payable	336	39,884
Contingent consideration	50,000	—
Deferred tax liability, net	6,259	275
Deferred revenue	1,138	1,138
Total current liabilities	204,028	191,538
Deferred revenue, non-current	5,718	6,776
Long-term debt, less current portion	544,404	427,073
Contingent consideration, non-current	—	34,800
Deferred tax liability, net, non-current	168,497	178,393
Other non-current liabilities	20,040	6,621
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Ordinary shares, nominal value $0.0001 per share; 300,000 shares authorized; 57,854 and 58,014 shares issued and outstanding at December 31, 2013 and 2012, respectively	6	6
Non-voting euro deferred shares, €0.01 par value per share; 4,000 shares authorized, issued and outstanding at both December 31, 2013 and 2012	55	55
Capital redemption reserve	471	471
Additional paid-in capital	1,220,317	1,151,010
Accumulated other comprehensive income	56,153	31,046
Retained earnings (accumulated deficit)	18,532	(61,296)

Total shareholders' equity	1,295,534	1,121,292
Total liabilities and shareholders' equity	$2,238,221	$1,966,493

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

Table of Contents

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

	Year Ended December 31,		
	2013	2012	2011
Revenues:			
Product sales, net	$865,398	$580,527	$266,518
Royalties and contract revenues	7,025	5,452	5,759
Total revenues	872,423	585,979	272,277
Operating expenses:			
Cost of product sales (excluding amortization of acquired developed technologies)	102,146	78,425	13,942
Selling, general and administrative	304,303	223,882	108,936
Research and development	46,620	20,477	14,120
Intangible asset amortization	79,042	65,351	7,448
Total operating expenses	532,111	388,135	144,446
Income from operations	340,312	197,844	127,831
Interest expense, net	(26,916)	(16,869)	(1,600)
Foreign currency loss	(1,697)	(3,620)	—
Loss on extinguishment and modification of debt	(3,749)	—	(1,247)
Income from continuing operations before income tax provision (benefit)	307,950	177,355	124,984
Income tax provision (benefit)	91,638	(83,794)	—
Income from continuing operations	216,312	261,149	124,984
Income from discontinued operations, net of taxes	—	27,437	—
Net income	$216,312	$288,586	$124,984
Basic income per ordinary share:			
Income from continuing operations	$3.71	$4.61	$3.01
Income from discontinued operations	—	0.48	—
Net income	$3.71	$5.09	$3.01
Diluted income per ordinary share:			
Income from continuing operations	$3.51	$4.34	$2.67
Income from discontinued operations	—	0.45	—
Net income	$3.51	$4.79	$2.67
Weighted-average ordinary shares used in per share computations:			
Basic	58,298	56,643	41,499
Diluted	61,569	60,195	46,798

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

Table of Contents

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

	Year Ended December 31,		
	2013	2012	2011
Net income	$216,312	$288,586	$124,984
Other comprehensive income (loss):			
Foreign currency translation adjustments	25,107	31,046	—
Available-for-sale securities:			
Net unrealized gain (loss) on available-for-sale securities, net of income taxes	—	8	(31)
Reclassification adjustments for gains included in earnings, net of income taxes	—	23	—
Other comprehensive income (loss)	25,107	31,077	(31)
Total comprehensive income	$241,419	$319,663	$124,953
Total comprehensive income arises from:			
Continuing operations	$241,419	$292,226	$124,953
Discontinued operations	—	27,437	—
Total comprehensive income	$241,419	$319,663	$124,953

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

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)

	Ordinary Shares		Non-voting Euro Deferred Shares		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Retained Earnings (Accumulated Deficit)	Total Shareholders' Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2010	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
Other comprehensive loss	—	—	—	—	—	—	(31)	—	(31)
Net income	—	—	—	—	—	—	—	124,984	124,984
Balance at December 31, 2011	42,468	4	—	—	—	542,697	(31)	(349,882)	192,788

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY—(Continued)
(In thousands)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemp-tion	Additional Paid-in	Accumu-lated Other	Retained Earnings	Total
	Shares	Amount	Shares	Amount	Reserve	Capital	Compre-hensive Income	(Accumulated Deficit)	Shareholders' Equity
Balance at December 31, 2011	42,468	$4	—	$—	$ —	$542,697	$ (31)	$ (349,882)	$192,788
Merger with Azur Pharma	12,360	2	4,000	55	471	575,936	—	—	576,464
Issuance costs related to Azur Merger	—	—	—	—	—	(241)	—	—	(241)
Shares issued under directors deferred compensation plan	45	—	—	—	—	—	—	—	—
Issuance of ordinary shares in conjunction with exercise of share options	1,951	—	—	—	—	14,212	—	—	14,212
Issuance of ordinary shares under employee stock purchase plan	151	—	—	—	—	3,707	—	—	3,707
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(25,299)	—	—	(25,299)
Issuance of ordinary shares in conjunction with exercise of warrants	1,039	—	—	—	—	7,084	—	—	7,084
Share-based compensation	—	—	—	—	—	23,129	—	—	23,129
Excess tax benefits from employee share options	—	—	—	—	—	9,785	—	—	9,785
	—	—	—	—	—	—	31,077	—	31,077

Other comprehensive income									
Net income	—	—	—	—	—	—	—	288,586	288,586
Balance at December 31, 2012	58,014	6	4,000	55	471	1,151,010	31,046	(61,296)	1,121,292

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY—(Continued)
(In thousands)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemp-tion Reserve	Additional Paid-in Capital	Accumu-lated Other Compre-hensive Income	Retained Earnings (Accumulated Deficit)	Total Shareholders' Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2012	58,014	$6	4,000	$55	$ 471	$1,151,010	$ 31,046	$ (61,296)	$1,121,292
Issuance of ordinary shares in conjunction with exercise of share options	904	—	—	—	—	20,895	—	—	20,895
Issuance of ordinary shares under employee stock purchase plan	147	—	—	—	—	5,410	—	—	5,410
Issuance of ordinary shares in conjunction with vesting of restricted stock units	146	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(5,590)	—	—	(5,590)
Issuance of ordinary shares in conjunction with exercise of warrants	471	—	—	—	—	4,398	—	—	4,398
Share-based compensation	—	—	—	—	—	44,367	—	—	44,367
Excess tax benefits from employee share options	—	—	—	—	—	(173)	—	—	(173)
Shares repurchased	(1,828)	—	—	—	—	—	—	(136,484)	(136,484)
Other comprehensive income	—	—	—	—	—	—	25,107	—	25,107
Net income	—	—	—	—	—	—	—	216,312	216,312

Balance at December 31, 2013	57,854	$6	4,000	$55	$ 471	$1,220,317	$ 56,153	$ 18,532	$1,295,534

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

Table of Contents

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

	Year Ended December 31,		
	2013	2012	2011
Operating activities			
Net income	$216,312	$288,586	$124,984
Adjustments to reconcile net income to net cash provided by operating activities:			
Amortization of intangible assets	79,042	72,922	7,448
Depreciation	3,048	1,307	379
Loss on disposal of property and equipment	46	163	33
Share-based compensation	44,551	23,006	20,704
Excess tax benefit from share-based compensation	173	(9,785)	—
Acquisition accounting inventory fair value step-up adjustments	3,826	19,939	—
Change in fair value of contingent consideration	15,200	(300)	—
Deferred income taxes	(10,097)	(113,862)	—
Gain on sale of business	—	(35,244)	—
Provision for losses on accounts receivable and inventory	2,446	4,654	59
Loss on extinguishment and modification of debt	3,749	—	1,247
Other non-cash transactions	6,278	3,523	394
Changes in assets and liabilities:			
Accounts receivable	(48,846)	(4,724)	(12,293)
Inventories	(8,516)	1,697	1,239
Prepaid expenses and other current assets	(13,871)	(13,091)	(934)
Other long-term assets	(4,306)	(3,491)	186
Accounts payable	5,089	(7,286)	2,080
Accrued liabilities	14,717	(11,428)	11,211
Income taxes payable	(38,984)	39,340	—
Deferred revenue	(1,061)	(1,205)	(1,273)
Other non-current liabilities	14,820	2,351	(82)
Liability under government settlement	—	(7,320)	(3,786)
Net cash provided by operating activities	283,616	249,752	151,596
Investing activities			
Acquisitions, net of cash acquired	—	(542,531)	—
Purchases of marketable securities	—	(37,443)	(79,886)
Net proceeds from sale of business	—	93,922	—
Proceeds from sale of marketable securities	—	81,246	—
Proceeds from maturities of marketable securities	—	31,988	4,033
Acquisition of intangible assets	(1,300)	—	—
Purchases of property and equipment	(9,976)	(5,976)	(1,279)
Purchase of product rights	—	(16,500)	(4,500)
Decrease in restricted cash	—	—	400
Net cash used in investing activities	(11,276)	(395,294)	(81,232)
Financing activities			
Net proceeds from issuance of debt	553,425	450,916	—
Proceeds from employee equity incentive and purchase plans and exercise of warrants	30,703	25,003	16,419

Share repurchases	(136,484)	—	—
Payment of employee withholding taxes related to share-based awards	(5,590)	(25,299)	—
Excess tax benefit from share-based compensation	(173)	9,785	—
Repayment of long-term debt	(465,910)	(11,875)	(41,668)
Payments of debt extinguishment costs	—	—	(483)
Net repayments under revolving credit facility	—	—	(7,350)
Net cash provided by (used in) financing activities	(24,029)	448,530	(33,082)
Effect of exchange rates on cash and cash equivalents	997	2,132	—
Net increase in cash and cash equivalents	249,308	305,120	37,282
Cash and cash equivalents, at beginning of period	387,196	82,076	44,794
Cash and cash equivalents, at end of period	$636,504	$387,196	$82,076

Table of Contents

JAZZ PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)
(In thousands)

	Year Ended December 31,		
	2013	2012	2011
Supplemental disclosure of cash flow information:			
Cash paid for interest	$18,278	$14,192	$1,621
Cash paid for income taxes	$137,616	$9,143	$—
Non-cash investing activities:			
Acquisition consideration for Azur Merger	$—	$576,464	$—

The consolidated statements of cash flows include the activities of discontinued operations.
The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

JAZZ PHARMACEUTICALS PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

Jazz Pharmaceuticals plc, a public limited company formed under the laws of Ireland, is a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing differentiated products that address unmet medical needs. Our strategy is to continue to create shareholder value by:

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

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, or the Azur Merger, accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company for accounting purposes. As part of the Azur Merger, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Prior to the Azur Merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc.

On June 12, 2012, we completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, which we refer to as the EUSA Acquisition.

In January and February 2014, pursuant to a tender offer, we acquired approximately 98% of the outstanding and fully diluted voting securities of Gentium S.p.A., or Gentium, for an acquisition cost of approximately $993 million, which we refer to as the Gentium Acquisition. Please see Note 20 for additional information regarding this acquisition.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our wholly-owned subsidiaries and intercompany transactions and balances have been eliminated. The results of operations of the acquired Azur Pharma and EUSA Pharma businesses, along with the estimated fair values of the assets acquired and liabilities assumed in each transaction, are included in our consolidated financial statements since the effective dates of the Azur Merger and the EUSA Acquisition, respectively. Certain prior period amounts presented in the accompanying footnotes have been reclassified to conform to current period presentation, as described in Note 4.

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem® (sodium oxybate) oral solution. In 2013, net product sales of Xyrem were $569.1 million, which represented 65.8% of total net product sales. Maintaining or increasing sales of Xyrem in its approved indications is subject to a number of risks and uncertainties, including the potential introduction of generic competition, changed or increased regulatory restrictions, and continued acceptance

of Xyrem as safe and effective by physicians and patients. Three abbreviated new drug applications, or ANDAs, have been filed with the United States Food and Drug Administration, or FDA, by third parties seeking to market generic versions of Xyrem. We initiated lawsuits against all three third parties, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings.

Although no trial date for the consolidated case with the first ANDA filer, Roxane Laboratories, Inc., or Roxane, has been scheduled, we anticipate that trial in that case could occur as early as late in the fourth quarter of 2014. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are continuing our efforts on various regulatory matters, including working with the FDA on updated documents that we have submitted to the FDA on our risk management and controlled distribution system for Xyrem, which we refer to as the Xyrem Risk Management Program. We are engaged in ongoing communications with the FDA with respect to our risk evaluation and mitigation strategies, or REMS, documents for Xyrem, but we have not reached agreement on certain significant terms. For example, we disagree with the FDA's current position that, as part of the current REMS process, the Xyrem deemed REMS should be modified to enable the distribution of Xyrem through more than one pharmacy, or potentially through retail pharmacies and wholesalers, as well as with certain modifications proposed by the FDA that would, in the FDA's view, make the REMS more consistent with the FDA's current practices for REMS documents.

The FDA has notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiate dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we will initiate dispute resolution procedures with the FDA by the end of February 2014. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

In January 2014, the FDA held an initial meeting with us and current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). We also expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared system REMS for Xyrem (sodium oxybate), licensing or sharing our REMS, or the FDA's response to a certification that a third party had been unable to obtain a license.

Our financial results are increasingly influenced by sales of our second largest product, Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in markets outside of the United States, which have continued to grow. In 2013, net product sales of Erwinaze/Erwinase were $174.3 million, which represented 20.1% of total net product sales in 2013. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing research and development activities. However, our ability to successfully and sustainably grow sales of Erwinaze is subject to a number of risks and uncertainties, including the limited population of patients with ALL and the incidence of hypersensitivity reactions to E. coli-derived asparaginase within that population, our ability to obtain approval for the intravenous administration of Erwinaze in the United States, our ability to obtain data on the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase, as well as our need to apply for and receive marketing authorizations, through the EU's mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries. Another significant challenge to maintenance of current sales level and continued growth is our need to ensure sufficient supply of Erwinaze on a timely basis. We have limited inventory of Erwinaze, and, during 2013, our supply of Erwinaze was nearly completely absorbed by demand for the product. In the past, we have experienced a disruption of supply of Erwinase in the European market due to manufacturing challenges, including shortages related to the failure of a batch to meet certain specifications in 2013, and we may experience similar or other manufacturing challenges in the future. If our continued efforts to avoid supply shortages are not successful, we could experience Erwinaze supply interruptions in the future, which could have a material adverse effect on our sales of and revenues from Erwinaze and

limit our potential future maintenance and growth of the market for this product. In addition, while we continue to work with the manufacturer of Erwinaze to evaluate potential steps to increase the supply of Erwinaze over the longer term to address expected growing worldwide demand, our ability to increase sales of Erwinaze may be limited by our ability to obtain an increased supply of the product.

In addition to risks related specifically to Xyrem and Erwinaze, we are subject to other challenges and risks specific to our business, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including: the challenges of protecting our intellectual property rights; delays or problems in the supply or manufacture of our products, particularly because we maintain limited inventories of certain products, including products for which our supply demands are growing, and we are dependent on single source suppliers to continue to meet our ongoing commercial needs; the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging

environment due to, among other things, the attention being paid to health care cost containment and other austerity measures in the United States and worldwide, and in particular the need to maintain reimbursement for Xyrem in the United States and obtain appropriate pricing approvals in order to launch Defitelio® (defibrotide) in certain EU countries which represent a significant market opportunity for Defitelio; the ongoing regulation and oversight by the FDA, the U.S. Drug Enforcement Administration, or DEA, and non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, adverse event reporting and product recalls or withdrawals; the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors, and in particular the successful commercial launch of Defitelio in the EU throughout 2014; the challenges inherent in the integration of the business of Gentium with our historic business, including the increase in geographic dispersion among our centers of operation and taking on the operation of a manufacturing plant; and the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval, especially as we continue to undertake increased activities, and make growing investment in, our product pipeline development projects. Other risks and uncertainties related to our ability to execute on our strategy include: our ability to identify and acquire, in-license or develop additional products or product candidates to grow our business; and possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations, which have increased significantly as a result of, among other things, the Gentium Acquisition and the acquisition of JZP-110.

Business Acquisitions

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

Concentrations of Risk

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

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

Health Group, Inc. which accounted for 9% of gross accounts receivable. As of December 31, 2012, five customers accounted for 78% of gross accounts receivable including Express Scripts which accounted for 51% of gross accounts receivable and Accredo Health Group, Inc. which accounted for 11% of gross accounts receivable.

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

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 accumulated other comprehensive income in shareholders' 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 expense, net in the consolidated statements of income. 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 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. The fair value of inventories acquired included a step-up in the value of inventories of $0.2 million and $4.0 million as of December 31, 2013 and 2012, respectively.

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 range from three to 10 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 expensed as incurred.

Goodwill

Goodwill represents the excess of the acquisition consideration 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. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable.

Intangible Assets

Intangible assets with finite useful lives consist primarily of purchased developed technology and are amortized on a straight-line basis over their estimated useful lives, which range from two to 15 years. The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Intangible assets with finite lives are reviewed for impairment when events or 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.

The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the

asset. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized over their estimated useful lives.

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

Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

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 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.

Revenues from sales of products 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. Provisions for returns, specialty distributor fees, wholesaler fees, government rebates, coupon programs and rebates under managed care plans are included within current liabilities in our consolidated balance sheets. Provisions for government chargebacks and prompt payment discounts are generally shown as a reduction in accounts receivable. 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. Adjustments to estimates for these allowances have not been material.

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. Non-refundable 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, non-refundable 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. Cost of product sales in 2013 and 2012 included $3.8 million and $16.8 million, respectively, of inventory costs associated with the fair value step-up in acquired inventory. Excluded from cost of product sales, as shown on the consolidated statements of income, is amortization of acquired developed technology of $78.8 million, $65.1 million and $7.2 million in 2013, 2012 and 2011, respectively.

Research and Development

Research and development expenses consist primarily of personnel expenses, costs related to clinical studies and outside services, and other research and development costs. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Clinical study and outside services costs relate primarily to clinical studies performed by clinical research organizations, materials and supplies, and other third-party fees. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. 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.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses for 2013, 2012 and 2011 were $1.0 million, $0.7 million and $1.0 million, respectively.

Income Taxes

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis 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. We account for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. A recognized tax position is then measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon settlement. Interest and penalties related to uncertain tax positions are included in the income tax provision (benefit) and classified with the related liability on the consolidated balance sheets.

Foreign Currency

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

Transactions in foreign currencies are translated into the functional currency of the relevant subsidiary at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the relevant functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign currency loss in our consolidated statements of income.

Financing Costs

Deferred financing costs are reported at cost, less accumulated amortization and the related amortization expense is included in interest expense, net in our consolidated statements of income. The carrying amount of debt includes any related unamortized original issue discount.

Contingencies

From time to time, we may become involved in claims and other legal matters arising in the ordinary course of business. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect the amounts and disclosures reported in the consolidated financial statements and accompanying notes. Management bases its estimates on historical experience

and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Net Income per Ordinary Share

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

	Year Ended December 31,		
	2013	2012	2011
Numerator:			
Income from continuing operations	$216,312	$261,149	$124,984
Income from discontinued operations	—	27,437	—
Net income	$216,312	$288,586	$124,984
Denominator:			
Weighted-average ordinary shares - basic	58,298	56,643	41,499
Dilutive effect of employee equity incentive and purchase plans	1,772	1,536	2,715
Dilutive effect of warrants	1,499	2,016	2,584
Weighted-average ordinary shares - diluted	61,569	60,195	46,798
Basic income per ordinary share:			
Income from continuing operations	$3.71	$4.61	$3.01
Income from discontinued operations	—	0.48	—
Net income	$3.71	$5.09	$3.01
Diluted income per ordinary share:			
Income from continuing operations	$3.51	$4.34	$2.67
Income from discontinued operations	—	0.45	—
Net income	$3.51	$4.79	$2.67

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

	Year Ended December 31,		
	2013	2012	2011
Options to purchase ordinary shares and RSUs	1,584	1,506	1,038

All references to “ordinary shares” in the discussion and tables above refer to Jazz Pharmaceuticals plc’s ordinary shares with respect to the years ended December 31, 2013 and 2012 and to Jazz Pharmaceuticals, Inc.’s common stock with respect to the year ended December 31, 2011. Our earnings per share in the year ended December 31, 2011 was not impacted by the Azur Merger in 2012 since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and automatically converted into and became the right to receive one ordinary share upon the consummation of the Azur Merger.

Share-Based Compensation

We account for compensation cost for all share-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. The estimation of share-based 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.

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2013-11, "Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists", or ASU No. 2013-11, which concludes that, under certain circumstances, unrecognized tax benefits should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. ASU No. 2013-11 will be effective for us beginning January 1, 2014. We do not anticipate that the adoption of this standard will have a material impact on our financial position.

In March 2013, the FASB issued ASU No. 2013-05, "Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity", or ASU No. 2013-05. The objective of ASU No. 2013-05 is to resolve the diversity in practice regarding the release into net income of the cumulative translation adjustment upon derecognition of a subsidiary or group of assets within a foreign entity. ASU No. 2013-05 will be effective for us beginning January 1, 2014. We do not anticipate that the adoption of this standard will have a material impact on our results of operations or financial position, absent any material transactions involving the derecognition of subsidiaries or groups of assets within a foreign entity.

3. Fair Value Measurement

Cash and cash equivalents consisted of the following:

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

	December 31, 2012				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents
Cash	$343,548	$—	$—	$343,548	$343,548
Money market funds	43,648	—	—	43,648	43,648
Totals	$387,196	$—	$—	$387,196	$387,196

Cash equivalents are considered available-for-sale. We use the specific-identification method for calculating realized gains and losses on securities sold and include them in interest expense, net in the consolidated statements of income. Proceeds from sales of available-for-sale securities in 2012 were $81.2 million and were used to partially fund the EUSA Acquisition. Gross realized gains and losses in 2012 were insignificant. All available-for-sale securities held as of December 31, 2013 and 2012 were cash equivalents.

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):

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	December 31, 2013		December 31, 2012		
	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Unobservable Inputs (Level 3)	Total Estimated Fair Value
Assets:					
Available-for-sale securities					
Time deposits	$140,514	$140,514	$—	$—	$—
Money market funds	—	—	43,648	—	43,648
Totals	$140,514	$140,514	$43,648	$—	$43,648
Liabilities:					
Contingent consideration	$50,000	$50,000	$—	$34,800	$34,800

As of December 31, 2013, our available-for-sale securities included time deposits which were measured at fair value using Level 2 inputs and their carrying values were approximately equal to their fair values. As of December 31, 2012, our available-for-sale securities included money market funds which were measured at fair value using Level 1 inputs and their carrying values were approximately equal to their fair values. We reviewed trading activity and pricing for these investments as of each 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 the different levels of the fair value hierarchy in 2013 or in 2012 except for the contingent consideration obligation as described below.

As part of the EUSA Acquisition, we agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze achieved U.S. net sales of $124.5 million or greater in 2013. In 2012, the fair value measurement of this contingent consideration obligation was determined using unobservable Level 3 inputs. These inputs included the probability of 2013 U.S. net sales of Erwinaze equaling or exceeding the $124.5 million threshold and the discount rate. In 2013, Erwinaze U.S. net sales were greater than $124.5 million and as a result, we are obligated to make the payment of $50.0 million in the first quarter of 2014.

The change in fair value of the contingent consideration payable was as follows (in thousands):

	Level 3
Balance at December 31, 2012	$34,800
Fair value adjustment recorded within selling, general and administrative expenses	15,200
Balance at December 31, 2013	$50,000

As of December 31, 2013, the principal amount outstanding and estimated fair value of our term loans was $554.4 million and the carrying amount was $550.0 million. The fair value was determined using quotes from the administrative agent of our credit facility that are based on bid/ask prices of our term loan (Level 2). For additional information regarding our term loans please see Note 8.

4. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2013	2012
Raw materials	$4,900	$4,979
Work in process	8,907	5,410

Finished goods	14,862	16,136
Total inventories	$28,669	$26,525

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Inventories of $4.2 million previously classified as raw materials as of December 31, 2012 have been reclassified to work in process to conform to our current period presentation. Inventories included $0.2 million and $4.0 million related to acquisition accounting inventory fair value step-up as of December 31, 2013 and 2012, respectively.

5. Property and Equipment

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

	December 31,	
	2013	2012
Computer software	$7,960	$4,292
Computer equipment	5,610	3,687
Leasehold improvements	4,587	3,899
Construction-in-progress	4,388	1,135
Furniture and fixtures	1,897	1,953
Machinery and equipment	417	94
Subtotal	24,859	15,060
Less accumulated depreciation and amortization	(10,613)	(7,779)
Property and equipment, net	$14,246	$7,281

6. Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2013	2012
Rebates and other sales deductions	$38,772	$29,235
Employee compensation and benefits	31,829	24,900
Sales returns reserve	21,110	26,385
Royalties	6,082	3,271
Professional fees	5,675	2,163
Other	16,250	18,712
Total accrued liabilities	$119,718	$104,666

7. Goodwill and Intangible Assets

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

Balance at December 31, 2012	$442,600
Foreign exchange	7,856
Balance at December 31, 2013	$450,456

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	December 31, 2013				December 31, 2012		
	Remaining Weighted-Average Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies	11.5	$957,089	$ (179,225)	$777,864	$930,834	$ (97,578)	$833,256
Trademarks	1.0	2,600	(2,327)	273	2,600	(2,054)	546
Total finite-lived intangible assets		959,689	(181,552)	778,137	933,434	(99,632)	833,802
Acquired IPR&D assets		34,259	—	34,259	36,150	—	36,150
Total intangible assets		$993,948	$ (181,552)	$812,396	$969,584	$ (99,632)	$869,952

Our two most significant intangible assets are related to Erwinaze/Erwinase, which we acquired in the EUSA Acquisition, and Prialt® (ziconotide) intrathecal infusion, which we acquired in the Azur Merger. The net book values of these assets as of December 31, 2013 were $458.7 million and $199.5 million, respectively.

The increase in the gross carrying amount of intangible assets in 2013 reflects the positive impact of foreign currency exchange which is primarily due to the strengthening of the Euro against the U.S. dollar.

Based on finite-lived intangible assets recorded as of December 31, 2013, and assuming the underlying assets will not be impaired in the future and that we will not change the expected lives of the assets, future amortization costs were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2014	$82,865
2015	76,816
2016	72,486
2017	72,395
2018	72,326
Thereafter	401,249
Total	$778,137

In 2012, we sold the women’s health business, a component of the acquired Azur Pharma business. Intangible assets related to the women’s health business had a net book value of $41.4 million. Please see Note 18 for information regarding discontinued operations.

8. Long-Term Debt

Amendment of Credit Facility and Term Loan Refinancing

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

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Scheduled maturities with respect to the term loans principal outstanding as of December 31, 2013 were as follows (in thousands):

Year ending December 31,	Scheduled Term Loan Maturities
2014	$5,572
2015	5,572
2016	5,572
2017	5,572
2018	532,114
Total	$554,402

The 2013 refinancing of the term loans involved multiple lenders who were considered members of a loan syndicate. In determining whether the refinancing was to be accounted for as a debt extinguishment or modification, we considered whether the creditors remained the same or changed and whether the change in debt terms was substantial. The debt terms were considered substantially different if the present value of the cash flows of the term loans under the credit agreement, as amended, was at least 10% different from the present value of the remaining cash flows of the original term loans, or the 10% Test. We performed a separate 10% Test for each individual creditor participating in the loan syndication. The loans of creditors who did not participate in the refinanced term loans were accounted for as a debt extinguishment. When there was a change in principal balance for individual creditors, in applying the 10% Test, we used the cash flows related to the lowest common principal balance, or the Net Method. Under the Net Method, any principal in excess of a creditor's reinvested principal balance was treated as a new, separate debt issuance, and any decrease in principal was treated as a partial extinguishment of debt.

For debt considered to be extinguished, the unamortized deferred financing costs and unamortized original issue discount associated with the extinguished debt were expensed. For debt considered to be modified, the unamortized deferred financing costs and unamortized original issue discount associated with the modified debt continue to be amortized, new creditor fees were capitalized and new third party fees were expensed. For new creditors, new creditor fees and new third party fees were capitalized. Deferred financing costs of $11.7 million and an original issue discount of $4.9 million were associated with the 2013 refinancing and are being amortized to interest expense using the interest method over the life of the term loans under the credit agreement.

As the borrowing capacity relating to each creditor under the revolving credit facility after giving effect to the June 2013 amendment was greater than that under the original revolving credit facility, unamortized deferred financing costs, new creditor fees and new third party fees, totaling $4.7 million, were associated with the new arrangement and were deferred and are being amortized to interest expense on a straight-line basis over the life of the facility. As of December 31, 2013, we had not borrowed under the revolving credit facility.

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

As of December 31, 2013, the interest rate on the term loans outstanding under the credit agreement was 3.5%. Interest expense associated with these term loans is recorded using the interest method and includes non-cash interest related to the amortization of the debt discount and debt issuance costs. As of December 31, 2013, the effective interest rate on the term loans outstanding was 4.3%. As of December 31, 2013, the current portion of the carrying amount of the term loans outstanding was $5.6 million and the non-current portion was $544.4 million.

In 2011, we terminated a credit agreement and repaid a term loan in full and as a result, 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.

On January 23, 2014, we entered into a second amendment to the credit agreement to provide for (i) a tranche of incremental term loans in the aggregate principal amount of $350.0 million, (ii) a tranche of term loans to refinance

the $554.4 million aggregate principal amount of term loans previously outstanding under the amended credit agreement, or the prior term loans, in their entirety and (iii) a $425.0 million revolving credit facility that replaces the $200.0 million revolving credit facility. We used the proceeds from the incremental term loans and $300.0 million of loans under the revolving credit facility together with cash on hand, to purchase the Gentium ordinary stock and American Depositary Shares properly tendered and accepted for payment on the January 22, 2014 expiration of the initial tender offer period relating to the Gentium Acquisition.

Please see Note 20 for additional information regarding this acquisition. The January 2014 amendment also reduced the interest rate margins on the terms loans by 25 basis points.

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

The term loans under the credit agreement, as amended in January 2014, bear interest, at our option, at a rate equal to either the LIBOR, plus an applicable margin of 2.50% per annum (subject to a 0.75% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 1.50% per annum (subject to a 1.75% prime rate floor). Borrowings under the new revolving credit facility bear interest, at our option, at a rate equal to either the LIBOR, plus an applicable margin of 2.50% per annum, or the prime lending rate, plus an applicable margin equal to 1.50% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio.

The borrowers' obligations under the credit agreement, as amended in January 2014, and any hedging or cash management obligations entered into with a lender or an affiliate of a lender are guaranteed by us and certain of our subsidiaries and are secured by substantially all of our, the borrower's and the subsidiary guarantors' assets.

We may make voluntary prepayments of principal at any time without payment of a premium except that a 1% premium
would apply to any repricing of the term loans effected on or prior to July 23, 2014. We are required to make mandatory prepayments of the term loans (without payment of a premium) with (1) net cash proceeds from certain non-ordinary course asset sales (subject to reinvestment rights and other exceptions), (2) net cash proceeds from issuances of debt (other than certain permitted debt), (3) beginning with the fiscal year ending December 31, 2014, 50% of our excess cash flow as defined in the amended credit agreement (subject to decrease to 25% if our secured leverage ratio is equal to or less than 2.25 to 1.00 and greater than 1.25 to 1.00 or 0% if our secured leverage ratio is equal to or less than 1.25 to 1.00), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

Principal repayments of the term loans are due quarterly beginning in March 2014 and are equal to 1.0% per annum of the original principal amount of $904.4 million with any remaining balance payable on the final maturity date.

The credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to Jazz Pharmaceuticals plc and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement contains a financial covenant that requires Jazz Pharmaceuticals plc and its restricted subsidiaries to maintain a maximum secured leverage ratio. We were, as of December 31, 2013, and are currently in compliance with this financial covenant.

9. Deferred Revenue

We have an agreement with UCB under which UCB has the right to market Xyrem for certain indications in various countries outside of the United States. We recognized contract revenues of $1.1 million during each of 2013, 2012, and 2011 relating to two upfront payments received from UCB in 2006 totaling $15.0 million. As of December 31, 2013, $6.8 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.

10. 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, 2013 and December 31, 2012. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

We have noncancelable operating leases for our office buildings and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force.

Rent expense under all operating leases was as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Rent expense	$6,213	$3,074	$2,593

Future minimum lease payments under our noncancelable operating leases at December 31, 2013, were as follows (in thousands):

Year ending December 31,	Lease Payments
2014	$9,760
2015	9,131
2016	6,415
2017	3,192
2018	681
Thereafter	130
Total	$29,309

In 2013, we entered into a new operating lease agreement for additional office space in Palo Alto for a term of three years with an option to extend for one additional year and we amended and extended the operating lease for our existing Philadelphia office building for additional space for a term of five years.

As of December 31, 2013, we had $52.0 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

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

Xyrem ANDA Matters: On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleged that all five patents then listed for Xyrem in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. Additional patents covering Xyrem have issued since the original suit was filed, and cases involving these patents have been consolidated with the original action. In December 2013, the District Court permitted Roxane to amend its Answer in the consolidated case to allege additional equitable defenses, and the parties have been given additional time for discovery on those new defenses. Although no trial date for the consolidated case has been scheduled, based on the current scheduling order, we anticipate that trial in the consolidated case could occur as early as late in the fourth quarter of 2014. However, the actual timing of events in this litigation may be significantly earlier or later than contemplated by the scheduling order, and we cannot predict the timing or outcome

of events in this litigation. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA had been

stayed until April 18, 2013, which was 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification, but that stay has expired. We cannot predict the timing or outcome of this matter.

On December 10, 2012, we received a Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Amneal's Paragraph IV Certification alleged that seven patents listed for Xyrem in the Orange Book are not infringed by Amneal's proposed generic product. Amneal's Paragraph IV Certification further alleged that an eighth patent listed in the Orange Book for Xyrem is invalid. On December 13, 2012, we received a supplemental Paragraph IV Certification alleging that a ninth patent listed in the Orange Book for Xyrem is invalid. On January 18, 2013, we filed a lawsuit against Amneal in response to Amneal's Paragraph IV Certifications in the District Court. An additional patent covering Xyrem issued since the original suit was filed and the case involving this patent has been consolidated with the original case. We are seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Amneal, FDA approval of Amneal's ANDA will be stayed until the earlier of (i) June 10, 2015, which is 30 months after our receipt of Amneal's Paragraph IV Certification on December 10, 2012, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of this matter.

On November 21, 2013, we received a Paragraph IV Certification from Par Pharmaceutical, Inc., or Par, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. Par's Paragraph IV Certification alleged that ten patents listed in the Orange Book for Xyrem are invalid, unenforceable, and/or will not be infringed by Par's proposed generic product. On December 27, 2013, we filed a lawsuit against Par in the United States District Court, in response to Par's Paragraph IV notice. We are seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Par, FDA approval of Par's ANDA will be stayed until the earlier of (i) May 21, 2016, which is 30 months after our receipt of Par's Paragraph IV Certification on November 21, 2013, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of this matter.

FazaClo ANDA Matters: Azur Pharma received Paragraph IV Certifications from three generics manufacturers, Barr Laboratories, Inc., or Barr, Novel Laboratories, Inc., or Novel, and Mylan Pharmaceuticals, Inc., or Mylan, indicating that ANDAs had been filed with the FDA requesting approval to market generic versions of FazaClo® (clozapine, USP) LD orally disintegrating clozapine tablets. Azur Pharma and CIMA Labs Inc., or CIMA, a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification against Barr on August 21, 2008, against Novel on November 25, 2008, and against Mylan on July 23, 2010. Each case was filed in the United States District Court for the District of Delaware. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product at the end of August 2012. The Novel and Mylan matters have been stayed pending reexamination of the patents in the lawsuits. In September 2013 and January 2014, reexamination certificates were issued for the two patents-in-suit, with the claims of the patents confirmed, and the parties have requested that the stay of litigation be lifted. We cannot predict the timing or outcome of this litigation.

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

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

Shareholder Litigation Matter: In January 2014, we became aware of a purported class action lawsuit filed in the Southern District of New York in connection with the Gentium Acquisition. The lawsuit, captioned Xavion Jyles, Individually and on Behalf of All Others Similarly Situated v. Gentium S.P.A. et al., names Gentium, each of the Gentium's directors, us and

our Italian subsidiary as defendants. The lawsuit alleges, among other things, that Gentium's directors breached their fiduciary duties to Gentium's shareholders in connection with a tender offer agreement that Gentium entered into with us and our Italian subsidiary valuing Gentium ordinary shares and ADSs at $57.00 per share, and that we and our Italian subsidiary violated Sections 14(e) and 20(a) of the Exchange Act by allegedly overseeing Gentium's preparation of an allegedly false and misleading Section 14D-9 Solicitation/Recommendation Statement. The lawsuit seeks, among other relief, class action status, rescission, and unspecified costs, attorneys' fees and other expenses. We cannot predict the timing or outcome of this matter.

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

Other Contingencies

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

11. Shareholders' Equity

Share Repurchase Program

In May 2013, our board of directors authorized a share repurchase program pursuant to which we may repurchase a number of ordinary shares having an aggregate repurchase price of up to $200 million, exclusive of any brokerage commissions. The authorization became effective immediately and has no set expiration date. Under this authorization, we may repurchase our ordinary shares through open market purchases, privately negotiated purchases or a combination of these transactions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the amended credit agreement, corporate and regulatory requirements and market conditions. Share repurchases may be suspended or discontinued at any time without prior notice. We initiated purchases under this program in May 2013. In 2013, we spent a total of $136.5 million to repurchase 1.8 million of our ordinary shares at an average total purchase price, including commissions, of $74.67 per share. All ordinary shares repurchased by the company were canceled. As of December 31, 2013, the remaining amount authorized under the share repurchase program was $63.6 million.

Additional Paid-in Capital

In April 2013, the Irish High Court approved a $1.6 billion reduction of the share premium account of Jazz Pharmaceuticals plc to offset its accumulated deficit, with the resulting reserve to be treated as distributable reserves of our parent company. This transaction impacted our parent company balance sheet only and had no impact on our U.S. GAAP consolidated balance sheet.

Authorized But Unissued Ordinary Shares

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

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	As of December 31, 2013
2011 Equity Incentive Plan	8,917
2007 Equity Incentive Plan	988
2007 Employee Stock Purchase Plan	704
Amended and Restated 2007 Non-Employee Directors Stock Option Plan	374
Amended and Restated Directors Deferred Compensation Plan	183
Exercise of warrants	1,552
Total	12,718

Warrants
As of December 31, 2013, we had ordinary shares issuable under the following warrants (in thousands):

Warrants Issued	Expiration Date	Ordinary Shares	Exercise Price
Warrants issued in 2008 in conjunction with registered direct public offering	July 20, 2014	604	$7.37
Warrants issued in 2009 in conjunction with private placement	July 5, 2016	948	$4.00
		1,552	

The fair values of these warrants were recorded in shareholders' equity when they were originally issued.

12. Comprehensive Income
Comprehensive income includes net income and all changes in shareholders' equity during a period, except for those changes resulting from investments by shareholders or distributions to shareholders.
Accumulated Other Comprehensive Income
The components of accumulated other comprehensive income at December 31, 2013 and December 31, 2012 were as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Income
Balance at December 31, 2012	$31,046	$31,046
Other comprehensive income	25,107	25,107
Balance at December 31, 2013	$56,153	$56,153

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

13. Share-Based Compensation
2011 Equity Incentive Plan
In connection with the Azur Merger, Jazz Pharmaceuticals, Inc.'s board of directors adopted the 2011 Equity Incentive Plan, or the 2011 Plan, in October 2011 and its stockholders approved the 2011 Plan at the special meeting of the stockholders held in December 2011 in connection with the Azur Merger. The 2011 Plan became effective immediately before the consummation of the Azur Merger and was assumed and adopted by us upon the consummation of the Azur Merger. The terms of the 2011 Plan provide for the grant of stock options, stock appreciation rights, restricted stock awards, RSUs, other stock awards, and performance awards that may be settled in cash, shares, or other property. All of the grants under the 2011 Plan were granted to employees and vest ratably over service periods of 4 years and expire no more than 10 years after the date of grant. As of December 31, 2013, a total of

10,945,888 of our ordinary shares had been authorized for issuance under the 2011 Plan. In addition, the share reserve under the 2011 Plan will automatically increase on January 1 of each year through January 1, 2022, by the least of (a) 4.5% of the total number of ordinary shares outstanding on December 31 of the preceding calendar year, (b) 5,000,000 shares, or (c) such lesser number of ordinary shares as determined by our board of directors. On

January 1, 2014, the share reserve under the 2011 Plan automatically increased by 2,603,448 ordinary shares pursuant to this provision.

2007 Equity Incentive Plan

The 2007 Equity Incentive Plan, or the 2007 Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders in connection with its initial public offering, was continued and assumed by us upon consummation of the Azur Merger. The 2007 Plan provided for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, RSUs, stock appreciation rights, performance stock awards and other forms of equity compensation to employees, including officers, non-employee directors and consultants. Prior to the consummation of the Azur Merger, 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 10 years after the date of grant. Effective as of the closing of the Azur Merger on January 18, 2012, the number of shares reserved for issuance under the 2007 Plan was set to 1,000,000 ordinary shares. The share reserve under the 2007 Plan will not automatically increase. Since the Azur Merger, all of the new grants under the 2007 Plan were granted to non-employee directors and vest ratably over service periods of one to three years and expire no more than 10 years after the date of grant.

2007 Employee Stock Purchase Plan

In 2007, Jazz Pharmaceuticals, Inc.'s employees became eligible to participate in the Employee Stock Purchase Plan, or ESPP. The ESPP was amended and restated by Jazz Pharmaceuticals, Inc.'s board of directors in October 2011 and approved by its stockholders in December 2011. The amended and restated ESPP became effective immediately prior to the effective time of the Azur Merger and was assumed by us upon the consummation of the Azur Merger. The amended and restated ESPP allows our eligible employee participants (including employees of any of a parent or subsidiary company if our board of directors designates such company as eligible to participate) to purchase our ordinary shares at a discount of 15% through payroll deductions. The ESPP consists 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 is 175,000 shares. As of December 31, 2013, a total of 2,660,000 of our ordinary shares had been authorized for issuance under the ESPP. The share reserve under the ESPP will automatically increase on January 1 of each year through January 1, 2022, by the least of (a) 1.5% of the total number of ordinary shares outstanding on December 31 of the preceding calendar year, (b) 1,000,000 shares, or (c) such lesser number of ordinary shares as determined by our board of directors. Our compensation committee determined not to automatically increase the share reserve under the ESPP on January 1, 2014.

Amended and Restated 2007 Non-Employee Directors Stock Option Plan

The Amended and Restated 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Option Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders in connection with its initial public offering, was continued and assumed by us upon the consummation of the Azur Merger. Until October 2011, the 2007 Directors Option Plan provided for the automatic grant of nonstatutory stock options to purchase shares of Jazz Pharmaceuticals, Inc.'s common stock to its non-employee directors initially at the time any individual first became a non-employee director, which vest over three years, and then annually over their period of service on its board of directors, which vest over one year. On October 24, 2011, Jazz Pharmaceuticals, Inc.'s board of directors amended the 2007 Directors Option Plan to eliminate all future initial and annual automatic grants so that future automatic grants would not be made that would be subject to the excise tax imposed by Section 4985 of the Internal Revenue Code of 1986, as amended, in connection with the merger with Azur Pharma. Accordingly, all future stock option grants under the 2007 Directors Option Plan will be at the discretion of our board of directors. Since the date of the Azur Merger and as of the date of this report, our board of directors has approved one grant to a non-employee director under the 2007 Directors Option Plan. 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, 2013, a total of 777,713 of our ordinary shares had been authorized for issuance under the 2007 Directors Option Plan. The number of shares

reserved for issuance under the 2007 Directors Plan automatically increases on each January 1, from January 1, 2008 through (and including) January 1, 2017, by the excess of (a) the number of shares subject to options granted, over (b) the number of shares added back to the share reserve, in each case, during the preceding calendar year under the 2007 Directors Plan; provided, that, for any year, the automatic increase may not exceed 200,000 shares and the board of directors may approve a lesser, or no, automatic increase. On January 1, 2014, the share reserve under the 2007 Directors Option Plan automatically increased by 60,000 ordinary shares pursuant to this provision.

Amended and Restated Directors Deferred Compensation Plan

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In May 2007, the Jazz Pharmaceuticals, Inc. board of directors adopted the Directors Deferred Compensation Plan, or the Directors Deferred Plan, which was amended in December 2008 and was then amended and restated in August 2010, and which was continued and assumed by us upon consummation of the Azur Merger. The Directors Deferred Plan allows each non-employee director to elect to defer receipt of all or a portion of his or her annual retainer fees to a future date or dates. Amounts deferred under the Directors Deferred Plan are credited as shares of Jazz Pharmaceuticals, Inc.'s common stock (or our ordinary shares following the Azur Merger) to a phantom stock account, the number of which are based on the amount of the retainer fees deferred divided by the market value of Jazz Pharmaceuticals, Inc.'s common stock (or our ordinary shares following the Azur Merger) on the first trading day of the first open window period following the date the retainer fees are deemed earned. On the 10th business day following the day of separation from the board of directors or the occurrence of a change in control, or as soon thereafter as practical once the non-employee director has provided the necessary information for electronic deposit of the deferred shares, each non-employee director will receive (or commence receiving, depending upon whether the director has elected to receive distributions from his or her phantom stock account in a lump sum or in installments over time) a distribution of his or her phantom stock account, in our ordinary shares (i) reserved under the 2007 Directors Option Plan prior to August 15, 2010 and (ii) from a new reserve of 200,000 shares set up under the Directors Deferred Plan on August 15, 2010. Although we continue to maintain the Directors Deferred Plan, since the consummation of the Azur Merger we have not permitted and will not permit the non-employee directors to defer any annual retainer fees under the Directors Deferred Plan. We recorded no expense in 2013 and in 2012 related to retainer fees earned and deferred, and in 2011 we incurred expense of $0.4 million. As of December 31, 2013, 19,170 of our ordinary shares which were unissued related to retainer fees that were deferred under the Directors Deferred Plan.

Share-Based Compensation

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

	Year Ended December 31,					
	2013		2012		2011	
Grant date fair value	$29.09		$25.28		$17.38	
Volatility	58	%	64	%	72	%
Expected term (years)	4.4		4.6		5.2	
Range of risk-free rates	0.5-1.4%		0.5-1.1%		0.0-2.7%	
Expected dividend yield	—	%	—	%	—	%

Since 2012, we rely on a blend of the historical and implied volatilities of our own ordinary shares to determine expected volatility for share option grants because our trading history exceeds the expected term of the share options. Prior to 2012, we used a blend of the historical volatility and implied volatility of our ordinary shares, as well as the historical volatility of a peer group, to determine expected volatility for share option grants, and we used the implied volatility of our ordinary shares for grants under our ESPP. We included consideration of the historical volatility of a peer group to estimate expected volatility for share option grants since the trading history of our ordinary shares was less than the expected term of the share options. In addition, we use a single volatility estimate for each share option grant. The weighted average volatility is determined by calculating the weighted average of volatilities for all share options granted in a given year.

The expected term of share option grants represents the weighted-average period the awards are expected to remain outstanding and our estimates were based on historical exercise data. 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 share option grants. The expected dividend yield assumption was based on our history and expectation of dividend payouts.

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Share-based compensation expense in continuing operations related to share options, RSUs, ordinary shares credited to the directors' phantom share accounts and grants under our ESPP was as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011(1)
Selling, general and administrative	$35,674	$18,950	$15,592
Research and development	6,673	2,640	4,488
Cost of product sales	2,204	1,416	624
Total share-based compensation expense, pre-tax	44,551	23,006	20,704
Tax benefit from share-based compensation expense	(13,822)	(7,499)	—
Total share-based compensation expense, net of tax	$30,729	$15,507	$20,704

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

We realized tax benefits related to share option exercises of $6.7 million and $18.3 million in 2013 and 2012, respectively, and none in 2011.

Share Options

The following table summarizes information as of December 31, 2013 and activity during 2013 related to our share 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, 2013	4,178	$32.21		
Options granted	1,348	62.46		
Options exercised	(904)	23.13		
Options forfeited	(316)	46.44		
Options expired	—	—		
Outstanding at December 31, 2013	4,306	42.54	7.9	$361,807
Vested and expected to vest at December 31, 2013	3,988	41.53	7.8	339,073
Exercisable at December 31, 2013	1,590	26.09	6.6	159,704

Aggregate intrinsic value shown in the table above is equal to the difference between the exercise price of the underlying share options and the fair value of our ordinary shares for share options that were in the money. The aggregate intrinsic value changes based on the fair market value of our ordinary shares. The aggregate intrinsic value of share options exercised was $46.0 million, $106.5 million and $33.5 million, during 2013, 2012 and 2011, respectively. We issued new ordinary shares upon exercise of share options.

As of December 31, 2013, total compensation cost not yet recognized related to unvested share options was $53.7 million, which is expected to be recognized over a weighted-average period of 2.6 years. As of December 31, 2013, total compensation cost not yet recognized related to grants under the ESPP was $3.0 million, which is expected to be recognized over a weighted-average period of less than one year.

Restricted Stock Units

In 2013, we granted RSUs covering an equal number of our ordinary shares to employees with a weighted-average grant date fair value of $61.80. The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares as of that date. The fair value of the RSUs is recognized as expense ratably over the vesting period

of four years. In 2013, 222,000 RSUs were released with 146,000 ordinary shares issued and 76,000 ordinary shares withheld for tax purposes.

As of December 31, 2013, total compensation cost not yet recognized related to unvested RSUs was $42.8 million, which is expected to be recognized over a weighted-average period of 2.8 years.

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table summarizes information as of December 31, 2013 and activity during 2013 related to our RSUs:

	Number of RSUs (in thousands)	Weighted-Average Grant-Date Fair Value	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2013	956	$49.04		
RSUs granted	585	61.80		
RSUs released	(222)	49.04		
RSUs forfeited	(155)	50.40		
RSUs expired	—	—		
Outstanding at December 31, 2013	1,164	55.28	1.6	$147,333

14. Segment and Other Information

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

	Year Ended December 31,		
	2013	2012	2011
Xyrem	$569,113	$378,663	$233,348
Erwinaze	174,251	72,083	—
Prialt	27,103	26,360	—
Psychiatry	49,226	76,489	33,170
Other	45,705	26,932	—
Product sales, net	865,398	580,527	266,518
Royalties and contract revenues	7,025	5,452	5,759
Total revenues	$872,423	$585,979	$272,277

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

	Year Ended December 31,		
	2013	2012	2011
United States	$792,518	$538,219	$265,718
Europe	61,843	38,590	6,224
All other	18,062	9,170	335
Total revenues	$872,423	$585,979	$272,277

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

	Year Ended December 31,		
	2013	2012	2011
Express Scripts	65%	64%	85%
Accredo	16%	N/A	N/A

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	December 31,	
	2013	2012
Ireland	$5,799	$2,437
United States	7,734	4,451
Other	713	393
Total long-lived assets (1)	$14,246	$7,281

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

15. Income Taxes

The components of income from continuing operations before the income tax provision (benefit) were as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Republic of Ireland	$186,903	$(73,949)	$—
United States	132,855	250,348	124,984
Other	(11,808)	956	—
Total	$307,950	$177,355	$124,984

The following table sets forth the details of the income tax provision (benefit) (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Current			
Republic of Ireland	$17,089	$(10,733)	$—
United States	71,964	33,387	—
Other	12,682	7,414	—
Total current income tax	101,735	30,068	—
Deferred			
Republic of Ireland	8,353	(315)	—
United States	(3,513)	(103,932)	—
Other	(14,937)	(9,615)	—
Total deferred income tax provision (benefit)	(10,097)	(113,862)	—
Total income tax provision (benefit)	$91,638	$(83,794)	$—

During 2013, we recognized an income tax provision of $91.6 million related to tax arising on income in Ireland, the United States and certain other foreign jurisdictions, certain uncertain tax positions and various expenses not deductible for tax purposes. During 2012, we recognized an income tax benefit of $83.8 million which resulted primarily from our reversal of a valuation allowance on most of our U.S. federal and state deferred tax assets, as described below. As discussed in Note 1, in January 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction accounted for as a reverse acquisition and the combined company changed its domicile from the United States to Ireland. During 2011, we had operations only in the United States and made no provision for income taxes due to our utilization of federal net operating loss carryforwards, or NOLs, to offset both regular taxable income and alternative minimum taxable income and to our utilization of deferred state tax benefits for which the related deferred tax assets were offset by a valuation allowance.

The effective tax rate for 2013 of 29.8% was higher than the Irish statutory rate of 12.5% primarily due to income taxable at a rate higher than the Irish statutory rate, certain uncertain tax positions, current year losses in some jurisdictions for which no tax benefit is available, and various expenses not deductible for tax purposes, partially offset by benefits from certain

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

originating income tax credits. In 2012, following the Azur Merger and the change in the combined company's domicile, the statutory income tax rate changed from the U.S. rate of 35.0% to the Irish rate of 12.5%. In June 2012, we completed the EUSA Acquisition, which further expanded our global operations. The 2012 effective income tax rate on continuing activities before utilization of NOLs and tax credit carryforwards and release in valuation allowance in 2012 of 42.5% was higher than the Irish statutory rate of 12.5% due to a number of factors, including income taxable at a rate higher than the Irish statutory rate, losses in certain tax jurisdictions for which no tax benefit is available and various expenses not deductible for tax purposes. The decrease in the effective tax rate in 2013 compared to 2012 was primarily due to changes in income mix among the various jurisdictions in which we operate as well as higher taxes in 2012 relating to acquisition restructuring. We are currently paying taxes in Ireland, the United States and certain other foreign jurisdictions where we have operations and either all NOLs have been utilized, or are restricted as a result of the Azur Merger.

A reconciliation of income taxes at the statutory income tax rate to our effective income tax rate was as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Statutory income tax rate	12.5 %	12.5 %	35.0 %
Income tax provision at statutory rate	$38,494	22,169	43,744
Acquisition-related costs	—	763	3,552
Research and other tax credits	(5,957)	(100)	(1,323)
Non-deductible share-based compensation	2,497	873	670
Foreign income tax rate differential	31,651	52,066	—
Change in unrecognized tax benefits	8,685	2,249	—
Prior period adjustments	3,375	(2,524)	—
Change in valuation allowance	3,220	(159,158)	(46,996)
Non-deductible contingent consideration	5,320	—	—
Other	4,353	(132)	353
Income tax provision (benefit)	$91,638	$(83,794)	$—
Effective income tax rate	29.8 %	(47.2)%	— %

In 2013, the change in valuation allowance was $3.2 million. In 2012, the change in valuation allowance of $159.2 million was comprised of NOLs and tax credit carryforwards of $55.0 million and a release in valuation allowance of $104.2 million as described below.

Deferred income taxes reflect the tax effects of NOLs 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 using currently enacted tax rates and regulations that are expected to be in effect when the differences are expected to be recovered or settled.

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Significant components of our net deferred tax assets/(liabilities) were as follows (in thousands):

	December 31, 2013	2012
Deferred tax assets:		
Net operating loss carryforwards	$71,364	$71,636
Tax credit carryforwards	11,374	6,034
Intangible assets	10,733	13,940
Share-based compensation	8,116	3,875
Accruals	30,730	32,594
Deferred revenue and other	9,252	13,797
Total deferred tax assets	141,569	141,876
Valuation allowance	(20,691)	(17,471)
Net deferred tax assets	120,878	124,405
Deferred tax liabilities:		
Acquired intangible assets	(176,576)	(191,341)
Other	(10,848)	(1,069)
Net deferred tax liabilities	$(66,546)	$(68,005)

The following table presents the breakdown between current and non-current deferred tax assets/(liabilities) (in thousands):

	Year Ended December 31, 2013	2012
Current deferred tax assets	$33,613	$35,813
Current deferred tax liabilities	(6,259)	(275)
Non-current deferred tax assets	74,597	74,850
Non-current deferred tax liabilities	(168,497)	(178,393)
Net deferred tax liabilities	$(66,546)	$(68,005)

As of December 31, 2013, we had NOL carryforwards and tax credit carryforwards for U.S. federal income tax purposes of approximately $227.9 million and $18.5 million, respectively, available to reduce future income subject to income taxes. The NOL carryforwards are inclusive of $114.6 million from the EUSA Acquisition in 2012. The federal NOL carryforwards will expire, if not utilized, in the tax years 2016 to 2031, and the federal tax credits will expire, if not utilized, in the tax years 2017 to 2033. In addition, we had approximately $292.2 million of NOL carryforwards and $2.6 million of tax credit carryforwards as of December 31, 2013 available to reduce future taxable income for state income tax purposes. The state NOL carryforwards will expire, if not utilized, in the tax years 2014 to 2032. The state tax credits have no expiration date. In addition, as of December 31, 2013, there were NOL carryforwards for income tax purposes of approximately $59.5 million and $4.3 million available to reduce future income subject to income taxes in the United Kingdom and Germany, respectively. The NOLs generated in the United Kingdom and Germany have no expiration period and we maintain a full valuation allowance against the associated deferred tax assets until sufficient positive evidence exists to support reversal.

Approximately $65.4 million of both the U.S. federal and state NOL carryforwards as of December 31, 2013 resulted from exercises of employee share options and certain sales by employees of shares issued under other employee equity compensation plans. 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 shareholders' equity rather than as a reduction of our income tax provision in our financial statements.

Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. Such assessment is required on a jurisdiction by jurisdiction basis. Our valuation allowance was $20.7 million and $17.5 million as of December 31, 2013 and 2012,

respectively, for certain U.S. state and foreign deferred tax assets which we maintain until sufficient positive evidence exists to support reversal. During the fourth quarter of 2012, we recognized an income tax benefit of $104.2 million relating to the reversal of a valuation allowance against

substantially all of our U.S. federal and state deferred tax assets. Management determined that a valuation allowance was no longer needed on these deferred tax assets based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2012, including an evaluation of cumulative income in recent years, future sources of taxable income exclusive of reversing temporary differences, and significant risks and uncertainties related to our business. We periodically evaluate the likelihood of the realization of deferred tax assets and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant tax authorities, the progress of tax audits and the regulatory approval of products currently under development.

Utilization of certain of our NOL and tax credit carryforwards in the United States is subject to annual limitation due to the ownership change limitations provided by Sections 382 and 383 of the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of certain NOLs and tax credits before future utilization. We currently estimate that we have an annual limitation on the utilization of certain acquired federal NOLs of $28.6 million for each of the years 2014 to 2016, $11.9 million for 2017, and a combined total of $3.3 million for 2018 to 2026. In addition, as a result of the Azur Merger, we are subject to certain limitations under the Internal Revenue Code in relation to the utilization of U.S. NOLs to offset U.S. taxable income resulting from certain transactions.

Temporary differences related to investments in foreign subsidiaries totaled approximately $664.3 million and $604.2 million as of December 31, 2013 and 2012, respectively. In the event of the distribution of those earnings in the form of dividends, a sale of the subsidiaries, or certain other transactions, we may be liable for income taxes, subject to an adjustment, if any, for foreign tax credits and foreign withholding taxes payable to certain foreign tax authorities. As of December 31, 2013 it was not practicable to determine the amount of the income tax liability related to these investments.

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have established a liability for certain tax benefits which we judge may not be sustained upon examination. A reconciliation of our unrecognized tax benefits follows (in thousands):

	December 31,		
	2013	2012	2011
Balance at the beginning of the year	$7,288	$3,764	$4,852
Increases related to current year tax positions	14,308	3,492	242
Increases related to prior year tax positions	183	40	213
Decreases related to prior year tax positions	(142)	(8)	(1,543)
Balance at the end of the year	$21,637	$7,288	$3,764

The unrecognized tax benefits were included in other non-current liabilities and deferred tax assets, net, non-current in our consolidated balance sheet. Interest related to our unrecognized tax benefits is recorded in income tax provision (benefit) in our consolidated statements of income. As of December 31, 2013 and 2012, our accrued interest and penalties related to uncertain tax positions were not significant. Included in the balance of unrecognized tax benefits were potential benefits of $16.3 million and $6.3 million at December 31, 2013 and 2012, respectively, that, if recognized, would affect the effective tax rate on income. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

Our major tax jurisdictions are Ireland, the U.S. and France. Because of our net operating loss and tax credit carryforwards, substantially all of our tax positions remain open to federal and state examination in the U.S. In France, tax periods open to examination include the periods 2010 to 2013. In Ireland, tax periods open to examination include the periods 2009 to 2013. Certain of our subsidiaries are currently under examination by the U.S. Internal Revenue Service in respect of periods from 2010 to 2012 and by the French tax authorities in respect of periods from 2010 to 2012.

16. Related Party Transactions

In 2013, we entered into an underwriting agreement with an underwriter and certain selling shareholders, pursuant to which the selling shareholders sold to the underwriter 5.4 million of our ordinary shares, resulting in aggregate gross proceeds to the selling shareholders of approximately $314.4 million, before deducting underwriting discounts, commissions and other offering expenses. The selling shareholders included entities affiliated with certain members of our board of directors and one of our directors. We did not receive any proceeds from the sale of our ordinary shares by the selling shareholders in the offering and, consistent with our obligations under existing registration rights agreements with those shareholders, we paid expenses of approximately $0.5 million in connection with the offering.

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

In 2012, in connection with the Azur Merger, we assumed a lease for office space in Dublin, Ireland. The lease agreement was with Seamus Mulligan, the former Chief Executive Officer of Azur Pharma, who is a member of our board of directors. Rentals paid on this lease amounted to $0.3 million in 2012. In November 2012, we terminated this lease at a cost of $1.2 million, which was the carrying value of our above market lease liability. There was no resulting gain or loss on the lease termination.

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

In 2011, Azur Pharma entered into an agreement with Circ Pharma Limited/Circ Pharma Research and Development Limited, or Circ, companies controlled by Seamus Mulligan, whereby Azur Pharma obtained an option to license certain rights and assets in relation to Tramadol (a chronotherapeutic formulation) and to conduct certain development activities. Azur Pharma paid Circ $0.3 million for this option in 2011. In 2012, we terminated the agreement at no cost.

17. Restructuring

Termination Benefits

In June 2012, we initiated a restructuring plan to re-align certain support functions across the company following the Azur Merger and the EUSA Acquisition. In connection with this restructuring, we incurred costs of severance for terminated employees as well as retention bonus costs for certain employees retained to assist with the transition process, which was completed in June 2013. The one-time termination benefits were recorded over the remaining service period where employees were required to stay through their termination date to receive the benefits. We recorded costs related to these one-time termination benefits of $1.0 million and $2.8 million in the years ended December 31, 2013 and 2012 respectively, within selling, general and administrative expenses in our consolidated statements of income. To date, we have incurred one-time termination benefit costs under this plan of $3.8 million. We do not expect to incur any additional one-time termination benefit costs in connection with this plan. There were no restructuring activities during 2011.

Facility Closure Costs

In connection with our restructuring plan, we vacated our Langhorne, Pennsylvania facility in June 2013. We incurred facility closure costs of $0.4 million in the year ended December 31, 2013 for the remaining operating lease obligations related to this facility, net of estimated sublease rentals that could be reasonably obtained. Facility closure costs are recorded within selling, general and administrative expenses in our consolidated statements of income. We do not expect to incur any additional facility closure costs in connection with this plan.

The following table summarizes the amounts related to restructuring for the year ended December 31, 2013 (in thousands):

	Termination Benefits	Facility Closure Costs	Total
Balance at December 31, 2012	$1,227	$—	$1,227
Costs incurred during the period	1,045	412	1,457
Cash payments	(2,272)	(160)	(2,432)
Balance at December 31, 2013	$—	$252	$252

The balance at December 31, 2013 was included within accrued liabilities in our consolidated balance sheet.

18. Discontinued Operations

In 2012, we sold the women's health business, a component of the acquired Azur Pharma business, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl, or collectively, Meda, for $97.6 million, including $2.6 million for certain inventory transferred to Meda upon the closing of the sale, less transaction costs of $3.7 million. As part of the transaction, Meda purchased six women's health products from us and offered positions to approximately 60 of our employees who directly supported the women's health business. We recorded a non-recurring gain on the sale of $35.2 million.

We decided to sell our women's health business to concentrate our commercial efforts on our core products in our target therapeutic areas. The results of the women's health business are included in income from discontinued operations in 2012. As

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

the women's health business was acquired in the Azur Merger, it is not included in the results for 2011. Goodwill was allocated to the divested women's health business using the relative fair value method.
Net revenue and income from discontinued operations were as follows (in thousands):

	Year Ended December 31, 2012
Product sales, net	$20,873
Loss from discontinued operations before income taxes (1)	$(5,787)
Income tax expense (1)	(2,020)
Loss from discontinued operations, net of taxes	(7,807)
Gain on sale of discontinued operations (2)	35,244
Income from discontinued operations, net of taxes	$27,437

(1) The income tax expense relates to profits generated by the women's health business in 2012 which are attributable to the United States.
(2) The gain on sale of discontinued operations was not impacted by income taxes as the value attributable to the women's health business was held in a non-taxable jurisdiction.

19. Employee Benefit Plans
We operate a number of defined contribution retirement plans. The costs of these plans are charged to the income statement in the period they are incurred. We recorded expense related to our defined contribution plans of $1.1 million and $0.3 million in the year ended December 31, 2013 and 2012, respectively, and none in 2011. In Ireland, we operate a defined contribution plan in which we contribute up to 8% of an employee's eligible earnings. We recorded expense of $0.3 million in the year ended December 31, 2013 and none in 2012 and 2011 in connection with the contributions we made under the Irish defined contribution plan. In the United States, we provide a qualified 401(k) savings plan for our U.S. based employees. All U.S. based employees are eligible to participate, provided they meet the requirements of the plan. In 2013, we elected to match employee contributions under the 401(k) savings plan and recorded expense of $0.4 million. No such matching contributions were made prior to 2013. In the United Kingdom, we operate a defined contribution plan in which we contribute up to 12% of an employee's eligible earnings. We recorded expense of $0.4 million and $0.2 million in the year ended December 31, 2013 and 2012, respectively, and none in 2011, in connection with contributions we made under the U.K. defined contribution plan. In France, we accrue for a potential liability which is payable if an employee retires. The accrued liability was $0.3 million as of December 31, 2013 and 2012.

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

period to acquire all remaining untendered ordinary shares and ADSs. The subsequent offering period expired on February 20, 2014 and we accepted and purchased an additional approximately 29% of the fully diluted Gentium ordinary shares and ADSs properly tendered during the subsequent offering period, resulting in total purchases pursuant to the tender offer of approximately 98% of the fully diluted number of Gentium ordinary shares and ADSs as of February 21, 2014. The acquisition cost of the total number of Gentium ordinary shares and ADSs we purchased pursuant to the tender offer was approximately $993 million. We intend to cause Gentium to seek the voluntary delisting of

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Gentium ADSs from the NASDAQ Stock Market, or NASDAQ, and the deregistration of Gentium ordinary shares and ADSs under the Exchange Act. We expect that there will not be an active trading market for outstanding ordinary shares and ADSs following the delisting.

To finance this transaction, in January 2014, we amended our credit agreement to provide for $350.0 million principal amount of incremental term loans and a $425.0 million revolving credit facility. Please see Note 8 for further information regarding the credit agreement and the January 2014 amendments thereto. We used the proceeds from the incremental term loans and loans under the revolving credit facility, together with cash on hand, to purchase the Gentium ordinary shares and American Depositary Shares properly tendered and accepted for payment pursuant to the tender offer. As a result of the January 2014 amendment to the credit agreement, the interest rate margin on our existing term loans was reduced by 25 basis points. As of February 19, 2014, the interest rate on the outstanding term loans was 3.25% and on revolving loan borrowings was 2.66%.

Gentium is a biopharmaceutical company focused on the development and manufacturing of therapies to treat and prevent a variety of rare diseases and conditions that currently have few or no treatment options, including orphan vascular diseases related to cancer treatments. In October 2013, the European Commission granted marketing authorization for Defitelio, Gentium's lead product, for the treatment of severe hepatic veno-occlusive disease (VOD) in adults and children undergoing hematopoietic stem cell transplantation. We believe the acquisition will provide us with an opportunity to diversify our development and commercial portfolio and complement our clinical experience in hematology/oncology and our expertise in reaching targeted physicians who treat serious medical conditions.

The acquisition of Gentium will be accounted for as a business combination using the acquisition method. We are in the process of determining fair values of the assets acquired and liabilities assumed in the business combination, 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, 2014.

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

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

21. Quarterly Financial Data (Unaudited)

The following interim financial information presents our 2013 and 2012 results of operations on a quarterly basis (in thousands, except per share amounts):

	2013			
	March 31	June 30	September 30	December 31
Revenues	$196,237	$208,252	$232,160	$235,774
Gross margin (1)	167,432	181,533	206,134	208,153
Net income	43,425	42,185	75,409	55,293
Net income per share, basic	0.74	0.72	1.30	0.96
Net income per share, diluted	0.71	0.69	1.23	0.90

Table of Contents
JAZZ PHARMACEUTICALS PLC
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	2012			
	March 31	June 30	September 30	December 31
Revenues (2)	$102,530	$124,231	$175,515	$183,703
Gross margin(1)(2)	93,708	110,714	141,501	156,179
Income from continuing operations	30,235	31,113	33,595	166,206
Income (loss) from discontinued operations	(2,554)	(3,968)	(386)	34,345
Net income	27,681	27,145	33,209	200,551
Net income per share, basic	0.51	0.48	0.58	3.46
Net income per share, diluted	0.48	0.45	0.55	3.28

(1) Gross margin excludes amortization of acquired developed technology of $19.5 million, $19.3 million, $19.5 million and $20.5 million in the first, second, third and fourth quarters of 2013, respectively, and $10.7 million, $12.9 million, $19.7 million and $21.8 million in the first, second, third and fourth quarters of 2012, respectively.

(2) In 2012, we sold our women's health business. The women's health business met the discontinued operations criteria in the third quarter of 2012. See Note 18 for information regarding discontinued operations. As a result, revenues and gross margin for the first two quarters of 2012 have been restated to reflect only our continuing operations. There was no effect on previously reported net income. Below is a reconciliation of the revenues and gross margin amounts as previously reported in our quarterly reports on Form 10-Q to the restated amounts reported above.

	2012	
	March 31	June 30
Revenues, as previously reported	$108,414	$129,539
Less product sales from discontinued operations	(5,884)	(5,308)
Revenues, as adjusted	$102,530	$124,231
Gross margin, as previously reported	$96,578	$112,940
Less gross margin from discontinued operations	(2,870)	(2,226)
Gross margin, as adjusted	$93,708	$110,714

The tables above include the following unusual or infrequently occurring items:

- As part of the EUSA Acquisition, we agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze achieved U.S. net sales of $124.5 million or greater in 2013. In 2013, Erwinaze U.S. net sales were greater than $124.5 million and as a result, we are obligated to make the payment of $50.0 million in the first quarter of 2014. The change in fair value of the contingent consideration payable was $4.5 million, $3.4 million, $5.0 million and $2.3 million in the first, second, third and fourth quarters of 2013, respectively;
- Upfront license fees of $4.0 million and $1.0 million in the first and third quarters of 2013, respectively;
- A loss on extinguishment and modification of debt of $3.7 million in the second quarter of 2013;
- Acquisition accounting inventory fair value step-up adjustments of $1.5 million, $1.1 million, $0.5 million and $0.7 million in the first, second, third and fourth quarters of 2013, respectively;
- Transaction costs of $0.4 million and $4.4 million in the second and fourth quarters of 2013, respectively;
- We completed the Azur Merger on January 18, 2012 and the EUSA Acquisition on June 12, 2012 and contributions of the acquired businesses to our total revenues from continuing operations were $18.4 million, $23.5 million, $59.9 million and $59.6 million in the first, second, third and fourth quarters of 2012, respectively, as measured from the date of each acquisition. The portion of gross margin and net income associated with the acquired businesses was not separately identifiable due to the integration with our operations;
- A gain from the sale of our women's health business of $35.2 million recorded in the fourth quarter of 2012;
- A tax benefit of $104.2 million on the release of an income tax valuation allowance in the fourth quarter of 2012;
- Acquisition accounting inventory fair value step-up adjustments in continuing operations of $1.3 million, $3.0 million, $10.3 million and $2.1 million in the first, second, third and fourth quarters of 2012, respectively; and

- Transaction costs of $3.5 million and $8.9 million in the first and second quarters of 2012, respectively.

Table of Contents

Schedule II
Valuation and Qualifying Accounts
(In thousands)

		Balance at beginning of period	Additions charged to costs and expenses	Other Additions	Deductions	Balance at end of period
For the year ended December 31, 2013						
Allowance for doubtful accounts	(1)	$715	$(4)	$—	$(117)	$594
Allowance for sales discounts	(1)	528	5,267	—	(5,417)	378
Allowance for chargebacks	(1)	2,536	21,047	—	(20,875)	2,708
Deferred tax asset valuation allowance	(2)	17,471	3,220	—	—	20,691
For the year ended December 31, 2012						
Allowance for doubtful accounts	(1)	$50	$678	$—	$(13)	$715
Allowance for sales discounts	(1)	296	6,022	—	(5,790)	528
Allowance for chargebacks	(1)	20	13,072	—	(10,556)	2,536
Deferred tax asset valuation allowance	(3)(4)	111,188	3,421	62,971	(160,109)	17,471
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
Deferred tax asset valuation allowance	(4)	155,519	—	—	(44,331)	111,188

(1) Shown as a reduction of accounts receivable. Charges related to sales discounts and chargebacks are reflected as a reduction of revenue.

(2) Additions to the deferred tax asset valuation allowance relate to movements on certain U.S. state and other foreign deferred tax assets where we continue to maintain a valuation allowance until sufficient positive evidence exists to support reversal.

(3) Other additions to the deferred income tax asset valuation allowance resulted from the Azur Merger and the EUSA Acquisition.

(4) Deductions to the deferred tax asset valuation allowance include movements relating to utilization of NOLs and tax credit carryforwards, release in valuation allowance and other movements including adjustments following finalization of tax returns.

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500) filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc. Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
2.5	Asset Purchase Agreement, dated as of September 5, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals International II Limited, Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on October 15, 2012).
2.6	Tender Offer Agreement, dated December 19, 2013, by and among Jazz Pharmaceuticals Public Limited Company, Jazz Pharmaceuticals Italy S.r.l. and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K/A (File No. 001-33500), as filed with the SEC on December 20, 2013).
2.7†	Asset Purchase Agreement, dated January 13, 2014, by and among Jazz Pharmaceuticals International III Limited, Aerial BioPharma, LLC and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 13, 2014).
3.1	Memorandum and Articles of Association of Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
4.1	Reference is made to Exhibit 3.1.
4.2A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3 in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007).
4.2B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3B in Jazz Pharmaceuticals, Inc.'s annual report on Form 10-K (File No. 001-33500), for the period ended December 31, 2007, as filed with the SEC on March 31, 2008).
4.2C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3C in Jazz Pharmaceuticals, Inc.'s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May

	9, 2008).
4.2D	Waiver and Amendment Agreement, dated as of July 6, 2009, by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 4.3D in Jazz Pharmaceuticals, Inc.'s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009).
4.2E	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.2E in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).

Table of Contents

4.3	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Registered Direct Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 4.5 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.4	Form of Jazz Pharmaceuticals plc Warrant to Purchase Ordinary Shares issued to holders of assumed Common Stock Warrants originally issued by Jazz Pharmaceuticals, Inc. on July 7, 2009 (incorporated herein by reference to Exhibit 4.6 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.5A	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).
4.5B	Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
4.6	Registration Rights Agreement made as of January 13, 2012, by and among Jazz Pharmaceuticals plc and certain shareholders named therein (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
10.1†	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).
10.2†	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).
10.3†	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).
10.4	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).
10.5†	Royalty Bearing License Agreement and Supply Agreement Re Erwinia-Derived Asparaginase, dated July 22, 2005, between the Health Protection Agency and EUSA Pharma SAS (formerly OPi, S.A.), as amended on each of December 22, 2009, March 23, 2012 and August 8, 2012 (incorporated herein by reference to Exhibit 10.11 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q/A (File No. 001-33500), as filed with the SEC on August 9, 2012).
10.6	Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., the Lenders and Barclays Bank PLC, as Administrative Agent, Collateral Agent, Swing Line Lender and L/C Issuer (incorporated herein by reference to Exhibit 10.1 in Jazz

	Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
10.7	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).
10.8	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).
10.9	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 (incorporated herein by reference to Exhibit 10.31 in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).
10.10	Lease, dated May 8, 2012, by and between John Ronan and Castle Cove Property Developments Limited and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).

Table of Contents

10.11+	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).
10.12+	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).
10.13+	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).
10.14+	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).
10.15+	Offer Letter from Jazz Pharmaceuticals, Inc. to Suzanne Sawochka Hooper (incorporated herein by reference to Exhibit 10.19 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on May 8, 2012).
10.16+	Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.17+	Amendment to Employment Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.18+	Noncompetition Agreement by and between Fintan Keegan and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.19A+	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).
10.19B+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.3B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).
10.19C+	Form of Notice of Grant of Stock Options and Form of Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27C in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.19D+	Form of Notice of Grant of Stock Options and Form of Option Agreement (Irish) under Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27D in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.19E+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27E in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.19F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (Irish) under the Jazz Pharmaceuticals plc 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.27F in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).

10.19G+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.19H+	Jazz Pharmaceuticals plc 2007 Equity Incentive Plan - Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).
10.20A+	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).
10.20B+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.39B in the annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).

Table of Contents

10.20C+	Form of Option Grant Notice and Form of Stock Option Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.20D+	Form of Stock Option Grant Notice and Form of Option Agreement (Irish) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.20E+	Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.28E in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.20F+	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Unit Award Agreement (U.S.) under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.20G+	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 (incorporated herein by reference to Exhibit 10.10 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on August 7, 2012).
10.20H+	Form of Non-U.S. Restricted Stock Unit Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.28H in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500), as filed with the SEC on February 26, 2013).
10.20I+	Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of U.S. Option Grant Notice and Form of U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500), as filed with the SEC on November 5, 2013).