Jazz Pharmaceuticals plc
Form 10-K
February 24, 2015
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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, 2014

or

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

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

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

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

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

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. ý

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 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $8,420,403,204 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 2,311,701 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 18, 2015, a total of 60,657,182 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 2015 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.

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We own or have rights to various copyrights, trademarks, and trade names used in our business in the United States and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Xyrem Success Program®, Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase®, Defitelio® (defibrotide), Prialt® (ziconotide) intrathecal infusion, FazaClo® (clozapine, USP), Versacloz® (clozapine) oral suspension, Leukotac™ (inolimomab) and ProstaScint® (capromab pendetide). This report also includes trademarks, service marks, and trade names of other companies. Service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

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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, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believ "estimate," "project," "predict," "propose," "intend," "continue," "potential," "possible," "foreseeable," "likely," "unforeseen" 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.

NOTE REGARDING COMPANY REFERENCE

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 January 18, 2012, in which case such terms are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. 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.

PART I

Item 1. Business

Overview

Jazz Pharmaceuticals plc is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying new growth opportunities;
- Acquiring additional differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing focused development of a pipeline of post-discovery differentiated product candidates.

We have made substantial progress in the execution of our strategy. We have a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology.

Our lead marketed products are:

- Xyrem® (sodium oxybate) oral solution, the only product approved by the United States Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in patients with narcolepsy;

- Erwinaze® (asparaginase Erwinia chrysanthemi), a treatment approved in the United States and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to E. coli-derived asparaginase; and
- Defitelio® (defibrotide), a product approved in Europe for the treatment of severe hepatic veno-occlusive disease, or VOD, in adults and children undergoing hematopoietic stem cell transplantation, or HSCT, therapy.

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Our research and development activities include clinical development of new product candidates, line extensions for existing products and the generation of additional clinical data for existing products. A summary of our development pipeline activities is provided below:

Project	Disease Area	Status
Sleep		
JZP-110	EDS in narcolepsy	Expect to initiate a Phase 3 clinical trial in the second quarter of 2015
	EDS in obstructive sleep apnea, or OSA	Expect to initiate two Phase 3 clinical trials in the second quarter of 2015
JZP-386	EDS in narcolepsy	Phase 1 clinical trial in progress; expect additional data in the second quarter of 2015
Xyrem	Cataplexy in narcolepsy in children and adolescents	Phase 3 clinical trial initiated in the fourth quarter of 2014
Hematology/Oncology		
Defibrotide	Severe VOD	Rolling new drug application, or NDA, submission initiated in the United States in December 2014; expect to complete the submission in mid-2015
Erwinaze	ALL in young adult population	Pharmacokinetic study in Phase 2 initiated in the second quarter of 2014
JZP-416	ALL	Phase 1 clinical trial in Europe completed; enrollment suspended in pivotal Phase 2 clinical trial in North America in first quarter of 2015
Leukotac™	Steroid refractory acute graft vs. host disease, or GvHD	Phase 3 clinical trial enrollment complete; expect preliminary data in mid-2015

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 in the United States 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 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 160,000 people in 2014. Less than half of those people have been definitively diagnosed with narcolepsy. In the fourth quarter of 2014, the average number of patients in the United States receiving Xyrem treatment was approximately 12,250

patients, 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 have implemented a number of initiatives including increased outreach to prescribers who treat narcolepsy and physician/healthcare provider disease education programs.

In 2014, net product sales of Xyrem were $778.6 million, which represented 67.0% 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, or Xyrem Risk Management Program, which was required in conjunction with Xyrem's approval by the

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FDA to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. The 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.

Under our current Xyrem Risk Management Program, all of the Xyrem sold in the United States must be dispensed and 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 Xyrem before the physician can prescribe, or a patient can receive, the product. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and must speak with the patient before each prescription of Xyrem is filled and 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 only be for up to a three-month supply.

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. For example, ESSDS provides reimbursement support to patients by coordinating insurance coverage for Xyrem, and as applicable, referring qualified patients to various patient savings or assistance programs. Our agreement with ESSDS, 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. We do not intend to exercise our termination right, and ESSDS has informed us that it does not intend to exercise its termination right, in connection with the expiration of the 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.

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 respect to our REMS documents for Xyrem, but have not reached agreement with the FDA on certain significant terms. In late 2013, the FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014, and the process is ongoing. See more discussion regarding this matter under “Business—Government Regulation—Approval of Pharmaceutical Products” in Part I, Item 1 of this Annual Report on Form 10-K.

Five 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 addition, certain of the ANDA filers have sought to challenge the validity of our patents covering the distribution system for Xyrem by filing petitions for covered business method, or CBM, post-grant patent review and/or inter partes review, or IPR, by the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO. The PTAB has issued decisions denying institution of CBM review for all of the CBM petitions and has not yet determined whether to institute proceedings with respect to the petitions for IPR. For a description of these matters, see “Legal Proceedings” in Part I, Item 3 of this Annual Report on Form 10-K.

We also expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. In January 2014, the FDA held an initial meeting

with us and the then-current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). The parties have had numerous interactions with respect to a single shared system REMS since the initial meeting, and we expect the interactions to continue. In addition, 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, elements to assure safe use, or ETASU. Similarly, it is possible that, consistent with the position that the FDA articulated in its December 2012 response denying a Citizen Petition we filed in July 2012, the FDA could approve an 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. For a more detailed explanation and discussion regarding these matters, see "Business—Government Regulation—The Hatch Waxman Act" in Part I, Item 1 of this Annual Report on Form 10-K.

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For further discussion regarding the challenges we face with respect to Xyrem, see the risk factors in Part 1, Item 1A of this Annual Report on Form 10-K 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 these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem," "If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected," "It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection," and "We have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products."

Xyrem is a controlled substance in the United States, subject to regulation by the U.S. Drug Enforcement Administration, or DEA, under the Controlled Substances Act, or CSA. 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. See more details regarding Xyrem supply under "Business—Manufacturing" in Part I, Item 1 of this Annual Report on Form 10-K.

Outside of the United States, UCB Pharma Limited, or UCB, has an exclusive license to market Xyrem for the treatment of narcolepsy in 54 countries and currently sells the product in 19 countries. 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 19 U.S. patents covering Xyrem, which expire at various times from December 2019 to March 2033. Our issued patents relate to Xyrem's stable and microbially resistant formulation, its manufacturing process, its method of use, including its restricted distribution system, and its method of administration.

Erwinaze® / Erwinase® (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 can be a crucial component of their therapeutic regimen. Erwinaze was originally developed by Public Health England, or PHE, a U.K. national executive agency. First approved by the FDA under a biologics license application, or BLA, for administration via intramuscular injection in conjunction with chemotherapy, Erwinaze was launched in the United States in November 2011. In December 2014, the FDA approved a supplemental BLA for administration of Erwinaze via intravenous infusion in conjunction with chemotherapy. 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 or 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 separate papers published in Pediatric Blood & Cancer and Journal of Clinical Oncology, respectively suggest that up to 20% of ALL patients may 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 ALL patients

between 15 and 39 years of age 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 in adult centers incorporate the use of asparaginase-based regimens, 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. A third party has introduced an assay to determine the enzyme activity of asparaginase in patients who have been treated with any E. coli-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 adoption of this assay to be limited until its use is included in existing pediatric and adult treatment protocols.

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In 2014, net product sales of Erwinaze/Erwinase were $199.7 million, which represented 17.2% of our total net product sales.

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. Our hematology and oncology sales force outside of the United States has approximately 25 hematology field specialists responsible for promoting Erwinase and Defitelio in approved markets where we commercialize these products. In those 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.

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. See more details regarding the supply of Erwinaze under “Business—Manufacturing” in Part I, Item 1 of this Annual Report on Form 10-K.

Erwinaze has no patent protection, although it has orphan drug exclusivity for the treatment of ALL in the United States until November 2018, and it is expected to receive exclusivity that prevents approval of a biosimilar in the United States through late 2023 under the U.S. Biologics Price Competition and Innovation Act, or BPCIA.

Defitelio® (defibrotide) / 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. Defibrotide has been developed for 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 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 calculated that: in Europe, of the estimated approximately 35,000 patients undergoing HSCT in 2014, approximately 6,300 were considered at high risk for the development of VOD and the incidence of VOD was approximately 3,600 patients; and, in the United States, of the estimated approximately 20,000 patients undergoing HSCT in 2014, approximately 3,000 were considered at high risk for the development of VOD and the incidence of VOD was approximately 1,000 to 2,000 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.

In October 2013, the European Commission, or EC, 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 European Union, or 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.

During 2014, Defitelio was launched in a number of European countries. We expect to continue to launch the product in additional European countries on a rolling basis in 2015 and are in the process of making pricing and reimbursement submissions with respect to Defitelio, and discussing them with regulatory authorities, in those European countries where Defitelio is not yet launched, including in countries where pricing and reimbursement

approvals are required for launch. We promote Defitelio along with Erwinase to many of the same hematology and oncology specialists, and believe that we benefit from operational synergies in commercializing these products to the same targeted audience. In addition, in those European markets where Defitelio is approved but not yet launched, our medical science liaisons and medical directors respond to medical information requests regarding defibrotide and provide information consistent with local treatment protocols. We intend eventually to commercialize Defitelio in all European markets where it has marketing authorization. We also continue to provide patients access to defibrotide where it is not commercially available through an expanded access treatment protocol that is open under an investigational new drug application, or IND, in the United States and on a named patient basis elsewhere.

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Defitelio/defibrotide product sales in 2014, beginning from the closing on January 23, 2014 of our acquisition of a controlling interest in Gentium S.p.A., or Gentium, which we refer to as the Gentium Acquisition, were $70.5 million, which represented 6.1% of our total net product sales. On a pro forma basis, assuming the Gentium Acquisition had closed on January 1, 2014, Defitelio/defibrotide product sales in 2014 were $73.4 million. For a detailed discussion of the Gentium Acquisition, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K.

In August 2014, we acquired from Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, the rights to defibrotide for the treatment and prevention of VOD in North America, Central America and South America. In exchange for the rights to defibrotide in the Americas, we made an upfront payment of $75.0 million to Sigma-Tau and are also obligated to make milestone payments of up to $175.0 million comprised of (i) $25.0 million upon the acceptance for filing by the FDA of the first NDA for defibrotide for VOD; and (ii) up to an additional $150.0 million based on the timing of potential FDA approval of defibrotide for VOD.

There are currently no approved treatments for VOD in the United States. Defibrotide has been granted orphan drug designation by the FDA to treat and prevent VOD and has 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. In December 2014, we initiated a rolling submission of an NDA to the FDA for defibrotide for the treatment of severe VOD. We expect to complete the submission in mid-2015. See more details regarding the rolling submission under "Business—Government Regulation—Approval of Pharmaceutical Products" in Part I, Item 1 of this Annual Report on Form 10-K.

We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in indications in addition to the treatment of severe VOD. For example, defibrotide has received orphan drug designation to treat and prevent VOD from the European Medicines Agency, or EMA, and 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 VOD. In addition, 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.

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, methods of use and methods of characterization, which will expire at various times between April 2017 and June 2032.

Prialt® (ziconotide) intrathecal infusion and other products

We also commercialize a portfolio of other products, including Prialt. 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. 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. We have worldwide rights to Prialt, excluding 34 countries outside of the United States licensed by Eisai Co. Limited, or Eisai, from Elan Pharmaceuticals, Inc. (subsequently acquired by Perrigo Company plc) in May 2010. We supply Prialt to Eisai.

Other products we sell include a number of psychiatry products in the United States and products in the oncology, critical care and oncology supportive care therapeutic areas, primarily in markets outside of the United States.

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 sleep and hematology/oncology therapeutic areas.

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

JZP-110. JZP-110 is a late-stage investigational compound being developed for potential treatment of EDS in patients with narcolepsy and EDS in patients with OSA. Based on feedback from the FDA on our development plans for JZP-110, we expect to commence our planned Phase 3 clinical program in the second quarter of 2015, subject to the availability of clinical trial materials. We plan to conduct one Phase 3 clinical trial in patients with EDS associated with narcolepsy and two Phase 3 clinical trials in patients with EDS associated with OSA. Approximately

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900 patients are expected to be enrolled in these three trials in the aggregate. In addition, we plan to evaluate the long-term safety of JZP-110 in an open label extension trial and expect to enroll up to 450 patients from the three Phase 3 clinical trials in this extension trial. The co-primary endpoints for all three Phase 3 clinical trials are change in the scores from baseline on the Maintenance of Wakefulness Test and Epworth Sleepiness Scale, with a key secondary endpoint of patient global impression of change.

In January 2014, we entered into an asset purchase agreement with Aerial BioPharma LLC, or 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 of $125.0 million to Aerial. We also paid a $2.0 million milestone to SK on assignment of the JZP-110 rights from Aerial to us. We are obligated to make milestone payments, in an aggregate amount of up to $270.0 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. JZP-386 is a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem, which we licensed from Concert Pharmaceuticals, Inc., or Concert, in February 2013. We have conducted preclinical research and development work on JZP-386 for potential use in patients with narcolepsy. We submitted an investigational medicinal product dossier, or IMPD, for JZP-386 in Europe at the end of 2013 and received approval of the IMPD in January 2014. The first study of JZP-386 in humans to evaluate the safety, pharmacokinetics and pharmacodynamics of the compound was conducted in 2014, and we initiated a second Phase 1 study in the first quarter of 2015, with data expected in the second quarter of 2015.
- Xyrem. While in many patients narcolepsy can begin during childhood and adolescence, there is limited information on the treatment of pediatric narcolepsy patients with Xyrem. We have worked with the FDA and several leading specialists to design a clinical trial to generate additional data on the treatment of pediatric narcolepsy patients with Xyrem. As a result, in the fourth quarter of 2014, we initiated a Phase 3 clinical trial to assess the safety and efficacy of Xyrem in children and adolescents aged seven to 17 who have narcolepsy with cataplexy.

In the hematology and oncology area, we also have a number of ongoing clinical trials.

- Erwinaze. In the second quarter of 2014, we initiated a pharmacokinetics study in Phase 2 to further evaluate the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase.
- JZP-416 (formerly known as Asparec). We completed a Phase 1 clinical trial in Europe of JZP-416 (pegcrisantaspase), a PEGylated recombinant Erwinia chrysanthemi L-asparaginase, being developed for the treatment of patients with ALL who are hypersensitive to E. coli-derived asparaginase. In June 2013, the FDA granted Fast Track designation to the investigation of JZP-416 for the treatment of ALL. We initiated our first study of JZP-416 in children in a pivotal Phase 2 clinical trial in North America in late 2014. In February 2015, we voluntarily suspended patient enrollment in this trial. Our decision to suspend enrollment and to discontinue treatment with JZP-416 for enrolled patients is based on the occurrence of hypersensitivity-like reactions following the administration of JZP-416 in some treated patients. We are in the process of collecting and evaluating the available data and plan to conduct additional research and analysis prior to determining whether to resume the study and determining next steps regarding the development of JZP-416. We license worldwide rights to develop and commercialize JZP-416 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.
- Leukotac. We are 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 completed enrollment for this study in March 2014 and expect to receive preliminary data in mid-2015. We acquired the rights to Leukotac from Biotest AG.

We are also engaged in activities related to the potential approval of defibrotide in the United States. We initiated a rolling submission of an NDA to the FDA for defibrotide for the treatment of severe VOD in December 2014 and expect to complete the submission in mid-2015. We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in indications in addition to the treatment of severe VOD. See more details regarding the rolling submission under “Business—Government Regulation—Approval of Pharmaceutical Products” in Part I, Item 1 of this Annual Report on Form 10-K.

For the years ended December 31, 2014, 2013 and 2012, we recorded $85.2 million, $41.6 million and $20.5 million, respectively, in research and development expenses. We also recorded charges of $202.6 million and $5.0 million, respectively, to in-process research and development in the years ended December 31, 2014 and 2013, and none in the year ended December 31, 2012.

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Sales and Marketing

We have commercial operations primarily in the United States and Europe. In the United States, our products are marketed through our commercial teams, including approximately 150 trained, experienced sales professionals who promote Xyrem, Erwinaze and Prialt directly to physicians in specialties appropriate for each product. Outside of the United States, our hematology and oncology sales force has approximately 25 hematology field specialists responsible for promoting Erwinase and Defitelio in approved markets where we commercialize these products.

Our commercial activities include marketing-related services, distribution services and commercial support services. We 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 geographic 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 marketed 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 products and develop product candidates in sleep, hematology/oncology, pain and other therapeutic areas. 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, EC 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. These competitors include established companies that 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 lead marketed products face competition as described below:

- Xyrem. 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 Pharmaceutical Industries Limited, or 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.

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

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adversely affected. For a description of these matters, please see "Legal Proceedings" in Part I, Item 3 of this Annual Report on Form 10-K.

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

- Erwinaze / Erwinase. 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 have developed or 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 adults and children undergoing HSCT. Various anti-clotting strategies have been tried by researchers in patients with VOD 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.

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;
- our ability to comply with applicable laws, regulations and regulatory requirements with respect to the commercialization of our products, including any changes or increases to regulatory restrictions;
- 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 provide a reliable supply of commercial quantities of a product to the market; and
- our ability to recruit, retain and develop skilled employees, including sales and marketing and clinical development employees.

Customers and Information About Geographic Areas

In the United States, our lead marketed product 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. Among the other products we commercialize in the United States, Prialt is sold through an exclusive wholesale distributor and pharmacy to medical facilities, while the others are sold primarily to distributors who distribute the product to pharmacies and hospitals. We have standard distribution services 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, 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 distribute Defitelio primarily

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through IDIS Limited, or IDIS, a U.K. based distributor, to the European countries where the product has been launched commercially. We also work with IDIS and a number of local distributors in Europe and elsewhere in the world to distribute defibrotide on a named patient basis. Xyrem is currently sold in 19 countries by UCB (which has rights to market Xyrem in 54 countries) and in Canada by Valeant. 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.

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 2014, 2013 and 2012, as well as the location of our long-lived assets, is included in Note 15 to our consolidated financial statements in this Annual Report on Form 10-K.

We are headquartered in Dublin, Ireland, and have offices in Palo Alto, California and Philadelphia, Pennsylvania in the United States and offices in Oxford, United Kingdom, Lyon, France, Villa Guardia (Como), Italy and elsewhere in Europe. For a discussion of risks related to our non-U.S. operations, see “Risk Factors—Risks Related to Our Business,” “—Risks Related to Our Industry” and “—Risks Relating to Our Financial Condition” in Part I, Item 1A of this Annual Report on Form 10-K and “Quantitative and Qualitative Disclosure About Market Risk” in Part II, Item 7A of this Annual Report on Form 10-K.

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 our product candidates and for the active pharmaceutical ingredients used in these products and product candidates. 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 and clinical trial 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, Inc., 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 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 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 of the DEA, see “Business—Government Regulation—Other Regulatory Requirements—Controlled Substance Regulations” in Part I, Item 1 of this Annual Report on Form 10-K.

Erwinaze is exclusively licensed to us, and manufactured for us, by PHE, which is our sole supplier for Erwinaze. Our 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

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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. The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product. As a consequence of constrained manufacturing capacity, we have had an extremely limited ability to build an excess level of product inventory that could be used to absorb disruptions to supply resulting from quality or other issues. If we continue to be subject to capacity constraints or experience quality or other manufacturing challenges in the future, we may be unable to build a desired excess level of product inventory, and our ability to supply the market may be compromised. Although we are taking steps to improve the Erwinaze manufacturing process, if our ongoing efforts are not successful, we could experience additional 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. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K 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” for a discussion of the challenges we face with respect to Erwinaze supply.

We manufacture the defibrotide drug substance in a single facility located in Villa Guardia, near Como, Italy. We are our sole supplier of, and we believe that we are currently the sole worldwide producer of, the defibrotide drug compound. Patheon UK Limited, or Patheon UK, currently processes the defibrotide compound into its finished vial form, and is the sole provider of our commercial supply of the finished product in Europe and of our future clinical supply. We are in the process of evaluating an appropriate provider to process defibrotide into finished product for the U.S. market in preparation for the potential approval of the product by the FDA.

In order to commence any of our planned clinical programs for JZP-110 or JZP-386, we need to have sufficient quantities of clinical product manufactured. While we believe that we will be able to obtain sufficient supplies of JZP-110 or JZP-386 before the commencement of our planned clinical trials, there can be no assurance that our suppliers will be able to produce sufficient clinical supplies of JZP-110 or JZP-386 in a timely manner. Any delay in receiving adequate 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 compliance with these requirements, and they may not be able to continue to do so.

Patents and Proprietary Rights

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products and related inventions and improvements that we consider important to our business. We own a portfolio of U.S 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 or relate to our products and product candidates, including certain formulations, uses to treat particular conditions, distribution methods and methods of administration, drug delivery technologies and delivery profiles and methods of production. 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 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.

The patents and patent applications that relate to our lead marketed products include:

- Xyrem. Xyrem is covered by 19 U.S. patents that expire at various times from December 2019 to March 2033, of which 14 are listed in the FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” or Orange Book. These patents relate to Xyrem’s stable and microbially resistant formulation, its manufacturing process, its method of use, including its restricted distribution system, and its method of administration. Of the patents listed in

the Orange Book, four are formulation patents expiring between December 2019 and July 2020; seven are method of use patents covering the distribution of Xyrem expiring between December 2022 and June 2024; two are method of use patents covering Xyrem's use in narcolepsy, both of which expire in December 2019; and one is a method of administration patent expiring in March 2033. An additional method of use patent covering Xyrem's use in narcolepsy expiring December 2019 is expected to be listed in the Orange Book. Four patents are not listed in the Orange Book but also relate to Xyrem: two for methods for making the formulation expiring December 2019, one for a distribution system expiring June 2024 and one for method of administration expiring March 2033. A Xyrem

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formulation patent has issued in multiple non-U.S. countries and will expire in December 2019. In addition to our issued patents, we have patent applications relating to Xyrem pending in the United States and other countries.

Five 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. In addition, certain of the ANDA filers have sought to challenge the validity of our patents covering the distribution system for Xyrem by filing petitions for CBM post-grant patent review and/or IPR by the PTAB. The PTAB has issued decisions denying institution of CBM review for all of the CBM petitions and has not yet determined whether to institute proceedings with respect to the petitions for IPR. For a description of these matters, see "Legal Proceedings" in Part I, Item 3 of this Annual Report on Form 10-K.

- Defitelio. The unique process of deriving defibrotide from porcine DNA is extensive and uses both chemical and biological processes that rely on complex characterization methods. We have a portfolio of U.S. and non-U.S. patents and patent applications relating to various compositions, methods of use and methods of characterization, which will expire at various times between April 2017 and June 2032.

Erwinaze has no patent protection, although it has orphan drug exclusivity for the treatment of ALL in the United States until November 2018, and it is expected to receive exclusivity that prevents approval of a biosimilar in the United States through late 2023 under the BPCIA. See "Business—Government Regulation—Orphan Drug and Other Exclusivities" in Part I, Item 1 of this Annual Report on Form 10-K for more details.

The patents and patent applications that relate to our product candidates include:

- 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 Aerial's patent rights relating to JZP-110, other than in certain jurisdictions in Asia where SK retains rights. The U.S. composition of matter patents begin to expire in September 2015. Two U.S. method of use patents covering treatment of sleep related conditions will expire in June 2026 and August 2027, subject to any patent term extension.
- JZP-386. Two U.S. patents cover the composition of deuterated analogs of sodium oxybate, including JZP-386, and their methods for treating certain diseases and disorders, including narcolepsy. The first patent expires in July 2030 and the second patent expires in February 2032. A European patent that corresponds to the first U.S. patent expires in April 2030. Further, patent applications corresponding to the second U.S. patent were filed in the United States, Europe and Japan, and, if issued, would expire in February 2032. We were granted exclusive licenses to these patent rights by Concert.
- JZP-416. JZP-416 is not yet covered by any issued U.S. patents. We have rights to patent applications for JZP-416 pending in the United States and many other countries that, if issued, would expire in July 2030, subject to any patent term extension. In addition, JZP-416 was granted orphan drug designation for the treatment of ALL by the EMA and by the FDA subject to certain conditions. See "Business—Government Regulation—Orphan Drug and Other Exclusivities" in Part I, Item 1 of this Annual Report on Form 10-K for more details.

We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents, that the patents we own and license, or any additional patents we may own or license, will prevent other companies from developing similar or therapeutically equivalent products, or 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.

We also rely on our trade secrets and those of our licensors, as well as other unpatented proprietary information, to protect our products and commercial position, particularly with respect to our products with limited or no patent protection, such as Erwinaze and Defitelio. 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. See the risk factors in Part I, Item 1A of this Annual Report on Form 10-K entitled “It is difficult and costly to

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protect our proprietary rights, and we may not be able to ensure their protection" and "We have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products." In addition, we have a number of trademarks and service marks to further protect the proprietary position of our products. We also have pending trademark and service mark applications in the United States and elsewhere in the world.

Government Regulation

The manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of our products and our research and development activities are subject to extensive regulation by the FDA, the EC, the competent authorities of the EU member states and other regulatory authorities. Regulations differ from country to country. As a result of these regulations, product development, approval and commercialization processes are expensive and time-consuming.

Approval of Pharmaceutical Products

We are not permitted to market a pharmaceutical product in the United States or in the EU member states until we receive approval from the FDA, the EC or the competent authorities of the EU member states, as applicable. An application for marketing approval 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 and stability of the finished pharmaceutical product and proposed product packaging and labeling.

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 our products. Our failure, or the failure of 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.

To obtain FDA approval of a product candidate, an applicant, also called a sponsor, must, among other things, submit the data and information described above in the form of an NDA or BLA, as applicable, and include payment of a user fee. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming, and the outcomes are uncertain. 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 the NDA or BLA; 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.

Human clinical trials conducted before approval of a product for a specific indication generally proceed in three sequential phases, although the phases may overlap. In Phase 1, the initial introduction of the drug into human subjects, frequently healthy volunteers, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves clinical trials in a limited patient population to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites. In addition, Phase 4, or post-approval, clinical trials may be required by the FDA and are used to gain additional experience from the treatment of patients in the intended

therapeutic indication and to document a clinical benefit in the case of products approved under accelerated approval regulations.

The FDA reviews an NDA or BLA submitted before it accepts them for filing and may request additional information rather than, or before, accepting an application for filing. For example, a prior NDA submission by Gentium seeking approval in the United States for defibrotide for the treatment of VOD was voluntarily withdrawn from consideration in 2011 in order to address issues raised by the FDA. We held pre-NDA meetings with the FDA relating to our plans for the submission of an NDA for defibrotide for the treatment of severe VOD. Based on these meetings and in light of the current status of our acquisition and remediation of key information to be included in the data package for the NDA, in December 2014, we initiated a rolling submission of an NDA to the FDA for defibrotide for the treatment of severe VOD and expect to complete the submission of the NDA in mid-2015. We do not expect to be required to complete any additional clinical trials prior to the

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completion of the NDA submission. However, we may be unable to acquire and remediate key information in the data package in a timely manner, which would delay or preclude the completion of our NDA submission. Furthermore, if we fail to acquire and remediate key information or if analysis of this data does not support an NDA submission, we may be required to complete additional clinical trials in order to obtain appropriate data for an NDA submission. Even if we are able to complete the NDA submission as planned, we may be required to conduct time-consuming and costly clinical trials as a condition of any U.S. marketing approval for the product. In any event, we may be unable to obtain regulatory approval of defibrotide in the United States in a timely manner, if at all.

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 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. In late 2013, the FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Among other things, we disagree with the FDA's position in the late 2013 notice 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, be sufficient to ensure that the REMS includes only those elements necessary to ensure that the benefits of Xyrem outweigh its risks, and that would, in the FDA's view, reduce the burden on the healthcare system. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We received the FDA's denial of our initial dispute resolution submission in the second quarter of 2014, and our dispute is currently subject to further supervisory review at the next administrative level of the FDA. We have received interim responses from the FDA, but the FDA has not yet communicated a decision on our further appeal to us. We expect to receive the FDA's decision in the first quarter of 2015. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem. See the discussion regarding REMS in the context of potential generic competition under "Business—Government Regulations—The Hatch-Waxman Act" below and in the risk factor in Part I, Item 1A of this Annual Report on Form 10-K 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 these restrictions and requirements,

subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

After the FDA evaluates a marketing application, including a REMS program when applicable, it also evaluates any manufacturing and nonclinical and clinical trial 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

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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. For example, the FDA has granted Fast Track designation to the investigation of JZP-416 for ALL and to defibrotide 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, such as JZP-416 and defibrotide, that the review time will be shorter than a standard review.

Outside of the United States, our ability to market a medicinal product generally depends upon receiving a marketing authorization from the appropriate regulatory authority. The requirements governing the conduct of clinical trials, obtaining marketing authorization, obtaining pricing and reimbursement and related matters 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. 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 below. 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.

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. The EC can, based on the opinion of the EMA, grant a centralized marketing authorization that is valid in all EU member states and three additional European countries. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and biologic products, and optional for certain other products. Unlike the centralized authorization procedure, the national authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU member state in which the product is to be marketed. There are two possible routes for companies to gain national authorization and both rely on the principal of mutual recognition. One is the decentralized procedure, which allows companies to file identical applications to several EU member states simultaneously for medicinal products that have not yet been authorized in any EU member state. The competent authority of one EU member state, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other EU member states are subsequently required to grant marketing authorization for their territories on the basis of this assessment except where grounds of potential serious risk to public health require this authorization to be refused. The other is the mutual recognition procedure which allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized in other EU member states.

The making available or placing on the EU market of unauthorized medicinal products is prohibited. However, the competent authorities of the EU member states may exceptionally and temporarily allow the making available of such products to individual patients or a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorized medicinal product.

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. All marketing authorization holders will be required to comply with the requirements of a new EU Clinical Trials Regulation which will come into force no later than May 28, 2016. As a regulation, it will be directly binding in all EU member states without the need for any national implementing legislation. The new EU Clinical Trials Regulation, which will replace the EU Clinical Trials Directive, introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU, including a new coordinated procedure for authorization of clinical trials which is reminiscent of the mutual recognition procedure for marketing authorization of medicinal products.

The initial marketing authorization granted in the EU is valid for five years, but once renewed is usually valid for an unlimited period unless the national competent authority or the EMA, decides, on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, to proceed with one additional five-year renewal. The renewal of a marketing authorization is subject to a re-evaluation of the risk-benefit balance of the product by the national competent authorities or the EMA. In addition, products for which the applicant can demonstrate that comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use cannot be provided as a result of certain specified objective and verifiable 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 conditions imposed by the competent authorities, including conditions relating to the safety of the medicinal product, notification to the national competent authorities of any incident relating to its use, and action to be taken. In October 2013, the EC granted marketing authorization under exceptional circumstances for Defitelio for the treatment of severe VOD in adults and children undergoing HSCT therapy.

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The Hatch-Waxman Act

The approval process described above for the United States 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 and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information as described above.

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 brand-name product, which is referred to as the "referenced drug." 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 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. To date, five generic drug manufacturers have 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. For a description of these matters, see "Legal Proceedings" in Part I, Item 3 of this Annual Report on Form 10-K.

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 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 Patent Certification." If the patent is for an approved method of use, an ANDA or Section 505(b)(2) applicant can also file a statement, called a "section viii statement," that the application does not seek approval of the use covered by the listed patent. 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.

If the applicant has provided a Paragraph IV Patent Certification, or Paragraph IV Certification, to the FDA, the applicant must also send a notice of such 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 notice of 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 Paragraph IV Certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant. 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 NDA for the referenced drug. 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.

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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. We have received notices of Paragraph IV Certification from five generic drug manufacturers notifying us 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 each of these ANDA filers seeking to prevent them from introducing a generic version of Xyrem that would infringe our patents. For a description of these matters, see "Legal Proceedings" in Part I, Item 3 of this Annual Report on Form 10-K. 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, also known as a "launch at risk." In the event of such commercialization, the generic manufacturer generally would be liable to us for damages if we ultimately prevail 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 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. 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, 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 the then-current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). The parties have had numerous interactions with respect to a single shared system REMS since the initial meeting, and we expect the interactions to continue. 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 Part I, Item 1A entitled "We have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, 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 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 the ANDA filed by Roxane Laboratories, Inc., or Roxane, the first ANDA filer, 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 an 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

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condition, results of operations and growth prospects. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled “We have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, 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, the 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. However, if a product that has 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 approved Xyrem as an orphan drug for the treatment of EDS and cataplexy in patients with narcolepsy, but those periods of orphan drug exclusivity have expired. Erwinaze has orphan drug exclusivity for the treatment of ALL until November 2018, seven years from its FDA approval. JZP-416 was granted orphan drug designation for the treatment of ALL by the FDA subject to certain conditions. Defibrotide has been granted orphan drug designation to treat and prevent VOD by the FDA.

Separately, Erwinaze, as a biologic product approved under a BLA, is subject to the BPCIA. The BPCIA authorizes the FDA to license a biological product that is biosimilar to an FDA-licensed biologic through an abbreviated pathway. The BPCIA establishes criteria for determining whether a product is biosimilar to an already-licensed biologic, or reference product, and establishes a process for an abbreviated BLA for a biosimilar product to be submitted, reviewed and approved. The BPCIA provides periods of exclusivity that protect a reference product from competition by biosimilars. Under the BPCIA, the FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar cannot be licensed until 12 years after the reference product was first licensed. Because the BPCIA is a relatively new law, we anticipate that its impact on both reference product sponsors and biosimilar applicants will evolve over a period of years. Its implementation likely will be shaped by a variety of factors, including FDA issuance of guidance documents,

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proposed regulations, and decisions in the course of considering specific applications. Erwinaze is expected to receive exclusivity that prevents approval of a biosimilar in the United States through late 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 such 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. For example, in the fourth quarter of 2014, in response to a written request from the FDA to generate additional data, we initiated a Phase 3 clinical trial to assess the safety and efficacy of Xyrem in children and adolescents aged seven to 17 who have narcolepsy with cataplexy.

In the EU, orphan drug designation may be granted to products that can be used to treat life-threatening diseases or chronically debilitating conditions with an incidence of no more than five in 10,000 people and that, for economic reasons, would be unlikely to be developed without incentives. In order to receive orphan designation, there must also be no satisfactory method of diagnosis, prevention or treatment of the condition, or if such a method exists, the medicine must potentially be of a significant benefit to those affected by the condition. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity in all EU member states and a range of other benefits during the development and regulatory review process, including scientific assistance for study protocols, access to the centralized marketing authorization procedure and a reduction or elimination of registration and marketing authorization fees. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if the similar product is deemed safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity. JZP-416 has received orphan drug designation for the treatment of ALL from the EMA subject to certain conditions. Defibrotide has received orphan drug designation to treat and prevent VOD from the EMA and 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 VOD. In addition, the EMA also granted orphan drug designation to defibrotide for the prevention of GvHD, another potentially fatal complication of HSCT.

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 regulatory 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. 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.

Similarly, outside of the United States, we are subject to a variety of post-authorization regulations, including with respect to clinical studies, product manufacturing, advertising and promotion, distribution, and safety reporting. For example, the marketing authorization in the EU for Defitelio was granted under exceptional circumstances and requires us to comply with a number of post-marketing obligations, including obligations relating to the manufacturing of the drug substance and finished product, the submission of data concerning patients treated with the product collected through a third-party patient registry and the establishment of a multi-center, multinational and prospective observational 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 FDA also periodically inspects the sponsor's records related to safety reporting. Following such inspections, the FDA may issue notices on Form FDA 483 and warning letters that could cause us to modify certain activities. A Form FDA 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated relevant FDA regulations or guidance. Failure to adequately and

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promptly correct the observation(s) can result in further regulatory enforcement action. For example, in April 2014, we received a Form FDA 483 at the conclusion of a pharmacovigilance inspection conducted by the FDA. The Form FDA 483 included observations relating to certain aspects of our adverse drug experience, or ADE, reporting system for all of our products, including Xyrem. We responded to the Form FDA 483 with a description of the corrective actions and improvements we had implemented before or shortly following the inspection and additional improvements that we planned to implement, and have now implemented, to address the observations in the Form FDA 483. In August 2014, the FDA issued an Establishment Inspection Report to us, which indicates that the inspection is closed.

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, potentially including withdrawal or suspension of the product from the market. 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 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 Part 1, Item 1A of this Annual Report on Form 10-K 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 these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.”

The holder of an EU marketing authorization for a medicinal product must also comply with the EU’s new pharmacovigilance legislation which entails many new and revised requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. This new legislation enhanced the authority of the EMA and the competent authorities of the EU member states to require companies to conduct additional post-approval clinical efficacy and safety studies and increased the burden on companies with respect to additional monitoring, adverse event management and reporting. As part of the legislation and its related regulations and guidelines, marketing authorization holders 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 profitability. The EMA reviews periodic safety update reports submitted by marketing authorization holders. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing marketing authorization for the product be varied and requiring the marketing authorization holder to conduct post-authorization safety studies. The opinion is then submitted for approval by the EC. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We and our third party manufacturers 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, the competent authorities of EU member states and other regulatory authorities. The FDA also periodically inspects the sponsor’s records related to manufacturing facilities, which effort includes assessment of compliance with cGMP. Following such inspections, the FDA may also issue notices on Form FDA 483 and warning letters. For example, the FDA inspected the PHE facility where Erwinaze is manufactured in January 2015 and issued a Form FDA 483 with observations relating to the manufacturing process. We and our third party manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. In addition to Form FDA 483 notices and warning letters, failure to comply with the statutory and regulatory requirements may result in suspension of manufacturing, product seizure, withdrawal of the product from the market, criminal penalties, and withdrawal of approved products, among other enforcement remedies. Marketing authorization holders may also be subject to civil, criminal or administrative

sanctions in case of non-compliance with the EU or EU member states' requirements applicable to the manufacturing and marketing of medicinal products.

Irrespective of the different marketing authorization procedures, 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 applicable EU laws, regulations and guidance. These requirements include compliance with EU equivalent cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of 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 the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states.

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United States Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Healthcare Reform Act, is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. 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 may impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, or 340B program, fraud and abuse and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Details of the changes to the Medicaid Drug Rebate program and the 340B program are discussed under "Business—Pharmaceutical Pricing and Reimbursement" in Part I, Item 1 of this Annual Report on Form 10-K.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. 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 Medicaid 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 sales of our existing products or to successfully commercialize our product candidates, if approved.

Other Regulatory Requirements

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the U.S. Department of Justice, or DOJ, the Federal Trade Commission, or FTC, the U.S. Department of Commerce, or DOC, the Office of Inspector General, or OIG, of the U.S. Department of Health and Human Services, or 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.

Controlled Substance Regulations

The DEA imposes various quota, 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.

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. 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 2015, both our active pharmaceutical ingredient supplier and finished product manufacturer have been allocated most, but not all, of their respective requested quotas. If, in the future, 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.

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As a Schedule III drug, Xyrem is also subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, including limitations on prescription refills.

The third parties who perform our clinical and commercial manufacturing, distribution, dispensing and clinical studies for Xyrem are required to maintain necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA or relevant state authorities could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, fines, injunctions, or civil or criminal penalties, and could have an adverse effect on our business and financial condition.

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.

Sales and Marketing Regulations

We are also subject to various U.S. federal and state laws restricting certain marketing practices in the pharmaceutical industry, including anti-kickback laws and false claims laws. 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 or recommending the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. Liability under the federal anti-kickback statute may be established without a person or entity having actual knowledge of the statute or specific intent to violate it. Violations of the federal anti-kickback statute may be punished by civil and criminal fines, imprisonment, and/or exclusion from participation in federal healthcare programs. The U.S. federal False Claims Act, or the False Claims Act, prohibits, among other things, 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. Violations of the False Claims Act may be punished by significant financial penalties. In addition, the Physician Payment Sunshine provisions of the Healthcare Reform Act require extensive tracking of payments and transfers of value to physicians and teaching hospitals and public reporting of the data collected.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and the False Claims Act, 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. Some states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to

implement compliance programs or marketing codes of conduct. Other states have considered similar proposals in recent years and may adopt them in the future. Non-U.S. governments often have similar regulations which we are also subject to in those countries where we market and sell products.

The number and complexity of both U.S. 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. See more discussions regarding these laws and regulations under the risk factor in Part 1, Item 1A of this Annual Report on Form 10-K 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—Other Regulatory Authorities.”

The FDA, the competent authorities of the EU member states and other governmental authorities require advertising and promotional labeling to be truthful and not misleading, and products to be marketed only for their 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

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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.

The FDA, the competent authorities of the EU member states and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. A company that is found to have promoted an approved product for off-label uses may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's sales, business and financial condition. The U.S. government has also required companies that have engaged in such activities 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 OIG 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.

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

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. These programs and related risks are discussed in greater detail under the risk factor in Part 1, Item 1A of this Annual Report on Form 10-K entitled "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."

Anti-Corruption Legislation

Our business activities outside of the United States are subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct 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 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

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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 DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, or Dodd-Frank 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.

Data Privacy and Protection

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 U.S. federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. In addition, we obtain patient health information from most healthcare providers who prescribe our products and research institutions we collaborate with, and they are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA. 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.

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. Furthermore, there is a development toward the public disclosure of clinical trial data in the EU which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation, EMA disclosure initiatives and voluntary commitments by industry. 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 EC 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 DOC. 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. Both Medicare and Medicaid are administered by the Centers for Medicare and Medicaid Services, or CMS. 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. The CMS is currently scheduled to issue final regulations in April 2015.

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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 U.S. 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. 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.

In addition, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. The Bipartisan Budget Act of 2013 extended the 2% reduction to 2023, and the Protecting Access to Medicare Act of 2014 extended the 2% reduction, on average, to 2024. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

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. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. For example, third party payors have started to require discounts and/or exclusivity arrangements with some drug manufacturers in exchange for including a specific product on their formularies. Any such requirements 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 and, since November 2013, CMS has been publishing final National Average Drug Acquisition Cost, or NADAC, data, which reflect retail community pharmacy invoice costs, 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 and have certain price reporting obligations to the Medicaid Drug Rebate program, several state Medicaid supplemental rebate programs and other governmental pricing programs, and we have obligations to report the average sales price for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program. 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 which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The status of price reporting submissions for two radiopharmaceutical products is discussed under the risk factor in Part 1, Item 1A of this Annual Report on Form 10-K entitled “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.” In addition, 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 the average sales price information each quarter to CMS for certain categories of drugs that are paid under Part B of the Medicare program.

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Manufacturers calculate the average sales price based on a statutorily defined formula and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing discount program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. 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, or VA, Federal Supply Schedule, or FSS, pricing program. 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 - the VA, U.S. Department of Defense, or DoD, 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 VA on a quarterly and annual basis. We also participate in the Tricare Retail Pharmacy program, 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 the 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 EU member states we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states. These EU member states include the United Kingdom, France, Germany and Sweden. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products, as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. For example, France requires the evaluation of the medical benefits of a new product as well as the added clinical value of a new product in comparison with existing therapies, and we are evaluating the impact of this evaluation on our ability to obtain favorable pricing and reimbursement for Defitelio in France. If we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, including France, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

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. 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.

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Employees

As of February 18, 2015, we had approximately 870 employees worldwide. We consider our employee relations to be good.

Environment, Health and Safety

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in Italy where we have, and in Ireland where we are building, manufacturing facilities. Environmental and health and safety authorities in the relevant jurisdictions administer laws, which implement EU directives and regulations governing, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. In certain cases, such laws, directives and regulations may impose strict liability for pollution of the environment and contamination resulting from spills, disposals or other releases of hazardous substances or waste and/or any migration of such hazardous substances or waste. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us and/or off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination. For our facility in Italy, 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). Our environmental policy for our Italian facility is designed to comply with current EU laws and 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 the location and to respect the safety of people living close to our facility and in the surrounding community.

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc was originally formed under the laws of Ireland (registered number 399192) 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, or Azur Pharma, in October 2011. On January 18, 2012, the business of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction, 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. We refer to this transaction as the Azur Merger.

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.

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 2014, we completed the Gentium Acquisition.

Available Information

We file or furnish pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, as applicable, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, amendments to those reports, proxy statements and other information electronically with 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.

The mailing address of our headquarters is Fourth Floor, One Burlington Road, Dublin 4, Ireland, and our telephone number at that location is 353-1-634-7800. Our website is www.jazzpharmaceuticals.com. Through a link entitled "SEC Filings" under the "Investors & Media" section of our website, we make copies of our periodic and current reports, proxy statements and other information available, free of charge, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. 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.

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Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our ordinary shares could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and accompanying 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 67.0% of our net product sales for the year ended December 31, 2014 and 65.8% of our net product sales for the year ended December 31, 2013. Our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2012 to 2013 and from 2013 to 2014, 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 2015, and we cannot assure you that price adjustments we have taken or may take in the future will not negatively affect Xyrem sales volumes.

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

- the potential introduction of a generic version of Xyrem or an alternative sodium oxybate product for treating cataplexy and/or EDS in narcolepsy;
- 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, or regulatory actions by the FDA, 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;
- any increase in restrictive conditions for reimbursement required by, and the availability of reimbursement from, third party payors, as discussed in more detail in the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled "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;"
- changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement and coverage by federal healthcare programs;
- continued acceptance of Xyrem as safe and effective by physicians and patients, even in the face of negative publicity that surfaces from time to time; and
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem.

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

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

If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.

Although Xyrem is covered by patents covering its manufacture, formulation, distribution system and method of use, five third parties have filed ANDAs seeking FDA approval of generic versions of Xyrem, and additional third parties

may also seek to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy. If one or more companies receive FDA approval of an ANDA for generic versions of Xyrem or an NDA for other sodium oxybate products, it is possible that such company or companies could introduce generic versions of Xyrem or other sodium oxybate products before our patents expire if they do not infringe our patents, if it is determined that our patents are invalid or

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unenforceable, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch competition to Xyrem at risk of potentially being held liable for damages for patent infringement.

Five companies have sent us notices of Paragraph IV Certification that each has filed an ANDA with the FDA seeking approval to market a generic version of Xyrem before the expiration of the Orange Book-listed patents relating to Xyrem. We have sued all five ANDA filers 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 any of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Although no trial date has been set in any of the ANDA suits, we anticipate that trial on some of the patents in the Roxane case could occur as early as the third quarter of 2015. However, the actual timing of events may be significantly earlier or later than we currently anticipate, and we cannot predict the timing or outcome of events in this or the other ANDA litigation.

In addition, between June and October 2014, petitions seeking CBM post-grant patent review by the PTAB were filed by certain of the ANDA filers with respect to the validity of six of our patents covering the distribution system for Xyrem. In early 2015, the PTAB issued decisions denying institution of CBM review for all of these petitions. In January 2015, petitions for IPR were filed by certain of the ANDA filers with respect to the validity of six of our patents covering the distribution system for Xyrem. The PTAB has not yet determined whether to institute proceedings with respect to the petitions for IPR. We cannot predict whether PTAB will institute any of the petitioned IPR proceedings, whether additional post-grant patent review challenges will be filed, the outcome of any IPR or other proceeding if instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings.

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 was stayed until April 18, 2013, 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. 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 risk factor in Part I, Item 1A of this Annual Report on Form 10-K 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 these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

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

A generic manufacturer or manufacturer of an alternative sodium oxybate product would need to obtain quota from the DEA in order to manufacture both the active pharmaceutical ingredient and the finished product to compete with 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. Through 2011, our active pharmaceutical ingredient supplier

obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for the last few years, our supplier was allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. Consequently, a generic manufacturer or manufacturer of an alternative sodium oxybate product may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In the past, we have also had to engage in lengthy efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2015, both our active pharmaceutical ingredient supplier and finished product manufacturer have been allocated most, but not all, of their respective requested quotas. If, in the future, 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

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

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

As a condition of approval of Xyrem, the FDA mandated that we maintain the Xyrem Risk Management Program, which includes parts of the Xyrem Success Program and 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. The 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 FDAAA. The Xyrem Risk Management Program, however, is not in the form that is now required for REMS documents. The FDAAA, which amends 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 respect to ours REMS documents for Xyrem, but have not reached agreement with the FDA on certain significant terms. In late 2013, the FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Among other things, we disagree with the FDA's position in the late 2013 notice 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, be sufficient to ensure that the REMS includes only those elements necessary to ensure that the benefits of Xyrem outweigh its risks, and that would, in the FDA's view, reduce the burden on the healthcare system. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We received the FDA's denial of our initial dispute resolution submission in the second quarter of 2014, and our dispute is currently subject to further supervisory review at the next administrative level of the FDA. We have received interim responses from the FDA, but the FDA has not yet communicated a decision on our further appeal to us. We expect to receive the FDA's decision in the first quarter of 2015. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

Section 505-1(i)(1) of the 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 the then-current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). The parties have had numerous interactions with respect to a single shared system REMS since

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the initial meeting, and we expect the interactions to continue. 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 Part I, Item 1A of this Annual Report on Form 10-K entitled "We have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products."

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

The 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. Three 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 the ANDA filed by Roxane, the first ANDA filer, 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 an 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 Part I, Item 1A of this Annual Report on Form 10-K entitled "We have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, 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 dispensed and shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under our program is complex and includes multiple mandatory steps, such as the enrollment of the patient in the Xyrem Success Program and calls between the central pharmacy and the patient before each prescription of Xyrem is filled and sent to the patient. 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, provides timely notice that it wants to terminate our agreement, refuses or fails to adequately serve patients, or fails to promptly and adequately address operational challenges, whether expected or unexpected, the fulfillment of Xyrem prescriptions 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

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patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us, as required. We reported these cases to the FDA when we discovered them, investigated the related data from ESSDS as well as additional data we gathered, and submitted an analysis of the data to the FDA. In October 2011, we received a warning letter from the FDA regarding certain aspects of our adverse event reporting system for Xyrem and drug safety procedures related to the deaths that we discovered in April 2011 which had not been reported. We completed the actions and submitted the data required to address the observations in the 2011 warning letter and arising from a subsequent inspection. In August 2013, we received a close-out letter from the FDA. In April 2014, we received a Form FDA 483 at the conclusion of a pharmacovigilance inspection conducted by the FDA. The Form FDA 483 included observations relating to certain aspects of our adverse drug experience, or ADE, reporting system for all of our products, including Xyrem. We responded to the Form FDA 483 with a description of the corrective actions and improvements we had implemented before or shortly following the inspection and additional improvements that we planned to implement, and have now implemented, to address the observations in the Form FDA 483. In August 2014, the FDA issued an Establishment Inspection Report to us, which indicates that the inspection is closed. Although we have implemented improvements to our ADE reporting system, there can be no assurance that the FDA or other regulatory agencies will not identify additional matters in future pharmacovigilance inspections or that we will be able to adequately address any matters identified by the FDA or other regulatory agencies in the future, and the failure to do so could have a material adverse effect on our business, financial condition and results of operations.

Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the satisfaction of the FDA or any other regulatory authority could result in such regulatory authorities taking actions in the future, which could have a material adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth prospects. See also the risk factor in Part I, Item 1A of this Annual Report on Form 10-K 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. We cannot predict whether the FDA will require additional warnings, including boxed warnings, to be included on Xyrem’s label. Moreover, 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. 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 lead marketed products Erwinaze (called Erwinase in markets outside the United States) and Defitelio.

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, was approved by the FDA under a BLA and was 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 maintain or 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 clinical data on the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase, as well as our need to apply for and receive marketing authorizations, through the EU's, mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries. Another significant challenge to our ability to maintain the current sales level and to increase sales is our limited inventory of Erwinaze and our need to avoid supply interruptions of Erwinaze due to capacity constraints, production delays, quality challenges or other manufacturing difficulties. See the discussion regarding Erwinaze supply issues in the risk factor in Part I, Item 1A of this Annual Report on Form 10-K 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

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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 future biosimilar products. In addition, if we fail to comply with our obligations under our agreement with PHE or lose exclusive rights to Erwinaze, or otherwise fail to maintain or grow sales of Erwinaze, our growth prospects could be negatively affected.

We made a significant investment in Defitelio/defibrotide in 2014, adding the product to our portfolio as a result of the Gentium Acquisition and then securing worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. Our ability to realize the anticipated benefits from this investment is subject to a number of risks and uncertainties, including our ability to successfully maintain or grow sales of Defitelio in Europe, or obtain marketing approval of defibrotide in other countries, including the United States, so that we can commercialize the product in those countries. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled "We may not be able to successfully maintain or grow sales of Defitelio in Europe, or obtain marketing approval of defibrotide 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 also face other challenges that could impact the anticipated value of Defitelio/defibrotide, including the limited size of the population of patients who undergo HSCT therapy and develop severe VOD, the need to establish U.S. pricing and reimbursement support for the product in the event we are able to obtain U.S. marketing approval for defibrotide, the possibility that we may be required to conduct time-consuming and costly clinical trials as a condition of any U.S. marketing approval for the product, the lack of experience of U.S. physicians in diagnosing and treating VOD, and challenges to our ability to develop the product for indications in addition to the treatment of severe VOD. If sales of Defitelio/defibrotide do not reach the levels we expect, our anticipated revenue from the product would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Failure to maintain or increase prescriptions and revenue from sales of our products, including Erwinaze and Defitelio, 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 maintain or grow sales of Defitelio in Europe, or obtain marketing approval of defibrotide 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 expect to continue to launch Defitelio in additional European countries on a rolling basis in 2015 and are in the process of making pricing and reimbursement submissions with respect to Defitelio, and discussing them with regulatory authorities, in those European countries where Defitelio is not yet launched, including in countries where pricing and reimbursement approvals are required for launch. We cannot predict the timing of Defitelio's launch in countries where we are engaged in pricing and reimbursement submissions. If we experience delays and unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected countries would be delayed, which could negatively impact anticipated revenue from Defitelio. Similarly, the process for

obtaining pricing and reimbursement approvals is complex and can vary from country-to-country. For example, France requires the evaluation of the medical benefits of a new product as well as the added clinical value of a new product in comparison with existing therapies, and we are evaluating the impact of this evaluation on our ability to obtain favorable pricing and reimbursement in France. If we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, including France, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

We have developed estimates of anticipated pricing, which are based on our research and understanding of the product and target market. However, due to efforts to provide for containment of health care costs, one or more countries may not support our estimated level of governmental pricing and reimbursement for Defitelio, particularly in light of the budget crises faced by a number of countries in Europe, which would negatively impact anticipated revenue from Defitelio. Furthermore,

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

Due to the recent commercialization of Defitelio in Europe and the limited amount of historical sales data, our Defitelio sales will be difficult to predict from period to period, particularly since we may experience delays and unforeseen difficulties in obtaining favorable pricing and reimbursement approvals in additional countries. As a result, you should not rely on Defitelio sales results in any period as being indicative of future performance. In addition, if sales of Defitelio do not reach the levels we expect, our anticipated revenue from Defitelio would be negatively affected which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

At the time of the Gentium Acquisition, Gentium had licensed to Sigma-Tau the rights to defibrotide for the treatment and prevention of VOD in North America, Central America and South America. We acquired these rights from Sigma-Tau in August 2014. Defibrotide has been, and continues to be, made available as an investigational drug to patients diagnosed with VOD in the United States through an expanded access treatment protocol open under an IND. We are engaged in activities related to the potential approval of defibrotide in the United States. A prior NDA submission by Gentium seeking approval in the United States for defibrotide for the treatment of VOD was voluntarily withdrawn from consideration in 2011 in order to address issues raised by the FDA. We held pre-NDA meetings with the FDA relating to our plans for the submission of an NDA for defibrotide for the treatment of severe VOD. Based on these meetings and in light of the current status of our acquisition and remediation of key information to be included in the data package for the NDA, in December 2014, we initiated a rolling submission of an NDA to the FDA and expect to complete the submission in mid-2015. We do not expect to be required to complete any additional clinical trials prior to the completion of the NDA submission. However, we may be unable to acquire and remediate key information in the data package in a timely manner, which would delay or preclude the completion of our NDA submission. Furthermore, if we fail to acquire and remediate key information or if analysis of this data does not support an NDA submission, we may be required to complete additional clinical trials in order to obtain appropriate data for an NDA submission. Even if we are able to complete the NDA submission as planned, we may be required to conduct time-consuming and costly clinical trials as a condition of any U.S. marketing approval for the product. In any event, we may be unable to obtain regulatory approval of defibrotide in the United States in a timely manner, if at all.

We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in indications in addition to the treatment of severe VOD. We cannot know when, if ever, defibrotide will be approved in any other country or under what circumstances, and what, if any, additional clinical or other development activities will be required in order to potentially obtain such regulatory approval and the cost associated with such required activities, if any. If we fail to obtain approval for defibrotide in other countries or for new indications, our anticipated revenue from defibrotide and our growth prospects would be negatively affected.

The Marketing Authorization Application, or MAA, Gentium initially filed with the EMA in 2011 sought approval for defibrotide for the treatment and prevention of VOD in adults and children. The approval Gentium received from the EC in October 2013 was for the narrower indication of treatment of severe VOD in adults and children undergoing HSCT therapy. The scope of any future approvals we receive may negatively affect defibrotide's growth prospects.
We cannot predict whether historical revenues from named patient programs for our hematology/oncology products will continue or whether we will be able to continue to distribute those products on a named patient basis.
In certain European countries, reimbursement for products that have not yet received marketing authorization may be provided through national named patient programs. Erwinase and defibrotide are available on a named patient basis in many countries where they are not commercially available. Such reimbursement may cease to be available if authorization for a named patient program expires or is terminated. While we generate revenue from the distribution of these products through named patient programs, we cannot predict whether historical revenues from these programs will continue, whether we will be able to continue to distribute our products on a named patient basis in these countries, whether we will be able to commercialize our products in countries where the products have historically been available on a named patient basis, or

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whether commercial revenues will exceed revenues historically generated from sales on a named patient basis. Any failure to maintain revenues from sales of Erwinase and/or defibrotide on a named patient basis and/or to generate revenues from commercial sales of these products exceeding historical sales on a named patient basis could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredient and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with 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, particularly Xyrem and Erwinaze since we maintain limited inventories for these products, we may be unable to meet 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 Xyrem and Erwinaze, as well as the ingredients or raw materials used to make them. Our limited inventory puts us at significant risk of not being able to meet product demand. The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product. As a consequence of constrained manufacturing capacity, we have had extremely limited ability to build an excess level of product inventory that could be used to absorb disruptions to supply resulting from quality or other issues. If we continue to be subject to capacity constraints or experience quality or other manufacturing challenges in the future, we may be unable to build a desired excess level of product inventory, and our ability to supply the market may be compromised.

Although we are taking steps to improve the Erwinaze manufacturing process, if our ongoing efforts are not successful, or we are subject to other challenges described elsewhere in this risk factor, we could experience additional 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 maintenance and growth of the market for this product. If, for any reason, our suppliers and manufacturers, including any new suppliers, do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, if one of our suppliers or manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or manufacturers could require us to obtain regulatory clearance in the form of a “prior approval supplement” and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product

manufacturing process. We believe that it could take up to two years, or longer in certain cases, to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a finished product manufacturer, we may not, as applicable, have sufficient salable product to meet market demands or a sufficient quantity of a product candidate for use in clinical trials while we wait for FDA or similar international regulatory body approval of a new supplier or manufacturer. Siegfried has been our sole supplier of sodium oxybate since 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.

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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. Inability to comply with regulatory requirements, including compliance with manufacturing-related post-marketing commitments that are part of the BLA approval, as well as other requirements monitored by the FDA, could adversely affect Erwinaze supply 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 increase its price 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.

Although there are long-term plans to expand production capacity of Erwinaze, we cannot assure you that our supplier will be able to continue to supply our ongoing commercial needs for the product in a timely manner, or at all, especially if our demand for product increases. If production difficulties occur as described elsewhere in this risk factor and result in a disruption to supply or capacity constraints, 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 or the cessation of manufacturing by our supplier. 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 our supplier to evaluate potential steps to increase the supply of Erwinaze over the longer term to address worldwide demand, our ability to maintain or increase sales of Erwinaze may be limited by our ability to obtain a sufficient supply of the product. Failure to obtain a sufficient supply of Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are our sole supplier of, and we believe that we are currently the sole worldwide producer of, the defibrotide drug compound. We manufacture the defibrotide drug compound in a single facility located in Villa Guardia, near Como, Italy. This facility could be damaged by fire, flood, earthquake, power loss, telecommunication and information system failure, terrorism or similar events. Any of these events could cause a delay or interruption in manufacturing and potentially a supply shortage of defibrotide, which could negatively impact our anticipated revenues. Patheon UK currently processes the defibrotide compound into its finished vial form, and is the sole provider of our commercial supply of the finished product in the EU and of our future clinical supply. If Patheon UK does not or is not able to perform these services for any reason, it may take time and resources to implement and execute the necessary technology transfer to another processor, and such delay could negatively impact our product launch and anticipated revenues and potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need.

We are also in the process of evaluating an appropriate provider to process defibrotide into finished product for the U.S. market in preparation for the potential approval of the product by the FDA. Part of the process to obtain FDA approval for defibrotide is to obtain certification from the FDA that the facilities we and our third party provider operate are in compliance with cGMP. The FDA may deny approval to manufacture defibrotide if the FDA determines that either our facility or our third party processor's facility does not meet applicable manufacturing and quality requirements. Following initial approval, if any, the FDA will continue to inspect and evaluate these facilities for ongoing compliance with applicable requirements. In addition, defibrotide is derived from porcine DNA. Our supplier of porcine materials may also be evaluated and inspected by the FDA in connection with our application for approval of defibrotide in the United States. If our supplier experiences safety or other issues that impact its ability to supply porcine materials to us as needed, we may not be able to find alternative suppliers in a timely fashion, which could negatively impact our supply of defibrotide.

In order to commence any of our planned clinical programs for JZP-110 or JZP-386, we need to have sufficient quantities of clinical product manufactured. While we believe that we will be able to obtain sufficient supplies of JZP-110 or JZP-386 before the commencement of our planned clinical trials, there can be no assurance that our

suppliers will be able to produce sufficient clinical supplies of JZP-110 or JZP-386 in a timely manner. Any delay in receiving adequate 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 2015, both our active pharmaceutical ingredient supplier and finished product manufacturer were allocated most, but not all, of their respective requested quotas. If, in the future, we and our supplier and

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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 ingredients for our products or backup manufacturers for our finished products.

Failure by our third party manufacturers to comply with regulatory requirements could adversely affect their ability to supply products or ingredients to us. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with the FDA's current cGMP requirements. DEA regulations also govern facilities where controlled substances such as 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 January 2015 and issued a Form FDA 483 with observations relating to the manufacturing process. We and our third party manufacturers 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. Failure to comply with applicable legal and regulatory requirements subjects our suppliers to possible legal or regulatory action, including shutdown, which may adversely affect a supplier's 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 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 870 in February 2015. This includes employees in fourteen countries in North America and Europe, a European commercial presence, a complex distribution network for products in Europe and additional territories, a manufacturing facility in Italy and a manufacturing facility under construction in Ireland. In addition, we may expand our international operations into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations and financial condition, including, among other things:

- the increased complexity and costs inherent in managing international operations;
- diverse regulatory, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- country-specific tax, labor and employment laws and regulations;
- applicable trade laws, tariffs, export quotas, custom duties or other trade restrictions and any changes to them;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations, as well as maintaining positive interactions with unionized employees in one of our international locations;
- liabilities for activities of, or related to, our international operations, products or product candidates;

- 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.

As a result of our rapid growth, 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

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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.

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. 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;
- 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 conditions for reimbursement required by, and the availability of reimbursement from, third party payors.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse events 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. Similarly, negative publicity resulting from our receipt of a Form FDA 483 in April 2014 or other related regulatory actions could adversely affect sales of our products.

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

For additional discussion about payor acceptance, see the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled "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."

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,

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obtain regulatory approval for and commercialize these product candidates. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for these opportunities. In order to compete successfully to acquire attractive products or product candidates in the current business climate, we may have to pay higher prices for assets than may have been paid historically, which may make it more difficult for us to realize an adequate return on any acquisition.

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.

In addition, product and product candidate acquisitions create other uncertainties and risks, particularly when the acquisition takes the form of a merger or other business consolidation. Our business acquisitions have required, and any similar future transactions will also 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 transition activities and integration efforts, which include:

- high acquisition costs;
- the need to incur substantial debt or engage in dilutive issuances of equity securities to pay for acquisitions;
- the potential disruption of our historical core business;
- 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;
- the failure to retain key managers and other personnel;
- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisition;
- the need to write down assets or recognize impairment charges;
- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures; and
- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

If any of these or other factors impair our ability to integrate any acquired business efficiently and 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 an 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.

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, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Since 2014, we have made significant investments into expanding our product development pipeline and expect to continue to increase our research and development organization to pursue targeted development activities. Significant clinical, development and financial resources will be required to progress product candidates through clinical trials and the regulatory approval process to develop them into commercially viable products. We have a number of product candidates under development, including JZP-110 and JZP-386 in the sleep area and JZP-416 and Leukotac in the hematology/oncology area. 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.

As a condition to regulatory approval, each drug product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The

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results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. Results of limited preclinical studies, including studies of our product candidates in animal models, may not predict the results of human clinical trials of those product candidates. Similarly, 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 any equivalent non-U.S. regulatory agency 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 preclinical studies or earlier clinical trials. 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 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.

In addition to issues relating to the results generated in clinical trials, 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 or failures 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 clinical trials 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.

For example, we initiated our first study of JZP-416 in children in a pivotal Phase 2 trial in North America in late 2014. In February 2015, we voluntarily suspended patient enrollment in this trial. Our decision to suspend enrollment and to discontinue treatment with JZP-416 for enrolled patients is based on the occurrence of hypersensitivity-like reactions following the administration of JZP-416 in some treated patients. We are in the process of collecting and evaluating the available data and plan to conduct additional research and analysis prior to determining whether to resume the study and determining next steps regarding the development of JZP-416. We cannot predict whether we will continue development of JZP-416 or resume enrollment in the pivotal Phase 2 clinical trial in a timely fashion, if at all. Under our license agreement with Alizé, under which we obtained rights to develop and commercialize

JZP-416, we are subject to contractual obligations to meet certain development milestones within the applicable timeframes provided under the license agreement. Our ability to meet some of these milestones is uncertain, and depends upon a number of factors, including our ability to obtain clinical material, to recruit study centers with appropriate expertise and patient populations and to develop a clinical program meeting the development requirements of both the FDA and European regulatory authorities in a timely fashion. If our development activities are delayed for reasons that are not excused under our license agreement, we may have to pay Alizé for extensions to meet our licensing obligations or we may lose our rights to develop and commercialize JZP-416.

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The FDA has granted Fast Track designation to the investigation of JZP-416 for ALL. Defibrotide has also been granted Fast Track designation by the FDA to treat severe VOD. The Fast Track program is designed to enable more frequent interactions with the FDA during drug development and to expedite new drug candidate review. Although we have obtained Fast Track designation from the FDA for JZP-416 and defibrotide, receipt of Fast Track designation may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures, and Fast Track designation may be withdrawn by the FDA at any time. In addition, Fast Track designation does not guarantee that we will be able to take advantage of the expedited review procedures and does not increase the likelihood that either JZP-416 or defibrotide will receive any regulatory approvals.

The clinical trial we initiated in the second quarter of 2014 to further evaluate the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase has not yet enrolled a patient, which has delayed our ability to generate additional clinical data necessary to support the expansion of Erwinaze's therapeutic uses and could materially and adversely affect the maintenance and growth of the market for Erwinaze.

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

The commercial potential of our current products and any future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, have fewer side effects, are easier to administer or are less expensive than our products. Many of our competitors, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. They can spend more on, and have more expertise in, research and development, regulatory, manufacturing, distribution and sales activities. As a result, our competitors may obtain FDA or other

regulatory approvals for their product candidates more rapidly than we may and may market their products more effectively than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

In addition, many of our competitors are able to deploy more personnel to market and sell their products than we do. We currently have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. The continued growth of our current products and the launch of any future products may require expansion of our sales force and sales support organization internationally, and we may need to commit significant additional funds, management and other resources to the growth of our sales organization. We may not be able to achieve any necessary growth in a timely or cost-effective manner or realize a positive return on our investment, and we may not have the financial resources

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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.

We compete with a significant number of pharmaceutical and life sciences companies with extensive sales, marketing and promotional experience in hematology/oncology markets, and our failure to compete effectively in this area could negatively affect our sales of Erwinaze, Defitelio and other products.

We also face competition, and may in the future face additional competition, from manufacturers of generic drugs. Generic competition often results in decreases in the prices at which branded products can be sold, particularly when there is more than one generic available in the marketplace. In addition, legislation enacted in the United States allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the dispensing of generic products rather than branded products where a generic version is available. Other companies could also develop products that are similar, but not identical, to our marketed products, such as an alternative formulation of our product or an alternative formulation combined with a different delivery technology, and seek approval in the United States by referencing our products and relying, to some degree, on the FDA's finding that our products are safe and effective. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled "If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected."

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

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

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

In addition, to grow our company we will need additional personnel. Competition for qualified personnel in the pharmaceutical industry is very intense. If we are unable to attract, retain and motivate quality individuals, including in our research and development operations, which are continuing to expand, 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.

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 personally identifiable 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,

and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. From time to time, our systems have been subject to cyber-attacks. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated

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information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent 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 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, regulatory and factual questions. 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 that cover or relate to our products and product candidates, including Xyrem and Defitelio. 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, potentially including by FDA approval of an ANDA that avoids infringement of our intellectual property.

On September 16, 2011, the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law. The final substantive provisions of the America Invents Act, including the first to file system, became effective on March 16, 2013. The America Invents 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, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as IPR, CBM reviews and other post grant reviews. These proceedings are conducted before the PTAB. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. The IPR process permits any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. The America Invents 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.

Although Xyrem is covered by patents covering its formulation, distribution system and method of use, third parties are seeking to introduce generic versions of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy. If one or more companies receive FDA approval of an ANDA for generic versions of Xyrem or an NDA for other sodium oxybate products, it is possible that such company or companies could introduce generic versions of Xyrem or other sodium oxybate products before our patents expire, if it is determined that our patents are invalid, unenforceable or non-infringed, or if such company or companies decide, before applicable ongoing patent litigation is concluded, to launch competition to Xyrem at risk of potentially being held liable for damages for patent infringement.

Five companies have sent us notices of Paragraph IV Certification that each has filed an ANDA with the FDA seeking approval to market a generic version of Xyrem before the expiration of the Orange Book-listed patents relating to Xyrem. We have sued all five ANDA filers 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 any of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Although no trial date has been set in any of the ANDA suits, we anticipate that trial on some of the patents in the Roxane case could occur as early as the third quarter of 2015. However, the actual timing of events may be significantly earlier or later than we currently anticipate, and we cannot predict the timing or outcome of events in this or the other ANDA litigation.

In addition, certain of the ANDA filers have also sought to challenge the validity of our patents covering the distribution system for Xyrem in the PTAB. Between June and October 2014, petitions seeking CBM post-grant patent review by the PTAB were filed by certain of the ANDA filers with respect to the validity of six of our patents covering the distribution system for Xyrem. In early 2015, the PTAB issued decisions denying institution of CBM review for all of these petitions. In January 2015, petitions for IPR were filed by certain of the ANDA filers with respect to the validity of six of our patents covering the

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distribution system for Xyrem. The PTAB has not yet determined whether to institute proceedings with respect to the petitions for IPR. We cannot predict whether PTAB will institute any of the petitioned IPR proceedings, whether additional post-grant patent review challenges will be filed, the outcome of any IPR or other proceeding if instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings.

In April 2014, we became aware of the completion of a "first in man" clinical trial by a company using its proprietary technology for delivery of a sodium oxybate formulation to eliminate second nighttime dosing for narcolepsy patients. This company has stated its intent to submit an NDA referencing Xyrem to the FDA by the end of 2016. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled "If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected."

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.

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 may not cover our competitors' products;
- 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. We rely on trade secrets and other unpatented proprietary information to protect our commercial position with respect to such products, which we may be unable to do. In some instances, we also rely on regulatory exclusivity. For example, Erwinaze has no patent protection. In addition to protection using trade secrets, Erwinaze has orphan drug exclusivity in the United States for a seven-year period from its FDA approval, which

precludes approval of another product with the same principal molecular structure for the same indication until November 2018. Erwinaze, as a biologic product approved under a BLA, is also subject to the BPCIA. Under the BPCIA, Erwinaze is expected to receive exclusivity that prevents approval of a biosimilar in the United States through late 2023. Because the BPCIA is a relatively new law, we anticipate that its impact on both reference product sponsors and biosimilar applicants will evolve over a period of

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years. Its implementation likely will be shaped by a variety of factors, including FDA issuance of guidance documents, proposed regulations, and decisions in the course of considering specific applications. As a result, it is possible that a potential competing drug product might obtain FDA approval before the orphan drug and expected BCPIA exclusivity periods have expired, which would adversely affect sales of Erwinaze. In the EU, the regulatory data protection and thus regulatory exclusivity period for Erwinase has lapsed. This also means that any new marketing authorizations for Erwinase in other EU member states will not receive any regulatory data protection. If a biosimilar product to Erwinaze is approved in the United States as interchangeable to Erwinaze or in other countries where Erwinaze is sold, a significant percentage of the prescriptions that would have been 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.

Similarly, although there are patent applications for JZP-416 pending in the United States and the product is covered by some patents outside of the United States, it is not yet covered by any U.S. patents. JZP-416 was granted orphan drug designation for the treatment of ALL by the EMA and by the FDA subject to certain conditions. JZP-416 is still in the early stage of clinical development and in February 2015, we voluntarily suspended enrollment in our first study of JZP-416 in children in a pivotal Phase 2 trial in North America. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled “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, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.” There is no guarantee that we will continue development of JZP-416 or resume enrollment in the pivotal Phase 2 clinical trial or that JZP-416 will succeed in clinical trials, that we will be able to file marketing applications for it, that it will receive marketing approval, or that JZP-416 will meet the conditions for orphan drug exclusivity. If we continue development, but fail to obtain orphan drug exclusivity and/or exclusivity under the BCPIA, and if we also fail to successfully execute on other strategies to protect our intellectual property with respect to JZP-416, including protection by one or more issued patents, JZP-416 would be subject to competition, 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 have incurred and expect to continue to incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, 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. 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. Under the America Invents Act, a third party may also have the option to challenge the validity of certain patents with the PTAB, whether they are accused of infringing our patents or not, and certain hedge funds have announced their intention of challenging valuable pharmaceutical patents through the IPR process. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, there is a risk that a court will decide that these patents are not valid or infringed, or that the PTAB will decide that certain patents are not valid, and that we do not have the right to stop a third party from using the patented subject matter.

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For example, five 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. In addition, certain of the ANDA filers have sought to challenge the validity of our patents covering the distribution system for Xyrem by filing CBM post-grant patent review and/or IPR by the PTAB. The PTAB has issued decisions denying institution of CBM review for all of the CBM petitions and has not yet determined whether to institute proceedings with respect to the petitions for IPR. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled "It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection." We cannot assure you that our pending lawsuits, other lawsuits or proceedings we may file in the future, or our defense against any lawsuits or other proceeding that have been or will be brought against us will be successful in stopping the infringement of our patents, that any such litigation or other proceedings will be cost-effective, or that any of them 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, which we may not be able to do.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many non-U.S. jurisdictions are typically not published until 18 months after their priority date, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our or our licensors' 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 patent 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, among other things, the formulation and method of use covering the administration for Xyrem. In July 2014, the USPTO issued us a new method of use patent relating to the safe and effective use of Xyrem by decreasing the dose of Xyrem when used concomitantly with divalproex sodium, which information was added to the Xyrem label in April 2014. We have listed this new patent in the Orange Book. While we believe the additional safety information is critical for the safe use of Xyrem and should be required to be included in the label for any proposed generic form of Xyrem, we do not know whether the FDA will require any proposed generic form of Xyrem to include this information in its product label or whether we will be successful in maintaining the validity of the applicable patent and protecting the patent from infringement.

We also own 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 respect to ours REMS documents for Xyrem, but have not reached agreement with the FDA on certain significant terms. In late 2013, the FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Among other things, we disagree with the FDA's position in the late 2013 notice 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, be sufficient to ensure that the REMS includes only those elements necessary to ensure that the benefits of Xyrem outweigh its risks, and that would, in the FDA's view, reduce the burden on the healthcare system. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We received the FDA's

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denial of our initial dispute resolution submission in the second quarter of 2014, and our dispute is currently subject to further supervisory review at the next administrative level of the FDA. We have received interim responses from the FDA, but the FDA has not yet communicated a decision on our further appeal to us. We expect to receive the FDA's decision in the first quarter of 2015. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K 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 these 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 of these matters 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 manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of our products and our research and development activities are subject to extensive regulation by the FDA, the EC and other regulatory authorities. Regulations differ from country to country. As a result of these regulations, product development, approval and commercialization processes are expensive and time-consuming. For example, we are not permitted to market a pharmaceutical product in the United States or in the EU member states until we receive approval from the FDA, the EC or the competent authorities of the EU member states, as applicable. An application for marketing approval 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 active pharmaceutical ingredient, analytical methods, product formulation, details on the manufacture and stability of the finished pharmaceutical product and proposed product packaging and labeling. 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 indications than sought, can have a negative impact on our financial performance.

If the FDA, the EC or the competent authorities of the EU member states determine that a REMS or the imposition of post-marketing obligations is necessary to ensure that the benefits of the drug outweigh the risks, we may be required

to include a proposed REMS as part of an NDA or BLA 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 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. 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 these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem" above, and other products that we sell are or may become subject to a REMS specific to our product or shared with other products in the same class of drug. We cannot predict the impact that any new REMS requirements applicable to any of our products would have on our business.

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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 to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use. If we fail to meet the post-marketing obligations imposed as part of the marketing authorization for Defitelio or if it is determined that the balance of risks and benefits of using Defitelio changes materially, the EMA could vary, suspend or withdraw the marketing authorization for Defitelio.

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.

The Healthcare Reform Act is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the “donut hole”), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service’s 340B drug pricing discount program, 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.

Details of the changes to the Medicaid Drug Rebate program and the 340B program are 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.”

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. 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 Medicaid 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 sales of our existing products or to successfully commercialize our product candidates, if approved.

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 healthcare 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 for our 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 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. Co-pay coupon programs, including

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our program for Xyrem, have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives. In recent years, other pharmaceutical manufacturers have been named in class action lawsuits challenging the legality of their co-pay programs under a variety of federal and state laws. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar lawsuits or insurer actions. 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. In September 2014, the OIG issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Medicare Part D beneficiaries from using co-pay coupons. It is possible that the outcome of litigation against other manufacturers, changes in insurer policies regarding co-pay coupons, and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these programs, which could result in fewer patients using affected products, which could include Xyrem, and therefore could have a material adverse effect on our sales, business and financial condition.

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

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

We are subject to significant ongoing regulatory obligations with respect to our marketed products, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of our products are, and any of our product candidates that may be approved by the FDA, the EC, the competent authorities of the EU member states and other non-U.S. regulatory authorities will be, subject to extensive and ongoing regulatory requirements. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. Failure by us or any of our third party partners, including suppliers, manufacturers, distributors and our respective central pharmacies for Xyrem and for Prialt, to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, withdrawal, suspension or variation of product approval, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall, withdrawal or seizure, total or partial suspension of production or distribution, interruption of manufacturing or clinical trials, operating restrictions, injunctions; suspension of licenses, civil penalties and/or criminal prosecution, any of which could have a significant impact on our sales, business and financial condition.

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, potentially including withdrawal or suspension of the product from the market, any of which could result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition and results of operations.

The FDA also periodically inspects the sponsor's records related to safety reporting. Following such inspections, the FDA may issue notices on Form FDA 483 and warning letters that could cause us to modify certain activities. A Form FDA 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated relevant FDA regulations or guidance. Failure to adequately and promptly correct the observation(s) can result in further regulatory enforcement action. For example, in April 2014, we received a Form FDA 483 at the conclusion of a pharmacovigilance inspection conducted by the FDA. The Form FDA 483 included observations relating to certain aspects of our ADE reporting system for all of our products, including Xyrem. We responded to the Form FDA 483 with a description of the corrective actions and improvements we had implemented

before or shortly following the inspection and additional improvements that we planned to implement, and have now implemented, to address the observations in the Form FDA 483. In August 2014, the FDA issued an Establishment Inspection Report to us, which indicates that the inspection is closed. Although we have implemented improvements to our ADE reporting system, there can be no assurance that the FDA or other regulatory agencies will not identify additional matters in future pharmacovigilance inspections or that we will be able to adequately address any matters identified by the FDA or other regulatory agencies in the future, and the failure to do so could have a material adverse effect on our business, financial condition and results of operations.

If we receive regulatory approvals to sell our products, the FDA, the EC, the competent authorities of the EU member states and other non-U.S. regulatory authorities 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

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potential of the product. If we become aware of problems with any of our products in the United States, the EU or elsewhere in the world or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or 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. The EU has adopted a new legislation related to pharmacovigilance, or the assessment and monitoring of the safety of medicinal products, and this new legislation enhanced the authority of the EMA and the competent authorities of the EU member states to require companies to conduct additional post-approval clinical efficacy and safety studies and increased the burden on companies with respect to additional monitoring, adverse event management and reporting. Under the legislation and its related regulations and guidelines, we may be required to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and may be required to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time consuming and expensive and could impact our profitability. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

The FDA approved the BLA for Erwinaze in the United States in November 2011, subject to certain post-marketing requirements, including developing and validating assays and conducting certain non-clinical studies. In addition, the BLA approval for Erwinaze is subject to compliance with numerous post-marketing commitments, including certain commitments which must be met by PHE with respect to product manufacturing, which are outside of our control. While activities are underway to complete the post-marketing requirements and to comply with the post-marketing commitments, if we and/or PHE 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 this or other 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.

Erwinase and defibrotide are available on a named patient basis in many countries where they are not commercially available. 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 Erwinase or defibrotide without proper authorization, 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.

The FDA, the competent authorities of the EU member states and other governmental authorities require advertising and promotional labeling to be truthful and not misleading, and products to be marketed only for their 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.

The FDA, the competent authorities of the EU member states and other governmental authorities also actively investigate allegations of off-label promotion activities in order to enforce regulations prohibiting these types of activities. A company that is found to have promoted an approved product for off-label uses may be subject to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties and other sanctions. Even when a company is not determined to have engaged in off-label promotion, the allegation from government authorities or market participants that a company has engaged in such activities could have a significant impact on the company's sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution

agreements that impose significant reporting and other burdens on the affected companies. For example, a predecessor company to Jazz Pharmaceuticals, Inc. was investigated for off-label promotion of Xyrem, and, while Jazz Pharmaceuticals, Inc. was not prosecuted, as part of the settlement Jazz Pharmaceuticals, Inc. entered into a corporate integrity agreement with the OIG, 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.

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Other Regulatory Authorities

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

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition to quota requirements, the DEA imposes various registration, importing, exporting, recordkeeping and reporting requirements, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the 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 World Health Organization 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 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 the requirements of the CSA and other regulatory bodies could result in, among other things, additional operating costs to us, delays in shipments outside or into the United States and adverse regulatory actions.

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 or recommending 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 and administrative sanction, 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 False Claims Act prohibits, among other things, 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 payments and transfers of value to physicians and teaching hospitals and public reporting of the data collected. On September 30, 2014, CMS published the first set of data collected under the Sunshine provisions. On or before March 31, 2015, and on or before the 90th day of each subsequent calendar year, manufacturers covered under the Sunshine provisions will be required to submit a report disclosing payments and transfers of value made in the preceding calendar year, and CMS then will publish the reported data on or before June 30 of the reporting year. It is widely anticipated that public reporting under the

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Physician Payment Sunshine provisions 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. In addition, if the data reflected in our reports are found to be in violation of any of the Physician Payment Sunshine provisions or any other U.S. federal, state or local regulations that may apply, we may be subject to significant civil, criminal and administrative penalties, damages or fines.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states restrict when pharmaceutical companies may provide meals to prescribers or engage in other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Other states have considered similar proposals in recent years. Non-U.S. governments often have similar regulations which we also will be subject to in those countries where we market and sell products.

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

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU member states. One example is the 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 also 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. 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 DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-

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Frank 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. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Moreover, EU member states and other jurisdictions have adopted data protection laws and regulations which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Furthermore, there is a move toward the public disclosure of clinical trial data in the EU, which also adds to the complexity of processing health data from clinical trials. Public disclosure of clinical trial data is provided for in the new EU Clinical Trials Regulation, EMA disclosure initiatives, and voluntary commitments by industry. 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, such as the United States, which are not considered by the EC to provide an adequate level of data protection. There are also similar restrictions imposed on transfer of data from Switzerland to the United States. 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 out of the EEA to third countries where different data protection rules apply. Our U.S. subsidiary, Jazz Pharmaceuticals, Inc., has certified compliance with the U.S. - EU Safe Harbor Framework through the DOC. A proposal for an EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration. The proposed EU Data Protection Regulation, if adopted, is expected to introduce new data protection requirements 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 U.S. 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 U.S. federal and state, EU and EU member state national laws that apply to pharmaceutical manufacturers is difficult and time consuming, and companies that violate these laws 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

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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. Three of the ANDA applicants have asserted that our patents covering the distribution system for Xyrem should not have been listed in the Orange Book, and that the Xyrem REMS is blocking competition. Such a challenge or any other challenge that we or our business partners have failed to comply with applicable laws and regulations could have a material adverse effect on our business, financial condition, results of operations and growth prospects. If we or the other parties with whom we work fail to comply with applicable regulatory requirements, we or they could be subject to a range of regulatory actions that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

We manufacture certain active pharmaceutical ingredients, including the defibrotide drug substance, at our manufacturing facilities in Italy. In addition, we have engaged a third party manufacturer to process defibrotide into the finished product in Italy. Our manufacturing facilities and those of our third party manufacturer are subject to continuing regulation by the Italian Health Authority and other Italian regulatory authorities with respect to the manufacturing of active pharmaceutical ingredients, including the defibrotide drug substance or its finished form. These facilities are also subject to inspection and regulation by the EMA with respect to the manufacturing of the defibrotide drug substance and its finished form. Also, part of the process to obtain approval for defibrotide is to pass a pre-approval inspection by the EMA, Italian Health Authority and the FDA to ensure that these facilities are in compliance with cGMP. Following initial approval in a jurisdiction, the applicable authorities will continue to inspect our manufacturing facilities and those of our third party manufacturer, in some cases, unannounced, to confirm ongoing compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our third party manufacturers will need to ensure that all of our processes, methods and equipment are compliant with cGMP. These authorities may deny approval to manufacture our products, require us to stop manufacturing our products, deny approval to the sale of our products or suspend the sale of our products, if they determine that either our facilities or our third party manufacturer's facility in Italy does not meet the standards of compliance required under applicable regulations.

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

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program, 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 available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Such data previously have not been submitted for ProstaScint® (capromab pendetide) and Quadramet® (samarium sm 153 lexidronam injection), which are radiopharmaceutical products. We 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 issues guidance on any requirements and reporting methodologies. 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

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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. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2015, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Sales of "orphan drugs" - those designated under section 526 of the FDCA - are excluded from this fee as long as no non-orphan indications have been approved for such orphan drugs.

In 2012, CMS issued proposed regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in April 2015. 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, and the Healthcare Reform Act expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's issuance of final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations. The initiation of any reporting of Medicaid pricing data for ProstaScint and Quadramet could result in retroactive 340B ceiling price liability for these two products as well as prospective 340B ceiling price obligations for ProstaScint. We are currently unable to reasonably estimate an amount or range of a contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results.

The Healthcare Reform Act also exempts "orphan drugs" from the ceiling price requirements for the covered entities added to the program by the Healthcare Reform Act. An interpretive rule to implement this statutory orphan drug exemption under a narrow interpretation was issued in July 2014 by the Health Resources and Services Administration, or HRSA, which administers the 340B program. However, a pending legal challenge to the validity of this interpretive rule has made the application of the statutory orphan drug exception uncertain. If the HRSA's narrow interpretation of the scope of the orphan drug exemption prevails, it could potentially negatively impact the price we are paid for certain of our products by certain entities for some uses and increase the complexity of compliance with the 340B program.

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. The HRSA currently is expected to issue proposed regulations in 2015 that will address many aspects of the 340B program. Any final regulation could affect our obligations under the 340B program in ways we cannot anticipate. In

addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. 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 average sales price 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

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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 any false price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit the required 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, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

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

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 VA FSS pricing program. 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 – VA, DoD, Public Health Service, and Coast Guard – that is no higher than the statutory FCP. The FCP is based on the Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, 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.

We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DoD formulary inclusion. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

If we overcharge the government in connection with our FSS contract or Tricare 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 and conditions for reimbursement. 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

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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.

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 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. 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.

In addition, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. The Bipartisan Budget Act of 2013 extended the 2% reduction to 2023, and the Protecting Access to Medicare Act of 2014 extended the 2% reduction, on average, to 2024. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue.

Third party payors' practices may affect the conditions required for reimbursement of our products, as well as the availability of reimbursement for our products, including Xyrem and Defitelio. Our business could be materially harmed if the Medicaid program, Medicare program or other third party payors in the United States or elsewhere were to deny reimbursement for our products or provide reimbursement only on unfavorable terms. This risk is particularly significant with respect to Xyrem in the United States and to Defitelio in Europe, in part due to payor sensitivity to the price of these products. Third party payors often require prior authorization for, require reauthorization for continuation of, or refuse to provide, reimbursement for our products, and others may do so in the future. Patients who cannot meet the conditions imposed by third party payors for prior authorizations or reauthorizations may not be able to obtain the prescribed medication due to an inability to afford the medication. For example, we are experiencing increasingly restrictive conditions for reimbursement required by some third party payors for Xyrem. While this increase has not had a material effect on the overall level of reimbursement coverage for Xyrem, it may do so in the future. In addition, increases in reimbursement-related activities have extended the time required to fill prescriptions and could continue to do so in the future. If we are unsuccessful in maintaining reimbursement for our products in a timely manner and at acceptable levels, if reimbursement for our products by third party payors is subject to overly restrictive conditions, or if third party payors refuse to provide reimbursement, the level of reimbursement for our products could be negatively impacted, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our business could also be harmed if the Medicaid program, Medicare program or other reimbursing bodies or payors limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances than we believe is appropriate. In addition, third party payors draw on diagnostic criteria to establish reimbursement

guidelines. Meaningful changes to the diagnostic criteria for narcolepsy are included in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) published in May 2013, and the third edition of International Classification of Sleep Disorders (ICSD-3) published in February 2014. As a result, third party payors may make changes to the coverage and reimbursement for our products, which may have a negative impact on revenues from our products, including Xyrem.

In many countries, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing approval. During 2014, Defitelio was launched in a number of European countries. We are in the process of making pricing and reimbursement submissions with respect to Defitelio, and discussing them with regulatory authorities, in those European countries where Defitelio is not yet launched, including in countries where pricing and reimbursement approvals are required for launch. We cannot predict the timing of Defitelio's launch in countries where we are awaiting pricing and reimbursement approvals. If we experience delays and unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected countries would be delayed, or, if we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, our growth prospects in Europe could be negatively affected. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled "We may not be

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

Third party payors frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. We have agreed to provide such discounts and rebates to some third party payors in relation to our products. We expect increasing pressure to offer larger discounts or discounts to a greater number of third party payors to maintain acceptable reimbursement levels and access for patients at co-pay levels that are reasonable and customary. 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. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. For example, third party payors have started to require discounts and/or exclusivity arrangements with some drug manufacturers in exchange for including a specific product on their formularies. Any such requirements 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 and since November 2013, CMS has been publishing final NADAC data, which reflect retail community pharmacy invoice costs, 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 our products appropriately, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the federal marketplace. As discussed above, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In various EU member states we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly

delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. We have periodically increased the price of Xyrem, most recently in February 2015, 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 and revenue.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states. These EU member states include the United Kingdom, France, Germany and Sweden. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products, as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment

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options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between EU member states and cannot be determined or anticipated in relation to our products at the present time. For example, France requires the evaluation of the medical benefits of a new product as well as the added clinical value of a new product in comparison with existing therapies, and we are evaluating the impact of this evaluation on our ability to obtain favorable pricing and reimbursement in France. If we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, including France, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

In the EU, our products are marketed through various channels and within different legal frameworks. In certain EU member states, reimbursement for unauthorized products may be provided through national named patient programs. Such reimbursement may no longer be available if authorization for named patient 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. 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 negatively affect our growth prospects in Europe.

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.

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 or adverse events known or reported to be associated with, 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 and Prialt, have boxed warnings in their labels. In addition, in the EU, Defitelio's label includes an inverted black triangle that indicates the product is subject to additional monitoring to permit quick identification of new safety information, as a condition of authorization of Defitelio under "exceptional circumstances." 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 our 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, or 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

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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. Such investigations 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. 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.

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

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in Italy where we have, and in Ireland where we are building, manufacturing facilities. Environmental and health and safety authorities in the relevant jurisdictions administer laws, which implement EU directives and regulations governing, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. Our manufacturing of active pharmaceutical ingredients in Italy involves, and our planned manufacturing activities in Ireland will also involve, the controlled storage, use and disposal of chemicals and solvents. For our facility in Italy, 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). Our environmental policy is designed to comply with current EU laws and 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 EU 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 EU 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, 2014, we had total indebtedness of approximately $1.5 billion, which included $895.4 million of outstanding secured indebtedness under a credit agreement that we entered into in June 2012 and subsequently amended in June 2013 and January 2014, which we refer to as our credit agreement, and $575.0 million of outstanding indebtedness under our 1.875% exchangeable senior notes due 2021, or the 2021 Notes, which were issued in August 2014. 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;
- result in dilution to our existing shareholders in the event exchanges of our 2021 Notes are settled in our ordinary shares;
- 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 or restructure 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.

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

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

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

Our credit agreement also includes a financial covenant that requires us to maintain a maximum secured leverage ratio. Our ability to comply with this financial covenant may be affected by events beyond our control. In addition, the covenants under the credit agreement could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the credit agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the revolving credit facility. In addition, the holders of our 2021 Notes have the ability to require us to repurchase their notes for cash if we undergo certain fundamental changes, such as a specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from The NASDAQ Global Select Market. Moreover, upon exchange of the 2021 Notes, unless we elect to cause to be delivered solely ordinary shares to settle such exchange, we will be required to make cash payments in respect of the 2021 Notes being exchanged. In this regard, it is our intent and policy to settle the principal amount of the 2021 Notes in cash upon exchange. However, we may not have enough available cash or be able to obtain financing at the time we are required to make any required repurchases of surrendered 2021 Notes or to pay cash upon exchanges of 2021 Notes. Our failure to repurchase 2021 Notes at a time when the repurchase is required by the indenture governing the 2021 Notes or to pay any cash payable on future exchanges of the 2021 Notes as required by the indenture governing the 2021 Notes would constitute a default under that indenture. A default under that indenture could also lead to a default under agreements governing our current or future indebtedness, including our credit agreement. If the repayment of the related indebtedness were to be accelerated, we may not have sufficient funds to repay the related indebtedness, which could have a material adverse effect on our financial condition and our business. In this regard, if we are unable to repay amounts under our credit agreement, 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 a series of transactions, including 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;

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- 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 acquisition or in-licensing and development of additional marketed or product candidates that are in late-stage development. 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, our substantial indebtedness 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 expect to opportunistically seek access to the capital and 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 and a number of other foreign jurisdictions. We are able to achieve a low average tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions, together with intra-group service and transfer pricing agreements, each on an arm's length basis. However, changes in tax laws in any of these jurisdictions could adversely affect our ability to do so in the future. 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 generally 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.

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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 under current law. 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, as well as a notice in September 2014 outlining further regulations the IRS plans to issue. 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. See the risk factor in Part I, Item 1A of this Annual Report on Form 10-K entitled “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.”

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, or NOLs, 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. and 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. NOLs prior to their expiration. As a result of this limitation, however, it may take Jazz Pharmaceuticals, Inc. longer to use its NOLs. Moreover, contrary to these plans, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Jazz Pharmaceuticals, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Jazz Pharmaceuticals, Inc. does not generate sufficient taxable income.

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

Our U.S. affiliates have a significant amount of NOLs. Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, or whether, our U.S. affiliates will generate sufficient taxable income to use all of the NOLs. In addition, realization of NOLs to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the “ownership change” provisions of Sections 382 and 383 of the Code and similar state provisions, which may result in the expiration of additional NOLs before future utilization. In general, an “ownership change” occurs if, during a three-year rolling period, there is a change of 50% or more in the percentage ownership of a company by 5% shareholders (and certain persons treated as 5% shareholders), as defined in the Code and the U.S. Treasury Department regulations, or Treasury Regulations, promulgated thereunder. 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 $28.8 million for 2015, $28.9 million for 2016, $15.0 million for 2017, $1.4 million for 2018 and a combined total of $4.9 million for 2019 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. However, changes to the Code or the Treasury Regulations or other IRS guidance promulgated thereunder, including under Section 7874 of the Code, could adversely affect our status as a foreign corporation for U.S. federal tax purposes or could otherwise affect our effective tax rate, and any such 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

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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 future impairment of our intangible assets and goodwill may significantly impact our profitability.

As of December 31, 2014, we had recorded $2.1 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 future periods could be negatively impacted should additional impairments 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.

The market price for our ordinary shares has fluctuated significantly from time to time, varying between a high of $183.84 on December 8, 2014 and a low of $120.38 on May 9, 2014 during the year ended December 31, 2014. The market price of our ordinary shares is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market, industry and other factors, including the risk factors described above. 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 our past transactions, including 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. The market price of our ordinary shares could also be affected by possible sales of our ordinary shares by holders of our 2021 Notes who may view the 2021 Notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity involving our ordinary shares by the holders of these notes.

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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 18, 2015, we had 60,657,182 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, future issuances by us of our ordinary shares upon the exercise or settlement of equity-based awards and exchanges of our 2021 Notes would dilute existing shareholders' ownership interest in our company and any sales in the public market of these ordinary shares, or the perception that these sales might occur, could also adversely affect the market price of our ordinary shares.

Moreover, 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 then-existing registration rights agreements, we entered into underwriting agreements with certain underwriters and selling shareholders pursuant to which selling shareholders sold an aggregate of approximately 13 million ordinary shares in two separate registered public offerings in March 2012 and in March 2013. If potential future holders of registration rights, by exercising their registration rights or otherwise, sell a large number of shares, the sale could adversely affect the market price of our ordinary shares. We have also filed registration statements to register the sale of our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and intend to file additional registration statements to register any shares automatically added each year to the share reserves under these plans.

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

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

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

Provisions of our articles of association, Irish law and the indenture governing our 2021 Notes could delay or prevent a takeover of us by a third party.

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

- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes;
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association; and
-

permit our board of directors to issue one or more series of preferred shares with rights and preferences, as our shareholders may determine by ordinary resolution.

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. Furthermore, the indenture governing our 2021 Notes requires us to repurchase the notes for cash if we undergo certain fundamental changes and, in certain circumstances, to increase the exchange rate for a

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holder of 2021 Notes. A takeover of us may trigger the requirement that we purchase our 2021 Notes and/or increase the exchange rate, which could make it more costly for a potential acquiror to engage in a business combination transaction with us.

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

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

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

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

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

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

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

Our auditor, like other independent registered public accounting firms operating in Ireland and a number of other European countries, is not currently permitted to be subject to inspection by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, our investors currently do not have the benefits of PCAOB oversight.

As an auditor of companies that are publicly-traded in the United States and as a firm registered with the PCAOB, our independent registered public accounting firm is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the laws of the United States and the professional standards of the PCAOB. However, because our auditor is located in Ireland, a jurisdiction where the PCAOB is currently unable to conduct inspections, our auditor is not currently inspected by the PCAOB. Inspections of other auditors conducted by the PCAOB outside of Ireland have at times identified deficiencies in those auditor's audit procedures and quality control procedures, which may be addressed 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

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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 2014 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 17,000 square feet of office space in Dublin, Ireland, 12,000 square feet of which is under one lease, or the Dublin Lease, that expires in May 2022, and 5,000 square feet of which is under a second lease that also expires in May 2022. We have an option to terminate these leases, in May 2017 for the Dublin Lease and in January 2019 for the second lease, with no less than six months' prior written notice and the payment of a termination fee. We are currently constructing a manufacturing and development facility on land owned by us in Athlone, Ireland. Once complete, the facility will be approximately 54,000 square feet in size.

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, 39,000 square feet of which is occupied under a sublease that expires in April 2016 and 17,000 square feet of which is occupied under a sublease that expires in July 2017. We have the right to extend the term of the Palo Alto Lease for up to an additional two years. In January 2015, we entered into an agreement to lease approximately 100,000 square feet of office space in Palo Alto, California. We expect to occupy this office space by the end of 2017. This lease has a term of 12 years from commencement and we have an option to extend the term of the lease twice for a period of five years each. We also have an option to terminate this lease 10 years from commencement, with no less than one year's prior written notice and the payment of a termination fee.

We occupy approximately 19,000 square feet of office space in Philadelphia, Pennsylvania under a lease that expires in April 2019. In addition, we have offices in Oxford, United Kingdom, Lyon, France, Villa Guardia (Como), Italy and elsewhere in Europe. We occupy approximately 14,000 square feet of office space in Oxford, United Kingdom under a lease that expires in August 2024. We have an option to terminate this lease in August 2019, with no less than six months' prior written notice and the payment of a termination fee. 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 €0.8 million ($1 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 and June 2015, respectively.

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

Xyrem ANDA Matters: On October 18, 2010, we received a notice of Paragraph IV Certification from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem (sodium oxybate) oral solution. Roxane's initial notice alleged that all five patents then listed for Xyrem in the Orange Book on the date of the notice 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 initial notice in the U.S. District Court for the District of New Jersey, or the District Court, seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. 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 was stayed for 30 months, or until April 18, 2013. That stay has expired. Additional patents covering Xyrem were issued between December 2010 and

December 2012, and, after receiving Paragraph IV Certification notices from Roxane, we filed additional lawsuits against Roxane on February 4, 2011, May 2, 2011, October 26, 2012 and December 5, 2012 to include these additional patents in the litigation. All of the lawsuits filed against Roxane between 2010 and 2012 have been consolidated by the District Court into a single case, or the Roxane consolidated case, alleging that 10 of our patents covering Xyrem are or will be infringed by Roxane's ANDA and seeking a permanent injunction to prevent Roxane from launching a generic version of Xyrem that would infringe these patents.

In December 2013, the District Court permitted Roxane to amend its answer in the Roxane consolidated case to allege additional equitable defenses, and the parties were given additional time for discovery on those new defenses. In addition, in

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March 2014, the District Court granted our motion to bifurcate and stay the portion of the Roxane consolidated case regarding patents related to the distribution system for Xyrem. Although no trial date has been scheduled, based on the District Court's current schedule, we anticipate that trial on the patents in the Roxane consolidated case that are not subject to the stay could occur as early as the third quarter of 2015. We do not have any estimate of a possible trial date for trial on the patents in the Roxane consolidated case that are currently subject to the stay. The actual timing of events in this litigation may be significantly earlier or later than we currently anticipate, and we cannot predict the specific timing or outcome of events in this litigation.

On April 1, 2014 and January 15, 2015, we received additional notices of Paragraph IV Certification from Roxane regarding newly issued patents for Xyrem listed in the Orange Book. On February 20, 2015, we filed a new lawsuit against Roxane in the District Court, alleging that three of our patents covering Xyrem are infringed or will be infringed by Roxane's ANDA and seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in this matter or its impact on the Roxane consolidated case.

On December 10, 2012, December 12, 2012 and August 8, 2013, we received notices of 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. On January 18, 2013 and September 12, 2013, we filed lawsuits against Amneal in the District Court, alleging that nine of our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. These lawsuits against Amneal were consolidated by the District Court on November 6, 2013.

On November 21, 2013 and November 24, 2013, we received notices of 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. On December 27, 2013, we filed a lawsuit against Par in the District Court, alleging that 13 of our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents.

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

On April 7, 2014 and January 19, 2015, we received additional notices of Paragraph IV Certification from Amneal regarding newly issued patents for Xyrem listed in the Orange Book. On May 20, 2014 and February 6, 2015, we filed additional lawsuits against Amneal in the District Court, alleging that four of our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. These additional lawsuits have not been consolidated with the Amneal/Par consolidated case. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Amneal.

On July 3, 2014, August 6, 2014 and November 25, 2014, we received additional notices of Paragraph IV Certification from Par regarding newly issued patents for Xyrem listed in the Orange Book. We filed additional lawsuits against Par in the District Court on August 15, 2014, October 2, 2014 and January 8, 2015, alleging that three of our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents. These additional lawsuits have not been consolidated with the Amneal/Par consolidated case. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Par.

On June 4, 2014, we received a notice of Paragraph IV Certification from Ranbaxy Laboratories Limited, or Ranbaxy, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On June 6,

2014, we received a notice of an amended Paragraph IV Certification from Ranbaxy. On July 15, 2014, we filed a lawsuit against Ranbaxy in the District Court, alleging that 14 of our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that will infringe these patents. On August 20, 2014 and December 1, 2014, we received additional notices of Paragraph IV Certification from Ranbaxy regarding newly issued patents for Xyrem listed in the Orange Book. On October 2, 2014 and January 9, 2015, we filed additional lawsuits against Ranbaxy in the District Court, alleging that two of our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Ranbaxy.

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On October 30, 2014, we received a notice of Paragraph IV Certification from Watson Laboratories, Inc., or Watson, that it has submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Watson in the District Court, alleging that 15 of our patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in this litigation.

In January 2015, Amneal, Ranbaxy and Watson proposed the consolidation of their respective cases and a consolidated schedule to the District Court. Under the proposed consolidated schedule, the District Court would hold a Markman hearing no earlier than January 2016. Par is currently seeking its own proposed schedule. Under Par's proposed schedule, the District Court would hold a Markman hearing in the Par case no earlier than September 2015. We cannot predict the timing or outcome of events in these proceedings, including what cases, if any, the District Court will consolidate and what cases, if any, the District Court will permit to go forward separately.

Between June and August 2014, petitions seeking CBM post-grant patent review by the PTAB were filed by certain of the ANDA filers with respect to the validity of six of our patents related to the distribution system for Xyrem. In the fall of 2014, we filed preliminary responses to the petitions in which, among other things, we asserted that the challenged patents should not be subject to CBM review. In early 2015, the PTAB issued decisions denying institution of CBM review for all of these petitions.

In January 2015, petitions for IPR were filed by certain of the ANDA filers with respect to the validity of six of our patents related to the distribution system for Xyrem. The PTAB has not yet determined whether to institute proceedings with respect to these petitions for IPR. We cannot predict whether PTAB will institute any of the petitioned IPR proceedings, whether additional post-grant patent review challenges will be filed, the outcome of any IPR or other proceeding if instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings.

FazaClo ANDA Matters: Azur Pharma received notices of 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, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification against Barr on August 21, 2008, against Novel on November 25, 2008 and against Mylan on July 23, 2010. Each case was filed in the U.S. District Court for the District of Delaware, or the Delaware Court. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015. 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. Teva has also exercised its option for supply of an authorized generic product for FazaClo HD. The Novel and Mylan matters had been stayed pending reexamination of the patents in the lawsuits. In September 2013 and January 2014, reexamination certificates were issued for the two patents-in-suit, and the patentability of the claims of the patents confirmed. The Delaware Court lifted the stay of litigation in the two cases in March 2014. On December 19, 2014, we and CIMA entered into an agreement with Novel settling the patent litigation against Novel and we granted Novel a sublicense to manufacture, market and sell a generic version of FazaClo LD and, if applicable, FazaClo HD. The sublicense will commence on May 1, 2017, or earlier upon the occurrence of certain events. Trial in the Mylan case is currently set for the third quarter of 2015, but we cannot predict the specific timing or outcome of this litigation.

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

breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to a $10.5 million and an additional $25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. In March 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. In July 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. That ruling was affirmed by the California Court of Appeal in January 2014, and the case was remanded to Superior Court for discovery and trial. Trial has been scheduled for October 2015. We cannot predict the specific timing or outcome of this litigation.

Shareholder Litigation Matter: In January 2014, we became aware of a purported class action lawsuit filed in the U.S. District Court for the Southern District of New York in connection with our acquisition pursuant to a tender offer of a majority of the voting securities of Gentium S.p.A., or Gentium, which we refer to as the Gentium Acquisition. The lawsuit named

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Gentium, each of the Gentium's directors, us and our Italian subsidiary as defendants. The lawsuit alleged, among other things, that Gentium's directors breached their fiduciary duties to Gentium's shareholders in connection with the Gentium tender offer agreement that Gentium entered into with us and our Italian subsidiary valuing Gentium ordinary shares and American Depositary Shares, or ADSs, at $57.00 per share, and that we and our Italian subsidiary violated Sections 14(e) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by allegedly overseeing Gentium's preparation of an allegedly false and misleading Section 14D-9 Solicitation/Recommendation Statement. On November 19, 2014, the plaintiff dismissed us and our Italian subsidiary from the lawsuit. On January 22, 2015, the entire lawsuit was dismissed with prejudice by the court.

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.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our ordinary shares trade on The NASDAQ Global Select Market under the trading symbol "JAZZ." The following table sets forth the high and low intraday sales prices of our ordinary shares on The NASDAQ Global Select Market for the periods indicated.

	High	Low
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
Calendar Quarter—2014		
First Quarter	$176.60	$123.55
Second Quarter	$156.34	$120.38
Third Quarter	$176.36	$131.69
Fourth Quarter	$183.84	$137.34

On February 18, 2015, the last reported sales price per share of our ordinary shares was $171.68 per share.

Holders of Ordinary Shares

As of February 18, 2015, there were three holders of record of our ordinary shares. Because almost 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 (1) a general exception for dividends and other restricted payments up to $30 million and (2) so long as there is no default or event of default under our credit agreement, another exception that is capped at $100 million plus a formula-based amount tied to our consolidated net income if our total leverage ratio (as defined in our credit agreement) exceeds 2:1 after giving pro forma effect to the dividend or distribution. 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 and current reports on Form 8-K filed with the Securities and Exchange Commission, or SEC, during the year ended December 31, 2014, there were no unregistered sales of equity securities by us during the year ended December 31, 2014.

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-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

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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, 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, countries that harbor certain terrorist groups and Ukraine 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 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

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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 being contemplated 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.

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, 2009 in (i) our ordinary shares; (ii) the NASDAQ Composite Index; and (iii) the NASDAQ Biotechnology Index through December 31, 2014. Information set forth in the graph below represents the performance of the Jazz Pharmaceuticals, Inc. common stock from December 31, 2009 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, 2014. 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 Securities Exchange Act of 1934, as

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amended, or 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.

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, 2014:

	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 - October 31, 2014	42,000	$151.75	42,000	$27,211,930
November 1 - November 30, 2014	11,058	$169.89	11,058	$25,333,480
December 1 - December 31, 2014	24,157	$165.15	24,157	$21,344,385
Total	77,215	$158.54	77,215	

(1) This table does not include ordinary shares that we withheld in order to satisfy minimum tax withholding requirements in connection with the vesting 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 our credit agreement, corporate and regulatory requirements and market conditions, and may 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 income data for the years ended December 31, 2014, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014 and 2013 from the audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statements of income data for the years ended December 31, 2011 and 2010, and the selected consolidated balance sheet data as of December 31, 2012, 2011 and 2010 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, 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.

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	Year Ended December 31,				
	2014(1)	2013	2012(2)	2011	2010
	(In thousands, except per share amounts)				
Consolidated Statements of Income Data:					
Revenues:					
Product sales, net	$1,162,716	$865,398	$580,527	$266,518	$170,006
Royalties and contract revenues	10,159	7,025	5,452	5,759	3,775
Total revenues	1,172,875	872,423	585,979	272,277	173,781
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technologies and intangible asset impairment)	117,418	102,146	78,425	13,942	13,559
Selling, general and administrative	406,114	304,303	223,882	108,936	68,996
Research and development	85,181	41,632	20,477	14,120	25,612
Acquired in-process research and development	202,626	4,988	—	—	—
Intangible asset amortization	126,584	79,042	65,351	7,448	7,825
Impairment charges	39,365	—	—		
Total operating expenses	977,288	532,111	388,135	144,446	115,992
Income from operations	195,587	340,312	197,844	127,831	57,789
Interest expense, net (including $570 for the year ended December 31, 2010 pertaining to a related party)	(52,713)	(26,916)	(16,869)	(1,600)	(12,724)
Foreign currency gain (loss)	8,683	(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 from continuing operations before income tax provision (benefit)	151,557	307,950	177,355	124,984	32,778
Income tax provision (benefit)	94,231	91,638	(83,794)	—	—
Income from continuing operations	57,326	216,312	261,149	124,984	32,778
Income from discontinued operations, net of taxes	—	—	27,437	—	—
Net income	57,326	216,312	288,586	124,984	32,778
Net loss attributable to noncontrolling interests, net of tax	(1,061)	—	—	—	—
Net income attributable to Jazz Pharmaceuticals plc	$58,387	$216,312	$288,586	$124,984	$32,778
Net income per ordinary share attributable to Jazz Pharmaceuticals plc (3):					
Basic:					
Income from continuing operations	$0.98	$3.71	$4.61	$3.01	$0.90
Income from discontinued operations	—	—	0.48	—	—
Net income attributable to Jazz Pharmaceuticals plc	$0.98	$3.71	$5.09	$3.01	$0.90
Diluted:					
Income from continuing operations	$0.93	$3.51	$4.34	$2.67	$0.83

Income from discontinued operations	—	—	0.45	—	—
Net income attributable to Jazz Pharmaceuticals plc	$0.93	$3.51	$4.79	$2.67	$0.83
Weighted-average ordinary shares used in calculating net income per ordinary share attributable to Jazz Pharmaceuticals plc (3):					
Basic	59,746	58,298	56,643	41,499	36,343
Diluted	62,614	61,569	60,195	46,798	39,411

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	As of December 31,				
	2014(1)	2013	2012(2)	2011	2010
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$684,042	$636,504	$387,196	$157,898	$44,794
Working capital	799,044	660,589	360,034	146,261	14,522
Total assets	3,338,955	2,238,221	1,966,493	253,573	135,729
Long-term debt, current and non-current	1,342,428	549,976	456,761	—	40,693
Retained earnings (accumulated deficit)	34,704	18,532	(61,296)	(349,882)	(474,866)
Total Jazz Pharmaceuticals plc shareholders' equity	1,371,144	1,295,534	1,121,292	192,788	30,551

(1) On January 23, 2014, pursuant to a tender offer, we became the indirect majority shareholder of Gentium S.p.A., or Gentium, acquiring control of Gentium on that date. In February 2014, we completed a subsequent offering period of the tender offer, resulting in total purchases pursuant to the tender offer of approximately 98% of the fully diluted voting securities of Gentium. As of December 31, 2014, we had acquired a further 1.8% interest in Gentium for cash consideration of $17.8 million, resulting in an aggregate acquisition cost to us of $994.1 million, comprising cash payments of $1,011.2 million offset by proceeds from the exercise of Gentium share options of $17.1 million. The results of operations of the acquired Gentium business, along with the estimated fair values of the assets acquired and liabilities assumed in the transaction, have been included in our consolidated financial statements since the completion of the acquisition of Gentium on January 23, 2014, which is referred to as the Gentium Acquisition in this report. We record noncontrolling interests in our consolidated financial statements which represent the ownership interest of minority shareholders in the equity of Gentium. In connection with the Gentium Acquisition, on January 23, 2014, we entered into a second amendment to our credit agreement. The credit agreement, as amended to date, provides 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 previously outstanding term loans and (iii) a $425.0 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 finance the Gentium Acquisition. Refer to Note 3 of Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for more information on the Gentium Acquisition. In August 2014, we completed a private placement of $575.0 million aggregate principal amount of 1.875% exchangeable senior notes due 2021, or the 2021 Notes, resulting in net proceeds to us, after debt issuance costs, of $558.9 million. We used a portion of the net proceeds from the issuance of the 2021 Notes to repay all outstanding borrowings under the revolving credit facility provided for under our credit agreement.

(2) 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 EUSA Pharma, which we refer to as 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 made 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.

(3) 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.

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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 impact our business. In particular, we encourage you to review the risks and uncertainties described in Part I, Item 1A "Risk Factors" in this Annual Report on Form 10-K. 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

Jazz Pharmaceuticals plc is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. We have a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology.

Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying new growth opportunities;
- Acquiring additional differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing focused development of a pipeline of post-discovery differentiated product candidates.

Throughout 2014 and so far in 2015, we have made substantial progress in the execution of our strategy. Some of the significant developments affecting our business in 2014 are summarized below.

Strong Revenue Growth

In 2014, our total net product sales increased by 34% compared to 2013, primarily from the growth in sales of Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase Erwinia chrysanthemi), and from the addition to our product portfolio of defibrotide, marketed under the name Defitelio® (defibrotide) in certain countries in Europe. Xyrem is the only product approved by the United States Food and Drug Administration, or FDA, for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in patients with narcolepsy. Sales of Xyrem increased 37% in 2014 compared to 2013.

Erwinaze is a treatment approved in the United States and in certain markets in Europe (where it is marketed as Erwinase®) for patients with acute lymphoblastic leukemia, or ALL, who have developed hypersensitivity to E. coli-derived asparaginase. First approved by the FDA for administration via intramuscular injection in conjunction with chemotherapy, Erwinaze received approval for administration via intravenous infusion in conjunction with chemotherapy in December 2014. Sales of Erwinaze/Erwinase increased 15% in 2014 compared to 2013.

Total product sales are expected to increase in 2015 over 2014, primarily due to anticipated growth in sales of our lead marketed products.

Expansion of Marketed Product Portfolio

We strengthened our commercial portfolio with the addition of Defitelio/defibrotide in January 2014 through our acquisition of a controlling interest in Gentium. Our aggregate acquisition cost for the Gentium Acquisition to date is $994.1 million, comprising cash payments of $1,011.2 million, offset by proceeds from the exercise of Gentium share options of $17.1 million. Defitelio was granted marketing authorization under exceptional circumstances by the European Commission, or EC, in October 2013 for the treatment of severe hepatic veno-occlusive disease, or VOD, in adults and children undergoing hematopoietic stem cell transplantation, or HSCT, therapy.

During 2014, Defitelio was launched in a number of European countries. We expect to continue to launch the product in additional European countries on a rolling basis in 2015 and are in the process of making pricing and reimbursement submissions with respect to Defitelio, and discussing them with regulatory authorities, in those European countries where Defitelio is not yet launched, including in countries where pricing and reimbursement approvals are required for launch. Defibrotide has been, and continues to be, provided to patients where it is not commercially available through an expanded access treatment protocol that is open under an investigational new drug application, or IND, in the United States and on a named patient basis elsewhere.

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Acquisition of Product Candidates

We have made significant investment in building our product development pipeline. In 2014, we acquired products and/or product candidates in the sleep and hematology/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.

•JZP-110. In January 2014, we entered into an asset purchase agreement with Aerial BioPharma LLC, or 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. JZP-110 is a late-stage investigational compound being developed for potential treatment of EDS in patients with narcolepsy and EDS in patients with obstructive sleep apnea, or OSA. Under the agreement, we made an upfront payment of $125.0 million to Aerial. We also paid a $2.0 million milestone to SK on assignment of the JZP-110 rights from Aerial to us. We are obligated to make milestone payments, in an aggregate amount of up to $270.0 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.

•Defibrotide. In August 2014, we acquired from Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, the rights to defibrotide for the treatment and prevention of VOD in North America, Central America and South America. In exchange for the rights to defibrotide in the Americas, we made an upfront payment of $75.0 million to Sigma-Tau and are also obligated to make milestone payments of up to $175.0 million comprised of (i) $25.0 million upon the acceptance for filing by the FDA of the first NDA for defibrotide for VOD; and (ii) up to an additional $150.0 million based on the timing of potential FDA approval of defibrotide for VOD.

Increased Research and Development Activities

We substantially increased our research and development activities, which include clinical development of new product candidates, line extensions for existing products and the generation of additional clinical data for existing products, all in our sleep and hematology/oncology therapeutic areas. A summary of our development pipeline activities is provided below:

Project	Disease Area	Status
Sleep		
JZP-110	EDS in narcolepsy	Expect to initiate a Phase 3 clinical trial in the second quarter of 2015
	EDS in OSA	Expect to initiate two Phase 3 clinical trials in the second quarter of 2015
JZP-386	EDS in narcolepsy	Phase 1 clinical trial in progress; expect additional data in the second quarter of 2015
Xyrem	Cataplexy in narcolepsy in children and adolescents	Phase 3 clinical trial initiated in the fourth quarter of 2014
Hematology/Oncology		
Defibrotide	Severe VOD	Rolling new drug application, or NDA, submission initiated in the United States in December 2014; expect to complete the submission in mid-2015
Erwinaze	ALL in young adult population	Pharmacokinetic study in Phase 2 initiated in the second quarter of 2014
JZP-416	ALL	Phase 1 clinical trial in Europe completed; enrollment suspended in pivotal Phase 2 clinical trial in North America in first quarter of 2015
Leukotac™	Steroid refractory acute graft vs. host disease, or GvHD	Phase 3 clinical trial enrollment complete; expect preliminary data in mid-2015

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

•JZP-110. Based on feedback from the FDA on our development plans for JZP-110, we expect to commence our planned Phase 3 clinical program in the second quarter of 2015, subject to the availability of clinical trial materials. We plan to conduct one Phase 3 clinical trial in patients with EDS associated with narcolepsy and two Phase 3 clinical

trials in patients with EDS associated with OSA. Approximately 900 patients are expected to be enrolled in these three trials in the aggregate. In addition, we plan to evaluate the long-term safety of JZP-110 in an open label extension trial and expect to enroll up to 450 patients from the three Phase 3 clinical trials in this extension trial.

JZP-386. JZP-386 is a deuterium-modified analog of sodium oxybate, the active pharmaceutical ingredient in Xyrem, which we licensed from Concert Pharmaceuticals, Inc., or Concert, in February 2013. We have conducted preclinical research and development work on JZP-386 for potential use in patients with narcolepsy. We submitted an investigational medicinal product dossier, or IMPD, for JZP-386 in Europe at the end of 2013 and received approval of the IMPD in January 2014. The first study of JZP-386 in humans to evaluate the safety, pharmacokinetics and

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pharmacodynamics of the compound was conducted in 2014, and we initiated a second Phase 1 study in the first quarter of 2015, with data expected in the second quarter of 2015.

- Xyrem. While in many patients narcolepsy can begin during childhood and adolescence, there is limited information on the treatment of pediatric narcolepsy patients with Xyrem. We have worked with the FDA and several leading specialists to design a clinical trial to generate additional data on the treatment of pediatric narcolepsy patients with Xyrem. As a result, in the fourth quarter of 2014, we initiated a Phase 3 clinical trial to assess the safety and efficacy of Xyrem in children and adolescents aged seven to 17 who have narcolepsy with cataplexy.

In the hematology and oncology area, we also have a number of development programs, including ongoing clinical trials.

- Defibrotide. We are engaged in activities related to the potential approval of defibrotide in the United States. We initiated a rolling submission of an NDA to the FDA for defibrotide for the treatment of severe VOD in December 2014 and expect to complete the submission in mid-2015. We are also assessing the potential for approval of defibrotide in other countries and for development of defibrotide in indications in addition to the treatment of severe VOD.
- Erwinaze. In the second quarter of 2014, we initiated a pharmacokinetics study in Phase 2 to further evaluate the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase.
- JZP-416 (formerly known as Asparec). We completed a Phase 1 clinical trial in Europe of JZP-416 (pegcrisantaspase), a PEGylated recombinant Erwinia chrysanthemi L-asparaginase, being developed for the treatment of patients with ALL who are hypersensitive to E. coli-derived asparaginase. In addition, we initiated our first study of JZP-416 in children in a pivotal Phase 2 clinical trial in North America in late 2014. In February 2015, we voluntarily suspended patient enrollment in this trial. Our decision to suspend enrollment and to discontinue treatment with JZP-416 for enrolled patients is based on the occurrence of hypersensitivity-like reactions following the administration of JZP-416 in some treated patients. We are in the process of collecting and evaluating the available data and plan to conduct additional research and analysis prior to determining whether to resume the study and determining next steps regarding the development of JZP-416.
- Leukotac. We are 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 completed enrollment for this study in March 2014 and expect to receive preliminary data in mid-2015.

For 2015 and beyond, we expect that our research and development expenses will increase substantially from historical levels, particularly as we initiate our planned clinical trials and related development work and potentially acquire rights to additional product candidates.

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 2012. In June 2013, we amended the credit agreement to provide for $557.2 million principal amount of term loans and a revolving credit facility of $200.0 million that replaced the $100.0 million revolving credit facility. We used a portion of the proceeds from the new term loans to refinance in full the $457.2 million principal amount of term loans outstanding under the credit agreement prior to the amendment. In January 2014, in connection with the Gentium Acquisition, we further amended the credit agreement to provide for a tranche of incremental term loans in the aggregate principal amount of $350.0 million, a tranche of term loans that refinanced the approximately $554.4 million principal amount of term loans outstanding prior to this amendment, and a $425.0 million revolving credit facility that replaced the $200.0 million revolving credit facility. We used the proceeds from the incremental term loans and $300.0 million of loans under the revolving credit facility, together with cash on hand, to purchase Gentium ordinary shares and American Depository Shares, or ADSs.

In August 2014, we completed a private placement of $575.0 million aggregate principal amount of 1.875% exchangeable senior notes due 2021, or the 2021 Notes, to several investment banks acting as initial purchasers who subsequently resold the 2021 Notes to qualified institutional buyers. The net proceeds from this offering were approximately $558.9 million, after deducting initial purchasers' discounts and related offering expenses. We used a portion of the net proceeds from this offering to repay all then outstanding borrowings under the revolving credit

facility provided for under our current credit agreement and intend to use the remainder of the net proceeds for general corporate purposes, including potential business development activities. For a more detailed discussion regarding our 2021 Notes, see “Liquidity and Capital Resources” below.

In 2013, we initiated purchases under a share repurchase program for up to $200 million of our ordinary shares. As of December 31, 2014, we had spent a total of $178.7 million, including brokerage commissions, to repurchase our ordinary shares under this program.

Over the past two years, we have made targeted investments to strengthen our operational capabilities to support our lead marketed products and product candidates in our primary therapeutic areas. During 2014, we reorganized our operations in Europe to focus on our hematology/oncology therapeutic area following the Gentium Acquisition and streamlined our U.S.

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commercial operations to devote more resources to our lead marketed products. In the fourth quarter of 2014, we entered into an agreement to sell certain products acquired as part of the EUSA Acquisition and the related business. The sale, subject to certain closing conditions, is expected to close in the first half of 2015. We acquired a manufacturing facility located in Italy in the Gentium Acquisition that produces active pharmaceutical ingredients, including defibrotide, and commenced construction of a manufacturing and development facility in Ireland.

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 2015. 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 67.0% of our net product sales in 2014 and 65.8% of our net product sales in 2013. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product. We are also focusing on the lifecycle management of Xyrem, including seeking to enhance and enforce our intellectual property rights and to develop product, service and safety improvements for patients.

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 “Risk Factors” of this Annual Report on Form 10-K. In particular, five abbreviated new drug applications, or ANDAs, have been filed with the FDA by third parties seeking to market generic versions of Xyrem, including the most recent in the fourth quarter of 2014. We have initiated lawsuits against all five third parties, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. Although no trial date has been set in any of the ANDA suits, we anticipate that trial on some of the patents in the case against the first ANDA filer, Roxane Laboratories, Inc., or Roxane, could occur as early as the third quarter of 2015. In addition, certain of the ANDA filers have sought to challenge the validity of our patents covering the distribution system for Xyrem by filing petitions for covered business method, or CBM, post-grant patent review and/or inter partes review, or IPR, by the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO. The PTAB has issued decisions denying institution of CBM review for all of the CBM petitions and has not yet determined whether to institute proceedings with respect to the petitions for IPR. We cannot predict whether PTAB will institute any of the petitioned IPR proceedings, whether additional post-grant patent review challenges will be filed, the outcome of any IPR or other proceeding if instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate products that compete with Xyrem, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are continuing our efforts on various regulatory matters, including updating documents that we have submitted to the FDA on our risk management and controlled distribution system for Xyrem, which we refer to as the Xyrem Risk Management Program. We are engaged in ongoing communications with respect to our risk evaluation and mitigation strategies, or REMS, documents for Xyrem, but have not reached agreement with the FDA on certain significant terms. In late 2013, the FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Among other things, we disagree with the FDA’s position in the late 2013 notice 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, be sufficient to ensure that the REMS includes only those elements necessary to ensure that the benefits of Xyrem outweigh its risks, and that would, in the FDA’s view, reduce the burden on the healthcare system. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We received the FDA’s denial of our initial dispute resolution submission in the second quarter of 2014, and our dispute is currently subject to further supervisory review at the next administrative level of the FDA. We have received interim responses from the FDA, but the FDA has not yet communicated a decision on our further appeal to us. We expect to receive the FDA’s decision in the first quarter of 2015. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate

additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem.

We also expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. In January 2014, the FDA held an initial meeting with us and the then-current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). The parties have had numerous interactions with respect to a single shared system REMS since the initial meeting, and we expect the interactions to continue. In addition, 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

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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, elements to assure safe use. Similarly, it is possible that, consistent with the position that the FDA articulated in its December 2012 response denying a Citizen Petition we filed in July 2012, the FDA could approve an 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 cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared system REMS for Xyrem (sodium oxybate), licensing or sharing our REMS, or the FDA's response to a certification that a third party had been unable to obtain a license.

Sales of our second largest product, Erwinaze/Erwinase, continue to grow. Sales of Erwinaze/Erwinase accounted for 17.2% of our net product sales in 2014 and 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 sales and marketing and research and development activities. However, our ability to successfully and sustainably maintain or 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 clinical 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, as well as those other risks and uncertainties discussed in Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K. In particular, a significant challenge to our ability to maintain current sales levels and to increase sales is our need to avoid supply interruptions of Erwinaze due to capacity constraints, production delays, quality challenges or other manufacturing difficulties. We have limited inventory of Erwinaze, which puts us at significant risk of not being able to meet product demand. The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product. As a consequence of constrained manufacturing capacity, we have had an extremely limited ability to build an excess level of product inventory that could be used to absorb disruptions to supply resulting from any quality or other issues. If we continue to be subject to capacity constraints or experience quality or other manufacturing challenges in the future, we may be unable to build a desired excess level of product inventory, and our ability to supply the market may be compromised. Although we are taking steps to improve the Erwinaze manufacturing process, if our ongoing efforts are not successful, we could experience additional 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 expand production capacity to increase the supply of Erwinaze over the longer term to address worldwide demand, our ability to maintain or increase sales of Erwinaze may be limited by our ability to obtain a sufficient supply of the product.

In furtherance of our growth strategy, we have made a significant investment in Defitelio. Our ability to realize the anticipated benefits from this investment is subject to a number of risks and uncertainties, including those discussed in Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K. In particular, we may not be able to successfully maintain or grow sales of Defitelio in Europe, or obtain marketing approval in other countries, including the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. A key challenge to our success in maintaining or growing sales of Defitelio in Europe is our ability to obtain appropriate pricing and reimbursement approvals in those European countries where Defitelio is not yet launched. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected countries would be delayed, or, if we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

We do not expect to be required to complete any additional clinical trials prior to completion of the submission of an NDA for defibrotide in the United States. However, we may be unable to acquire and remediate key information to be included in the data package for the NDA in a timely manner or our analysis of such information may not support submission, which would delay or preclude the completion of our NDA submission, and we may be unable to

otherwise obtain regulatory approval of defibrotide in the United States in a timely manner, if at all. We also face other challenges that could impact the anticipated value of Defitelio/defibrotide, including the limited size of the population of patients who undergo HSCT therapy and develop severe VOD, the need to establish U.S. pricing and reimbursement support for the product in the event we are able to obtain U.S. marketing approval for defibrotide, the possibility that we may be required to conduct time-consuming and costly clinical trials as a condition of any U.S. marketing approval for the product, the lack of experience of U.S. physicians in diagnosing and treating VOD, and challenges to our ability to develop the product for indications in addition to the treatment of severe VOD. If sales of Defitelio/defibrotide do not reach the levels we expect, our anticipated revenue from the product would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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addition to risks specifically related to Xyrem, Erwinaze and Defitelio/defibrotide, other key challenges and risks that we face include risks and uncertainties related to:

- the challenges of protecting and enhancing our intellectual property rights;
- delays or problems in the supply or manufacture of our products, particularly with respect to certain products as to which we maintain limited inventories, including products for which our supply demands are growing, and our dependence on single source suppliers to continue to meet our ongoing commercial demand or our requirements for clinical trial supplies;
- the need to obtain and maintain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the United States and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the United States in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by third party payors;
- the challenges of compliance with the requirements of 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;
- the risks associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historic business, the increase in geographic dispersion among our centers of operation, taking on the operation of a manufacturing plant as a result of the Gentium Acquisition and the risks that we may acquire unanticipated liabilities along with acquired businesses or otherwise fail to realize the anticipated benefits (commercial or otherwise) from such transactions;
- the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, and the uncertainty of clinical success, such as the risk that results from preclinical studies and/or early clinical trials may not be predictive of results obtained in later and larger clinical trials planned or anticipated to be conducted for our product candidates;
- the inherent uncertainty associated with the regulatory approval process, 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 increased significantly in 2014.

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

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Results of Operations

The following table presents revenues and expenses for the years ended December 31, 2014, 2013 and 2012 (amounts in thousands):

	2014 (1)	Change		2013	Change		2012 (2)
Product sales, net	$1,162,716	34	%	$865,398	49	%	$580,527
Royalties and contract revenues	10,159	45	%	7,025	29	%	5,452
Cost of product sales (excluding amortization of acquired developed technologies and intangible asset impairment)	117,418	15	%	102,146	30	%	78,425
Selling, general and administrative	406,114	33	%	304,303	36	%	223,882
Research and development	85,181	105	%	41,632	103	%	20,477
Acquired in-process research and development	202,626	N/A(3)		4,988	N/A(3)		—
Intangible asset amortization	126,584	60	%	79,042	21	%	65,351
Impairment charges	39,365	N/A(3)		—	N/A(3)		—
Interest expense, net	52,713	96	%	26,916	60	%	16,869
Foreign currency (gain) loss	(8,683)	N/A(3)		1,697	(53)%		3,620
Loss on extinguishment and modification of debt	—	N/A(3)		3,749	N/A(3)		—
Income tax provision (benefit)	94,231	3	%	91,638	N/A(3)		(83,794)
Net loss attributable to noncontrolling interests, net of tax	(1,061)	N/A(3)		—	N/A(3)		—

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

(2) 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. The following discussions of our results of 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 was segregated from continuing operations and reflected as a discontinued operation for the 2012 period.

(3) Comparison to prior period is not meaningful.

Revenues

The following table presents product sales, royalties and contract revenues, and total revenues for the years ended December 31, 2014, 2013 and 2012 (amounts in thousands):

	2014	Change		2013	Change		2012
Xyrem	$778,584	37	%	$569,113	50	%	$378,663
Erwinaze/Erwinase	199,665	15	%	174,251	142	%	72,083
Defitelio/defibrotide	70,537	N/A(1)		—	N/A(1)		—
Prialt® (ziconotide) intrathecal infusion	26,421	(3)%		27,103	3	%	26,360
Psychiatry	40,879	(17)%		49,226	(36)%		76,489
Other	46,630	2	%	45,705	70	%	26,932
Product sales, net	1,162,716	34	%	865,398	49	%	580,527
Royalties and contract revenues	10,159	45	%	7,025	29	%	5,452
Total revenues	$1,172,875	34	%	$872,423	49	%	$585,979

(1) Comparison to prior period is not meaningful.

Product Sales, Net

Xyrem product sales increased in 2014 and 2013 compared to the immediately preceding years, primarily due to higher average net selling prices in the 2014 and 2013 periods and, to a lesser extent, increases in sales volume. Price increases in

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2014 and 2013 were based on market analysis. Xyrem product sales volumes increased by 10% and 12% in 2014 and 2013, 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. We acquired Erwinaze/Erwinase in the EUSA Acquisition in June 2012. Erwinaze/Erwinase product sales increased by 15% in 2014 compared to 2013 primarily due to an increase in sales volume and, to a lesser extent, price increases in 2014. 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 Erwinaze/Erwinase sales volume increases in 2014 and 2013 were driven primarily by a growth in new treatment sites prescribing Erwinaze/Erwinase as well as existing treatment sites identifying additional ALL patients with hypersensitivity to E. coli-derived asparaginase. Defitelio/defibrotide product sales in 2014, beginning from the closing of the Gentium Acquisition on January 23, 2014, were $70.5 million. On a pro forma basis, Defitelio/defibrotide product sales in 2014 were $73.4 million compared with $44.6 million in 2013. On a pro forma basis, Defitelio/defibrotide product sales increased in 2014 compared to 2013 primarily due to territory-specific price increases instituted in April 2013, continuing roll-out to new launch territories and commercial pricing in launch territories. Prior to the commencement of the commercial launch of Defitelio in Europe in March 2014 we provided, and we continue to provide, access to defibrotide to patients where it is not commercially available. Prialt product sales decreased by 3% in 2014 compared to 2013 and increased by 3% in 2013 compared to 2012. Psychiatry product sales decreased in 2014 and in 2013 compared to the immediately preceding years, 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® (clozapine, USP) LD orally disintegrating clozapine tablets. Commencing in 2015, we discontinued sales representative-led promotion of our psychiatry products. We expect total product sales will increase in 2015 over 2014, primarily due to anticipated growth in sales of our lead marketed products, partially offset by decreases in sales of certain other products.

Royalties and Contract Revenues

Royalties and contract revenues increased in 2014 compared to 2013, primarily due to a $2.0 million milestone payment we received under an agreement with UCB Pharma Limited, or UCB, under which UCB has the right to market Xyrem for certain indications in various countries outside of the United States, and increased royalties in relation to our out-licensed products. 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 2015 to be lower than 2014 due to the UCB milestone payment received in 2014.

Cost of Product Sales

Cost of product sales increased in 2014 compared to 2013, primarily due to increased sales and the cost of product sales in relation to products acquired in the Gentium Acquisition, including an increase in acquisition accounting inventory fair value step-up adjustments of $6.7 million. 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. Gross margins as a percentage of net product sales were 89.9%, 88.2% and 86.5% in 2014, 2013 and 2012, respectively. The increase in our gross margin percentage in 2014 as compared to 2013 was primarily due to a change in product mix. 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. We expect our product gross margin in 2015 to be consistent with 2014.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in 2014 compared to 2013, primarily due to an increase in salary and benefit-related expenses (including share-based compensation expense) of $48.2 million, driven by increased headcount primarily due to our expanded business and the Gentium Acquisition, an increase in sales and

promotional expenses of $23.7 million, an increase in transaction and integration expenses of $22.1 million and an increase in professional services expenses of $15.6 million, partially offset by a $15.2 million change in fair value of contingent consideration in connection with the EUSA Acquisition in 2012 in which we agreed to make a contingent payment of $50.0 million in cash if Erwinaze achieved net sales in the United States of $124.5 million or more in 2013. 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 primarily 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

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and restructuring expenses of $13.9 million. We expect that selling, general and administrative expenses will be higher in 2015 than in 2014 due to an increase in direct marketing spend and support of our lead marketed products, increased legal expenses, costs of preparing for a potential launch of defibrotide in the United States and increased headcount to support our larger, global organization.

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 services 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,		
	2014	2013	2012
Personnel expenses	$38,228	$22,019	10,432
Clinical studies and outside services	41,769	16,385	8,566
Other	5,184	3,228	1,479
Total	$85,181	$41,632	$20,477

Research and development expenses increased by $43.5 million in 2014 compared to 2013, primarily due to increased clinical studies and outside services costs of $25.4 million as a result of higher costs incurred to develop our sleep and hematology/oncology product candidates including, but not limited to, JZP-386, JZP-110 and JZP-416, as well as the addition of costs related to development programs for defibrotide. Personnel expenses increased by $16.2 million, primarily due to salary and benefit-related expenses (including share-based compensation) in support of our development programs and, to a lesser extent, increased headcount due to the Gentium Acquisition. Research and development expenses increased by $21.2 million in 2013 compared to 2012, primarily due to increased personnel expenses of $11.6 million due to a 40% increase in headcount and increased clinical studies and outside services costs of $7.8 million. 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.

For 2015 and beyond, we expect that our research and development expenses will continue to increase substantially from historical levels due to 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 Part I, Item 1A “Risk Factors” of this Annual Report on Form 10-K.

Acquired In-Process Research and Development

In 2014, we acquired the rights to defibrotide in the Americas from Sigma-Tau for an upfront payment of $75.0 million and we also acquired the worldwide development, manufacturing and commercial rights to JZP-110, other than in certain jurisdictions in Asia where SK retained rights, for an upfront payment of $125.0 million to Aerial. We also paid a $2.0 million milestone to SK, which was triggered on assignment of the JZP-110 rights from Aerial to us. In addition, we paid $0.6 million in license fees in connection with JZP-416. In 2013, we incurred $4.0 million in

upfront license fees in connection with our licensing of JZP-386 and $1.0 million in license fees with respect to JZP-416.

Intangible Asset Amortization

The increase in amortization expense in 2014 compared to 2013 was primarily due to the Gentium Acquisition. We acquired finite-lived intangible assets of $734.4 million in connection with the Gentium Acquisition that are expected to be amortized over their weighted-average useful economic lives of approximately 16 years. The increase in amortization expense

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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. We expect intangible asset amortization to decrease in 2015 compared to 2014 as a result of the cessation of amortization on intangible assets classified as assets held for sale as of December 31, 2014 and certain other intangible assets becoming fully amortized in 2014.

Impairment Charges

In 2014, we recorded impairment charges of $39.4 million. The impairment charge resulted from the reorganization of our operations in Europe to focus on our hematology/oncology therapeutic area following the Gentium Acquisition and the decision to sell certain products acquired as part of the EUSA Acquisition. In the fourth quarter of 2014, we entered into a definitive agreement to sell these products and the related business for approximately $34 million in cash, subject to certain working capital adjustments. The sale, subject to certain closing conditions, is expected to close in the first half of 2015.

Interest Expense, Net

Interest expense, net increased by $25.8 million in 2014 compared to 2013, primarily due to a larger debt balance, partially offset by a decrease in interest rates associated with our long-term debt under our current credit agreement. 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 loans under the revolving credit facility. As of December 31, 2014, $895.4 million principal amount of term loans was outstanding and the interest rate on these term loans was 3.25%. In August 2014, we issued $575.0 million principal amount of the 2021 Notes, which remained outstanding at December 31, 2014. We used a portion of the net proceeds from the issuance of the 2021 Notes to repay all then outstanding borrowings under the revolving credit facility. 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 first amendment of our credit agreement in June 2013. We expect interest expense will be higher in 2015 compared to 2014 due to the increase in our debt balance and the amortization of the debt discount on the 2021 Notes.

Foreign Currency (Gain) Loss

The foreign currency gain in 2014 primarily related to the translation of Euro denominated net monetary liabilities, including intercompany balances, held by subsidiaries with a U.S. dollar functional currency. 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.

Income Tax Provision (Benefit)

During 2014, we recognized an income tax provision of $94.2 million. The effective tax rate for 2014 was 62.2%. After adjusting the income before income tax provision for 2014 by excluding a total of $202.0 million in upfront and milestone payments for rights to JZP-110 and to defibrotide in the Americas, which were acquired by our subsidiaries in a non-taxable jurisdiction, the effective tax rate on the resulting income before income tax provision for 2014 was 26.7%. 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 2014 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, 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 changes in U.S. state valuation allowances and benefits resulting from certain originating income tax credits. 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

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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 various expenses not deductible for tax purposes. The decrease in the effective tax rate, after excluding the upfront and milestone payments, for 2014 compared to 2013 was primarily due to changes in income mix among the various jurisdictions in which we operate, changes in valuation allowances and benefits from certain originating income tax credits. 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.

Net Loss Attributable to Noncontrolling Interests, Net of Tax

Net loss attributable to noncontrolling interests, net of tax relates to the portion of the net loss of Gentium not attributable, directly or indirectly, to our ownership interest. The net loss attributable to noncontrolling interests, net of tax was $1.1 million in 2014.

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 related to profits generated by the women's health business in 2012 which were 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 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 us. 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-

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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 purposes of our non-GAAP financial measures; likewise, we have ceased and may in the future cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures. In this regard, we have determined that, beginning with results to be reported for the first quarter of 2015, we will no longer include an adjustment for depreciation expense in our non-GAAP financial measures. Accordingly, any historical non-GAAP financial measures presented by us in the future, beginning with financial results to be reported for the first quarter of 2015, will not include an adjustment for depreciation expense. Any comparative historical periods presented will be updated to reflect this change beginning with financial results to be reported for the first quarter of 2015. However, for purposes of comparability with the company's prior presentations of non-GAAP financial measures, the historical non-GAAP financial measures presented in the table below include an adjustment for depreciation expense. In addition, because of the non-standardized definitions of non-GAAP financial measures, 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. In the table below, adjusted net income measures attributable to Jazz Pharmaceuticals plc (and the related per share measures) exclude from GAAP reported income from continuing operations attributable to Jazz Pharmaceuticals plc (and the related per share measures), as applicable, intangible asset amortization, share-based compensation expense, acquired in-process research and development, impairment charges, transaction and integration costs, acquisition accounting inventory fair value step-up adjustments, depreciation expense, restructuring charges, change in fair value of contingent consideration, loss on extinguishment and modification of debt and non-cash interest expense; adjust the income tax provision to the estimated amount of taxes payable in cash; and adjust for the amount attributable to noncontrolling interests.

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

	Year Ended December 31,		
	2014	2013	2012
GAAP reported income from continuing operations attributable to Jazz Pharmaceuticals plc	$58,387	$216,312	$261,149
Intangible asset amortization	126,584	79,042	65,351
Share-based compensation expense	69,638	44,551	23,006
Acquired in-process research and development	202,626	4,988	—
Impairment charges	39,365	—	—
Transaction and integration costs	28,840	6,240	18,821
Acquisition accounting inventory fair value step-up adjustments	10,477	3,826	16,794
Depreciation expense	7,097	3,048	—
Restructuring charges	1,941	1,457	2,789
Change in fair value of contingent consideration	—	15,200	(300)
Loss on extinguishment and modification of debt	—	3,749	—
Non-cash interest expense	13,725	4,591	2,860
Income tax adjustments (1)	(29,620)	5,253	(100,076)
Adjustments for amount attributable to noncontrolling interests (2)	(1,506)	—	—
Non-GAAP adjusted net income attributable to Jazz Pharmaceuticals plc (3)	$527,554	$388,257	$290,394
GAAP reported income from continuing operations attributable to Jazz Pharmaceuticals plc per diluted share	$0.93	$3.51	$4.34

Non-GAAP adjusted net income attributable to Jazz Pharmaceuticals plc per diluted share	$8.43	$6.31	$4.82
Shares used in computing GAAP reported income from continuing operations attributable to Jazz Pharmaceuticals plc and non-GAAP adjusted net income attributable to Jazz Pharmaceuticals plc per diluted share amounts	62,614	61,569	60,195

(1) Tax adjustments to convert the income tax provision to the estimated amount of taxes payable in cash. In 2012, income tax adjustments included a valuation allowance reversal of $104.2 million against deferred tax assets, primarily in the United States.

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(2) The noncontrolling interests' share of the above adjustments, as applicable.

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

Liquidity and Capital Resources

As of December 31, 2014, we had cash and cash equivalents of $684.0 million, borrowing availability under the revolving credit facility of $425.0 million and long-term debt of $1,472.0 million. Our long-term debt included $895.4 million aggregate principal amount of term loans, $575.0 million principal amount of the 2021 Notes and other borrowings of $1.7 million. During 2014, 2013 and 2012, we generated cash flows from operations of $405.8 million, $288.6 million and $249.8 million, respectively, and we expect to continue to generate positive cash flow from operations.

In January 2014, we amended our credit agreement to provide for $350.0 million aggregate principal amount 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 $300.0 million of 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 in January and February 2014. As of December 31, 2014, we had acquired a further 1.8% interest in Gentium for cash consideration of $17.8 million, resulting in an aggregate acquisition cost to us of $994.1 million, comprising cash payments of $1,011.2 million, offset by proceeds from the exercise of Gentium share options of $17.1 million. In August 2014, we completed the private placement of the 2021 Notes resulting in net proceeds to us, after debt issuance costs, of approximately $558.9 million. We used a portion of the net proceeds from the issuance of the 2021 Notes to repay all then outstanding borrowings under the revolving credit facility provided for under our current credit agreement and intend to use the remainder of the net proceeds for general corporate purposes, including potential business development activities.

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 retains rights. Under the agreement, we made an upfront payment of $125.0 million to Aerial. We also paid a $2.0 million milestone to SK on assignment of the JZP-110 rights from Aerial to us. We are obligated to make milestone payments, in an aggregate amount of up to $270.0 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.

In July 2014, we signed a definitive agreement to acquire rights to defibrotide in the United States and all other countries in the Americas from Sigma-Tau. Pursuant to the agreement, upon the closing of the transaction in August 2014, we paid Sigma-Tau an upfront payment of $75.0 million. Sigma-Tau is also eligible to receive milestone payments of $25.0 million upon the acceptance for filing by the FDA of the first NDA for defibrotide for VOD and up to an additional $150.0 million based on the timing of potential FDA approval of defibrotide for VOD. We funded the upfront payment with cash on hand.

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

We believe that our existing cash balances, cash we expect to generate from operations and funds 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. 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 "Risk Factors" 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 versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected," "The manufacture, distribution and sale of Xyrem are subject to

significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements, as well as the potential impact of changes to these restrictions and requirements, subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem," and "To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business." Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

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To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, 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 continue the expansion of our existing operations, such as the construction and opening of a manufacturing and development facility in Ireland announced in February 2014, in which we expect to invest approximately €45 to €50 million. Accordingly, we expect to continue to opportunistically seek access to additional capital 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 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 $200.0 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 depends on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under our credit agreement, corporate and regulatory requirements and market conditions. Share repurchases may be suspended or discontinued at any time without prior notice. In 2014, we spent a total of $42.2 million to repurchase 0.3 million of our ordinary shares under the share repurchase program at an average total purchase price, including brokerage commissions, of $138.64 per share. All ordinary shares repurchased were canceled. As of December 31, 2014, the remaining amount authorized under the share repurchase program was $21.3 million.

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

	Year Ended December 31,		
	2014	2013	2012
Net cash provided by operating activities	$405,765	$288,604	$249,752
Net cash used in investing activities	(1,067,649)	(16,264)	(395,294)
Net cash provided by (used in) financing activities	712,875	(24,029)	448,530
Effect of exchange rates on cash and cash equivalents	(3,453)	997	2,132
Net increase in cash and cash equivalents	$47,538	$249,308	$305,120

Net cash provided by operating activities of $405.8 million in 2014 related to net income of $57.3 million, adjusted for upfront and milestone payments totaling $202.6 million primarily in connection with our acquisition of rights to JZP-110 and to defibrotide in the Americas and non-cash items of $212.2 million primarily related to intangible asset amortization, share-based compensation expense, impairment charges, acquisition accounting inventory fair value step-up adjustments and deferred income taxes. This was partially offset by $66.3 million of net cash outflow related to changes in operating assets and liabilities which included an increase of $55.0 million in our accounts receivable, primarily due to an increase in sales, and $14.9 million in respect of the payment of the contingent consideration in connection with the EUSA Acquisition. Net cash provided by operating activities of $288.6 million in 2013 related to net income of $216.3 million, adjusted for non-cash items of $153.3 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 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 used in investing activities in 2014 primarily related to the funding of the Gentium Acquisition, the acquisition of rights to JZP-110 and to defibrotide in the Americas and, to a lesser extent, expenditures related to property and equipment. Net cash used in investing activities in 2013 primarily related to purchases of property and equipment and acquisition of in-process research and development. 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.

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Net cash provided by financing activities in 2014 primarily related to net proceeds of $1,194.4 million from our long-term debt and proceeds of $58.5 million from employee equity incentive and purchase plans and exercise of warrants, partially offset by $300.0 million used to repay outstanding borrowings under the revolving credit facility, $137.0 million for the acquisition of noncontrolling interests in Gentium, $35.1 million in respect of the payment of the contingent consideration in connection with the EUSA Acquisition and $42.2 million used to repurchase our ordinary shares under our share repurchase program. 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 amendment to our 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.

Credit Agreement

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

As a result of the June 2013 amendment, the interest rate margins on the term loans and the revolving loans were reduced by 150 basis points, and as a result of the January 2014 amendment, the interest rate margins on the terms loans were reduced by a further 25 basis points. The term loans under the current credit agreement bear interest, at our option, at a rate equal to either the LIBOR, plus an applicable margin of 2.50% per annum (subject to a 0.75% LIBOR floor), or the prime lending rate, plus an applicable margin equal to 1.50% per annum (subject to a 1.75% prime rate floor). Borrowings under the current revolving credit facility bear interest, at our option, at a rate equal to either the LIBOR, plus an applicable margin of 2.50% per annum, or the prime lending rate, plus an applicable margin equal to 1.50% per annum, subject to reduction by 0.25% or 0.50% based upon our secured leverage ratio. The revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. As of December 31, 2014, the interest rate on the outstanding term loans was 3.25%.

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 on a senior secured basis by Jazz Pharmaceuticals plc and certain of its subsidiaries (including the issuer of the 2021 Notes as described below) and are secured by substantially all of Jazz Pharmaceuticals plc's, the borrowers' and the guarantor subsidiaries' assets.

We may make voluntary prepayments of principal at any time without payment of a premium. 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) 50% of our excess cash flow as defined in the current credit agreement (subject to decrease to 25% if our total 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 total leverage ratio is equal to or less than 1.25 to 1.00), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

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

Our credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to us and our restricted subsidiaries, including, among other things, restrictions on indebtedness,

liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement also contains a financial covenant that requires us and our restricted subsidiaries to maintain a maximum secured leverage ratio. We were, as of December 31, 2014, and are currently in compliance with this financial covenant.

2021 Notes

In August 2014, Jazz Pharmaceuticals plc, through its wholly-owned finance subsidiary Jazz Investments I Limited, completed a private placement of $575.0 million principal amount of the 2021 Notes. The 2021 Notes are the senior unsecured

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obligations of Jazz Investments I Limited and are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. Interest on the 2021 Notes is payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2015, at a rate of 1.875% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2021 Notes. The 2021 Notes mature on August 15, 2021, unless earlier exchanged, repurchased or redeemed.

The holders of the 2021 Notes have the ability to require us to repurchase all or a portion of their 2021 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from The NASDAQ Global Select Market. Prior to August 15, 2021, we may redeem the 2021 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2021 Note additional amounts as a result of certain tax-related events. We also may redeem the 2021 Notes on or after August 20, 2018, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2021 Notes are exchangeable at an initial exchange rate of 5.0057 ordinary shares per $1,000 principal amount of 2021 Notes, which is equivalent to an initial exchange price of approximately $199.77 per ordinary share. Upon exchange, the 2021 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2021 Notes in cash upon exchange. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2021 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2021 Notes who elect to exchange their 2021 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to February 15, 2021, the 2021 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

Contractual Obligations

The table below presents a summary of our contractual obligations as of December 31, 2014 (in thousands):

	Payments due by period				
Contractual Obligations (1)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
Term and other loans - principal	$897,042	$9,428	$18,871	$868,593	$150
Term and other loans - interest (2)	100,297	29,451	58,048	12,792	6
2021 Notes - principal	575,000	—	—	—	575,000
2021 Notes - interest (3)	75,529	10,841	21,562	21,563	21,563
Revolving credit facility - commitment fee (4)	3,958	1,616	2,342	—	—
Purchase obligations (5)	36,343	34,583	400	410	950
Operating lease obligations (6)	25,046	10,165	12,767	2,114	—
Total	$1,713,215	$96,084	$113,990	$905,472	$597,669

(1) This table does not include potential future milestone payment or royalty obligations to third parties under asset purchase, product development, license and other 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. In 2014, we signed a definitive agreement with Aerial under which we acquired worldwide development, manufacturing and commercial rights to JZP-110 (other than in certain jurisdictions in Asia where SK retains rights). Under the agreement, Aerial received an upfront payment of $125.0 million and SK received a milestone payment of $2.0 million. Aerial and SK are eligible to receive additional milestone payments up to an

aggregate of $270.0 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. In 2014, we entered into a definitive agreement to acquire rights to defibrotide in the United States and all other countries in the Americas from Sigma-Tau. Pursuant to the agreement, upon the closing of the transaction in 2014, we paid Sigma-Tau an upfront payment of $75.0 million. Sigma-Tau is also eligible to receive milestone payments of $25.0 million upon the acceptance for filing by the FDA of the first NDA for defibrotide for VOD and up to an additional $150.0 million based on the timing of potential FDA approval of defibrotide for VOD. Potential future milestone payments to other third parties under other agreements could be up to an aggregate of $286.0 million, of

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which up to $120.0 million will become due and payable to Perrigo Company plc (formerly Elan Pharmaceuticals, Inc.) in tiered contingent payments, with the first such payment becoming due if net sales of Prialt of at least $75.0 million are achieved in a calendar year. The remainder would become due and payable to other third parties upon the achievement of certain developmental, clinical, regulatory and/or commercial milestones, the timing and likelihood of which are not known. We are also obligated under these agreements to pay royalties on net sales of certain products at specified rates, which royalties are dependent on future product sales and are not provided for in the table above as they are not estimable.

(2) The interest rate was 3.25% at December 31, 2014, which we used to estimate interest owed on the term loans outstanding as of December 31, 2014 until the final maturity date in June 2018.

(3) We used the fixed interest rate of 1.875% to estimate interest owed on the 2021 Notes as of December 31, 2014 until the final maturity date in August 2021.

(4) Our revolving credit facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.50% per annum based upon our secured leverage ratio. In the table above, we used a rate of 0.375% and assumed undrawn amounts of $425.0 million to estimate commitment fees owed.

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

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

In January 2015, we entered into an agreement to lease approximately 100,000 square feet of office space in Palo Alto, California. We expect to occupy this office space by the end of 2017. This lease has a term of 12 years from commencement, and we have an option to extend the term of the lease twice for a period of five years each. As a result, we are obligated to make lease payments over the initial term of the lease totaling approximately $96 million in addition to estimated operating expenses totaling $25 million. We also have an option to terminate this lease 10 years from commencement, with no less than one year’s prior written notice and the payment of a termination fee. The obligations related to this lease are 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 $736.9 million at December 31, 2014. 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, 2014, 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, 2014, our liability for unrecognized tax benefits amounted to $40.8 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 2014, sales of Xyrem to Express Scripts accounted for 66.9% of our net product sales. We recognize revenues from sales of

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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 2014, we issued credits totaling less than $0.1 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 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, 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
Provision	88,729	3,148	28,722	71,864	192,463
Payments/credits	(75,854)	(10,219)	(28,588)	(71,879)	(186,540)
Balance at December 31, 2014 (2)	$44,433	$14,039	$4,544	$5,875	$68,891

(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 $192.5 million, $142.9 million and $102.4 million, or 14.2%, 14.2% and 15.0% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2014, 2013 and 2012, 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 each of the years ended December 31, 2014, 2013 and 2012.

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

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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 $88.7 million, $66.9 million and $51.4 million, or 6.5%, 6.6% and 7.5% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2014, 2013 and 2012, respectively. Rebates as a percentage of gross product sales did not materially change in 2014 compared to 2013. 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. 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 2015 compared to 2014.

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 $3.1 million, $2.8 million and $5.9 million, or 0.2%, 0.3% and 0.9% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2014, 2013 and 2012, respectively. Sales returns as a percentage of gross product sales did not materially change in 2014 compared to 2013. 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 are not expected to materially change in 2015 compared to 2014.

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 $28.7 million, $21.8 million and $12.3 million, or 2.1%, 2.2%, and 1.8% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2014, 2013 and 2012, respectively. Chargebacks as a percentage of gross product sales did not change materially in 2014 compared to 2013. 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. 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 2015 compared to 2014.

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

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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 $71.9 million, $51.4 million and $32.8 million, or 5.3%, 5.1% and 4.8% as a percentage of gross product sales from continuing operations, for the years ended December 31, 2014, 2013 and 2012, respectively. Discounts and distributor fees as a percentage of gross product sales increased slightly in 2014 compared to 2013 due primarily to an increase in patient coupon programs. 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. We expect that discounts and distributor fees as a whole will continue to significantly impact our reported net product sales. In this regard, discounts and distributor fees as a percentage of gross product sales are expected to increase slightly in 2015 compared to 2014 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 2014 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, 2014, we had $702.7 million of goodwill primarily resulting from the Azur Merger on January 18, 2012, the EUSA Acquisition on June 12, 2012 and the Gentium Acquisition on January 23, 2014.

Intangible Assets

In connection with the Azur Merger, the EUSA Acquisition and the Gentium 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 16 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

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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, 2014, we had $1,200.7 million of finite-lived intangible assets and $236.7 million of IPR&D assets related to the marketed products and the IPR&D projects that we acquired in the Azur Merger, the EUSA Acquisition and the Gentium Acquisition. In 2014, we recorded impairment charges of $39.4 million. The impairment charge resulted from the reorganization of our operations in Europe to focus on our hematology/oncology therapeutic area following the Gentium Acquisition and the decision to sell certain products acquired as part of the EUSA Acquisition. In the fourth quarter of 2014, we entered into a definitive agreement to sell these products and the related business for approximately $34 million in cash, subject to certain working capital adjustments. The sale, subject to certain closing conditions, is expected to close in the first half of 2015.

We did not recognize an impairment charge related to our intangible assets during 2013 and 2012. Please refer to the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for further information about our intangible assets and the remaining useful lives of our finite-lived intangible assets as of December 31, 2014.

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, Italy 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

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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).

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,		
	2014	2013	2012
Volatility	45%	58%	64%
Expected term (years)	4.3	4.4	4.6
Range of risk-free rates	1.1-1.4%	0.5-1.4%	0.5-1.1%
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.

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. 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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2014-09, “Revenue from Contracts with Customers”, or ASU No. 2014-09, which states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this, an entity will need to identify the contract with a customer; identify the separate performance obligations in the contract; determine the transaction price; allocate the transaction price to the separate performance obligations in the contract; and recognize revenue when (or as) the entity satisfies each performance obligation. ASU No. 2014-09 will be effective for us beginning January 1, 2017 and can be adopted on a full retrospective basis or on a modified retrospective basis. We are currently assessing our approach to the adoption of this standard and the impact on our results of operations and financial position.

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

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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Related Parties

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

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. 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 the offering.

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 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 states, agencies and municipalities in the United States. Our cash equivalents as of December 31, 2014 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 $895.4 million as of December 31, 2014, a 1.0% change in interest rates, above the LIBOR floor, would increase net interest expense on our term loans for 2015 by approximately $9.0 million. As of December 31, 2014, there were no borrowings outstanding under our revolving credit facility.

In August 2014, we completed a private placement of $575.0 million aggregate principal amount of the 2021 Notes. The 2021 Notes have a fixed annual interest rate of 1.875% and we, therefore, do not have economic interest rate

exposure on the 2021 Notes. However, the fair value of the 2021 Notes is exposed to interest rate risk. Generally, the fair value of the 2021 Notes will increase as interest rates fall and decrease as interest rates rise. The fair value of the 2021 Notes is also affected by volatility in our ordinary share price. As of December 31, 2014, the fair value of the 2021 Notes was estimated to be $654 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

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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 (loss) in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposures are related to our subsidiaries that have functional currencies denominated in the Euro and the British Pound. 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, 2014 by approximately $8.5 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 foreign currency gain (loss) in the consolidated statements of income. At December 31, 2014, our primary exposure to transaction risk related to Euro net monetary liabilities held by subsidiaries with a U.S. dollar functional currency. At December 31, 2014, a 10% strengthening/(weakening) in the Euro against the U.S. dollar would have (decreased)/increased net income by approximately $1.4 million.

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-45.

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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, 2014.
Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.
Changes in Internal Control over Financial Reporting. During the quarter ended December 31, 2014, 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. Our management used the Committee of Sponsoring Organizations of the Treadway Commission Internal Control - Integrated Framework (2013), or the COSO framework, to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of
2. 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.
   Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2014
3. 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.
   KPMG, our independent registered public accounting firm, has audited the consolidated financial statements of Jazz
4. Pharmaceuticals plc as of and for the year ended December 31, 2014, included herein, and has issued an audit report on our internal control over financial reporting, which is included below.

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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, 2014, based on criteria established in Internal Control - Integrated Framework (2013) 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, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Jazz Pharmaceuticals plc and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of income, comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2014, and the related financial statement schedule, and our report dated February 24, 2015 expressed an unqualified opinion on those consolidated financial statements and the related financial statement schedule.

/s/ KPMG
Dublin, Ireland
February 24, 2015

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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 2015 annual general meeting of shareholders to be filed pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, or Exchange Act. 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 2015 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 2015 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 2015 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 2015 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 2015 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 2015 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 2015 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 2015 annual general meeting of shareholders under the sections entitled “Certain Relationships and Related Party Transactions” and “Corporate Governance and Board Matters—Independence of the Board of Directors” and is incorporated herein by reference.

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Item 14. Principal Accountant Fees and Services

The information required by this item is to be included in our proxy statement for our 2015 annual general meeting of shareholders under the section entitled “Proposal 2—Approve 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-46 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).

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Exhibit Number	Description of Document
2.8†	Assignment Agreement, dated July 1, 2014, by and among Jazz Pharmaceuticals International II Limited, Sigma-Tau Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Gentium S.p.A. (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 August 5, 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	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).
4.2B	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).
4.3A	Indenture, dated as of August 13, 2014, by and among Jazz Pharmaceuticals plc, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.3B	Form of 1.875% Exchangeable Senior Note due 2021 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
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 Public Health England (formerly 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) for the period ended June 30, 2012, as filed with the SEC on August 9, 2012).
10.6A	

	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).
10.6B	Amendment No. 1, dated as of June 13, 2013, to the 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).
10.6C	Amendment No. 2, dated as of January 23, 2014, to the Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Financing I Limited and Jazz Pharmaceuticals Ireland Limited, as borrowers, Jazz Pharmaceuticals Public Limited Company, as guarantor, the Lenders thereto and Barclays Bank PLC, as Administrative Agent, Collateral Agent, L/C Issuer and Swing Line Lender (incorporated herein by reference to Exhibit 10.32 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).

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Exhibit Number	Description of Document
10.7	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).
10.8A	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).
10.8B	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).
10.8C	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).
10.9	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.10	Commercial Lease, dated as of January 7, 2015, by and between The Board of Trustees of the Leland Stanford Junior University and Jazz Pharmaceuticals, Inc.
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 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) for the period ended September 30, 2011, as filed with the SEC on November 8, 2011).
10.13+	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) for the period ended March 31, 2012, as filed with the SEC on May 8, 2012).
10.14+	Offer Letter from Jazz Pharmaceuticals, Inc. to Matthew Young (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 March 31, 2014, as filed with the SEC on May 8, 2014).
10.15A+	Employment Agreement by and between EUSA Pharma Inc. and Iain McGill (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2014, as filed with the SEC on November 4, 2014).
10.15B+	Amendment to Employment Agreement by and between Iain McGill and EUSA Pharma (Europe) Limited.
10.16+	Offer Letter from Jazz Pharmaceuticals, Inc. to Michael Miller (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2014, as filed with the SEC on November 4, 2014).
10.17A+	

	Employment Agreement by and between Jazz Pharmaceuticals Ireland Limited and Paul Treacy (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 September 30, 2014, as filed with the SEC on November 4, 2014).
10.17B+	Amendment to Employment Agreement by and between Jazz Pharmaceuticals Ireland Limited and Paul Treacy.
10.18A+	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).
10.18B+	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).

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Exhibit Number	Description of Document
10.18C+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.18D+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.18E+	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).
10.18F+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.18G+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.18H+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.19A+	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).
10.19B+	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).
10.19C+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19D+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19E+	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) for the period ended December 31, 2012, 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 (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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19G+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19H+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.19I+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).

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Exhibit Number	Description of Document
10.19J+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.19K+	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 10.5 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.19L+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.20+	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).
10.21A+	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).
10.21B+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.21C+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.22A+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.22B+	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 10.14C 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 May 8, 2012).
10.23A+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.23B+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2014) (incorporated herein by reference to Exhibit 10.24D in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).
10.24+	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) for the period ended

	September 30, 2013, as filed with the SEC on November 5, 2013).
10.25A+	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).
10.25B+	Jazz Pharmaceuticals plc 2014 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2014, as filed with the SEC on May 8, 2014).
10.26A+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.26B+	Jazz Pharmaceuticals plc Non-Employee Director Compensation Policy (approved May 1, 2014) (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, 2014, as filed with the SEC on May 8, 2014).

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Exhibit Number	Description of Document
10.27+	Named Officer 2015 Target Bonus Opportunity (incorporated herein by reference to Exhibit 10.1 in JazzPharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on February 18, 2015).
21.1	Subsidiaries of Jazz Pharmaceuticals plc.
23.1	Consent of KPMG, 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.

*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.

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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 24, 2015

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

/s/ MATTHEW P. YOUNG
Matthew P. Young
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

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

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bruce C. Cozadd, Matthew P. Young, 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 24, 2015
/s/ MATTHEW P. YOUNG Matthew P. Young	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 24, 2015
/s/ KAREN J. WILSON Karen J. Wilson	Senior Vice President, Finance (Principal Accounting Officer)	February 24, 2015
/s/ PAUL L. BERNS Paul L. Berns	Director	February 24, 2015
/s/ PATRICK G. ENRIGHT Patrick G. Enright	Director	February 24, 2015
/s/ PETER GRAY Peter Gray	Director	February 24, 2015
/s/ HEATHER ANN MCSHARRY Heather Ann McSharry	Director	February 24, 2015
/s/ SEAMUS C. MULLIGAN Seamus C. Mulligan	Director	February 24, 2015
/s/ KENNETH W. O'KEEFE Kenneth W. O'Keefe	Director	February 24, 2015
/s/ NORBERT G. RIEDEL, PH.D. Norbert G. Riedel, Ph.D.	Director	February 24, 2015
/s/ ELMAR SCHNEE Elmar Schnee	Director	February 24, 2015
/s/ CATHERINE A. SOHN, PHARM.D. Catherine A. Sohn, Pharm.D.	Director	February 24, 2015
/s/ RICK E WINNINGHAM Rick E Winningham	Director	February 24, 2015

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Report of 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, 2014 and 2013, and the related consolidated statements of income, comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2014. 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, 2014, 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, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for the years ended December 31, 2014, 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, 2014, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 24, 2015 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG
Dublin, Ireland
February 24, 2015

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

	December 31, 2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$684,042	$636,504
Accounts receivable, net of allowances of $3,483 and $3,680 at December 31, 2014 and 2013, respectively	186,371	124,805
Inventories	30,037	28,669
Prepaid expenses	12,800	7,183
Deferred tax assets, net	48,440	33,613
Other current assets	21,322	33,843
Assets held for sale	32,833	—
Total current assets	1,015,845	864,617
Property and equipment, net	58,363	14,246
Intangible assets, net	1,437,435	812,396
Goodwill	702,713	450,456
Deferred tax assets, net, non-current	75,494	74,597
Deferred financing costs	33,174	14,605
Other non-current assets	15,931	7,304
Total assets	$3,338,955	$2,238,221
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$25,126	$21,005
Accrued liabilities	164,091	119,718
Current portion of long-term debt	9,428	5,572
Income taxes payable	7,588	336
Contingent consideration	—	50,000
Deferred tax liability, net	9,430	6,259
Deferred revenue	1,138	1,138
Total current liabilities	216,801	204,028
Deferred revenue, non-current	4,499	5,718
Long-term debt, less current portion	1,333,000	544,404
Deferred tax liability, net, non-current	375,054	168,497
Other non-current liabilities	38,393	20,040
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Ordinary shares, nominal value $0.0001 per share; 300,000 shares authorized; 60,643 and 57,854 shares issued and outstanding at December 31, 2014 and 2013, 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, 2014 and 2013	55	55
Capital redemption reserve	471	471
Additional paid-in capital	1,458,005	1,220,317
Accumulated other comprehensive income (loss)	(122,097)	56,153
Retained earnings	34,704	18,532

Total Jazz Pharmaceuticals plc shareholders' equity	1,371,144	1,295,534
Noncontrolling interests	64	—
Total shareholders' equity	1,371,208	1,295,534
Total liabilities and shareholders' equity	$3,338,955	$2,238,221

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

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

	Year Ended December 31,		
	2014	2013	2012
Revenues:			
Product sales, net	$1,162,716	$865,398	$580,527
Royalties and contract revenues	10,159	7,025	5,452
Total revenues	1,172,875	872,423	585,979
Operating expenses:			
Cost of product sales (excluding amortization of acquired developed technologies and intangible asset impairment)	117,418	102,146	78,425
Selling, general and administrative	406,114	304,303	223,882
Research and development	85,181	41,632	20,477
Acquired in-process research and development	202,626	4,988	—
Intangible asset amortization	126,584	79,042	65,351
Impairment charges	39,365	—	—
Total operating expenses	977,288	532,111	388,135
Income from operations	195,587	340,312	197,844
Interest expense, net	(52,713)	(26,916)	(16,869)
Foreign currency gain (loss)	8,683	(1,697)	(3,620)
Loss on extinguishment and modification of debt	—	(3,749)	—
Income from continuing operations before income tax provision (benefit)	151,557	307,950	177,355
Income tax provision (benefit)	94,231	91,638	(83,794)
Income from continuing operations	57,326	216,312	261,149
Income from discontinued operations, net of taxes	—	—	27,437
Net income	57,326	216,312	288,586
Net loss attributable to noncontrolling interests, net of tax	(1,061)	—	—
Net income attributable to Jazz Pharmaceuticals plc	$58,387	$216,312	$288,586
Net income per ordinary share attributable to Jazz Pharmaceuticals plc:			
Basic:			
Income from continuing operations	$0.98	$3.71	$4.61
Income from discontinued operations	—	—	0.48
Net income attributable to Jazz Pharmaceuticals plc	$0.98	$3.71	$5.09
Diluted:			
Income from continuing operations	$0.93	$3.51	$4.34
Income from discontinued operations	—	—	0.45
Net income attributable to Jazz Pharmaceuticals plc	$0.93	$3.51	$4.79
Weighted-average ordinary shares used in calculating net income per ordinary share attributable to Jazz Pharmaceuticals plc:			
Basic	59,746	58,298	56,643
Diluted	62,614	61,569	60,195

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

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

	Year Ended December 31,		
	2014	2013	2012
Net income	$57,326	$216,312	$288,586
Other comprehensive income (loss):			
Foreign currency translation adjustments	(178,264)	25,107	31,046
Available-for-sale securities:			
Net unrealized gain on available-for-sale securities, net of income taxes	—	—	8
Reclassification adjustments for gains included in earnings, net of income taxes	—	—	23
Other comprehensive income (loss)	(178,264)	25,107	31,077
Total comprehensive income (loss)	(120,938)	241,419	319,663
Comprehensive loss attributable to noncontrolling interests, net of tax	(1,075)	—	—
Comprehensive income (loss) attributable to Jazz Pharmaceuticals plc	$(119,863)	$241,419	$319,663
Total comprehensive income (loss) attributable to Jazz Pharmaceuticals plc arises from:			
Continuing operations	$(119,863)	$241,419	$292,226
Discontinued operations	—	—	27,437
Total comprehensive income (loss) attributable to Jazz Pharmaceuticals plc	$(119,863)	$241,419	$319,663

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

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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 (Loss)	Retained Earnings (Accumulated Deficit)	Total Jazz Pharmaceuticals plc Shareholders' Equity	Non-controlling interest	Total Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2011	42,468	$4	—	$—	$—	$542,697	$(31)	$(349,882)	$192,788	$—	$192,788
Merger with Azur Pharma	12,360	2	4,000	55	471	575,936	—	—	576,464	—	576,464
Issuance costs related to Azur Merger	—	—	—	—	—	(241)	—	—	(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	—	14,212
Issuance of ordinary shares under employee stock purchase plan	151	—	—	—	—	3,707	—	—	3,707	—	3,707
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(25,299)	—	—	(25,299)	—	(25,299)
Issuance of ordinary shares in conjunction with exercise of warrants	1,039	—	—	—	—	7,084	—	—	7,084	—	7,084
Share-based compensation	—	—	—	—	—	23,129	—	—	23,129	—	23,129
Excess tax benefits from employee share options	—	—	—	—	—	9,785	—	—	9,785	—	9,785

Other comprehensive income	—	—	—	—	—	—	31,077	—	31,077	—	31,077
Net income	—	—	—	—	—	—	—	288,586	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	$—	$1,121,292

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

	Ordinary Shares		Non-voting Euro Deferred Shares		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Jazz Pharmaceuticals plc Shareholders' Equity	Non-controlling interest	Total 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	$—	$1,121,292
Issuance of ordinary shares in conjunction with exercise of share options	904	—	—	—	—	20,895	—	—	20,895	—	20,895
Issuance of ordinary shares under employee stock purchase plan	147	—	—	—	—	5,410	—	—	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)	—	(5,590)
Issuance of ordinary shares in conjunction with exercise of warrants	471	—	—	—	—	4,398	—	—	4,398	—	4,398
Share-based compensation	—	—	—	—	—	44,367	—	—	44,367	—	44,367
Excess tax benefits from employee share options	—	—	—	—	—	(173)	—	—	(173)	—	(173)
Shares repurchased	(1,828)	—	—	—	—	—	—	(136,484)	(136,484)	—	(136,484)
	—	—	—	—	—	—	25,107	—	25,107	—	25,107

Other comprehensive income											
Net income	—	—	—	—	—	—	—	216,312	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	$—	$1,295,534

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

	Ordinary Shares		Non-voting Euro Deferred Shares		Capital Redemption Reserve	Additional Paid-in Capital	Accumu-lated Other Compre-hensive Income (Loss)	Retained Earnings (Accumu-lated Deficit)	Total Jazz Pharma-ceuticals plc Share-holders' Equity	Non-controlling interest	Total Share-holders' Equity
	Shares	Amount	Shares	Amount							
Balance at December 31, 2013	57,854	$6	4,000	$55	$471	$1,220,317	$56,153	$18,532	$1,295,534	$—	$1,295,534
Noncontrolling interest on Gentium Acquisition	—	—	—	—	—	—	—	—	—	136,578	136,578
Acquisition of noncontrolling interest	—	—	—	—	—	(1,530)	—	—	(1,530)	(135,439)	(136,969)
Issuance of exchangeable senior notes	—	—	—	—	—	126,863	—	—	126,863	—	126,863
Issuance of ordinary shares in conjunction with exercise of share options	1,185	—	—	—	—	43,043	—	—	43,043	—	43,043
Issuance of ordinary shares under employee stock purchase plan	117	—	—	—	—	7,197	—	—	7,197	—	7,197
Issuance of ordinary shares in conjunction with vesting of restricted stock units	222	—	—	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(18,030)	—	—	(18,030)	—	(18,030)
Issuance of ordinary shares in conjunction with exercise of warrants	1,552	—	—	—	—	8,247	—	—	8,247	—	8,247

Shares issued under directors deferred compensation plan	17	—	—	—	—	—	—	—	—	—	—
Share-based compensation	—	—	—	—	—	70,057	—	—	70,057	—	70,057
Excess tax benefits from employee share options	—	—	—	—	—	1,841	—	—	1,841	—	1,841
Shares repurchased	(304)	—	—	—	—	—	—	(42,215)	(42,215)	—	(42,215)
Other comprehensive loss	—	—	—	—	—	—	(178,250)	—	(178,250)	(14)	(178,264)
Net income	—	—	—	—	—	—	—	58,387	58,387	(1,061)	57,326
Balance at December 31, 2014	60,643	$6	4,000	$55	$471	$1,458,005	$(122,097)	$34,704	$1,371,144	$64	$1,371,208

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

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

	Year Ended December 31,		
	2014	2013	2012
Operating activities			
Net income	$57,326	$216,312	$288,586
Adjustments to reconcile net income to net cash provided by operating activities:			
Amortization of intangible assets	126,584	79,042	72,922
Share-based compensation	69,638	44,551	23,006
Impairment charges	39,365	—	—
Depreciation	7,097	3,048	1,307
Acquired in-process research and development	202,626	4,988	—
Loss on disposal of property and equipment	24	46	163
Excess tax benefit from share-based compensation	(1,841)	173	(9,785)
Acquisition accounting inventory fair value step-up adjustments	10,477	3,826	19,939
Change in fair value of contingent consideration	—	15,200	(300)
Deferred income taxes	(43,423)	(10,097)	(113,862)
Gain on sale of business	—	—	(35,244)
Provision for losses on accounts receivable and inventory	2,493	2,446	4,654
Loss on extinguishment and modification of debt	—	3,749	—
Other non-cash transactions	1,739	6,278	3,523
Changes in assets and liabilities:			
Accounts receivable	(55,041)	(48,846)	(4,724)
Inventories	(7,630)	(8,516)	1,697
Prepaid expenses and other current assets	11,936	(13,871)	(13,091)
Other long-term assets	(8,891)	(4,306)	(3,491)
Accounts payable	(37,966)	5,089	(7,286)
Accrued liabilities	20,997	14,717	(11,428)
Income taxes payable	8,634	(38,984)	39,340
Deferred revenue	(1,203)	(1,061)	(1,205)
Contingent consideration	(14,900)	—	—
Other non-current liabilities	17,724	14,820	2,351
Liability under government settlement	—	—	(7,320)
Net cash provided by operating activities	405,765	288,604	249,752
Investing activities			
Acquisitions, net of cash acquired	(828,676)	—	(542,531)
Acquisition of in-process research and development	(202,626)	(4,988)	—
Purchases of property and equipment	(36,347)	(9,976)	(5,976)
Purchases of marketable securities	—	—	(37,443)
Net proceeds from sale of business	—	—	93,922
Proceeds from sale of marketable securities	—	—	81,246
Proceeds from maturities of marketable securities	—	—	31,988
Acquisition of intangible assets	—	(1,300)	—
Purchase of product rights	—	—	(16,500)
Net cash used in investing activities	(1,067,649)	(16,264)	(395,294)
Financing activities			

Net proceeds from issuance of debt	1,194,385	553,425	450,916
Proceeds from employee equity incentive and purchase plans and exercise of warrants	58,487	30,703	25,003
Share repurchases	(42,215)	(136,484)	—
Acquisition of noncontrolling interests	(136,969)	—	—
Payment of contingent consideration	(35,100)	—	—
Payment of employee withholding taxes related to share-based awards	(18,030)	(5,590)	(25,299)
Excess tax benefit from share-based compensation	1,841	(173)	9,785
Repayments of long-term debt	(9,524)	(465,910)	(11,875)
Repayments under revolving credit facility	(300,000)	—	—
Net cash provided by (used in) financing activities	712,875	(24,029)	448,530
Effect of exchange rates on cash and cash equivalents	(3,453)	997	2,132
Net increase in cash and cash equivalents	47,538	249,308	305,120
Cash and cash equivalents, at beginning of period	636,504	387,196	82,076
Cash and cash equivalents, at end of period	$684,042	$636,504	$387,196

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

	Year Ended December 31,		
	2014	2013	2012
Supplemental disclosure of cash flow information:			
Cash paid for interest	$31,978	$18,278	$14,192
Cash paid for income taxes	$108,189	$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.

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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 an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. We have a diverse portfolio of products and product candidates with a focus in the areas of sleep and hematology/oncology. In these areas, we market Xyrem® (sodium oxybate) oral solution and Erwinaze® (asparaginase Erwinia chrysanthemi) in the United States, and market Erwinase® and Defitelio® (defibrotide) in Europe and other countries outside the United States. Our strategy is to create shareholder value by:

- Growing sales of the existing products in our portfolio, including by identifying new growth opportunities;
- Acquiring additional differentiated products that are on the market or product candidates that are in late-stage development; and
- Pursuing focused development of a pipeline of post-discovery differentiated 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.

On January 23, 2014, pursuant to a tender offer, we became the indirect majority shareholder of Gentium S.p.A., or Gentium, thereby acquiring control of Gentium on that date. In February 2014, we completed a subsequent offering period of the tender offer, resulting in total purchases pursuant to the tender offer of approximately 98% of the fully diluted voting securities of Gentium. As of December 31, 2014, we had acquired a further 1.8% interest in Gentium, resulting in an aggregate acquisition cost to us of $994.1 million, comprising cash payments of $1,011.2 million, offset by proceeds from the exercise of Gentium share options of $17.1 million. Please see Note 3 for additional information regarding our acquisition of Gentium, which we refer to as the Gentium 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 "ordinary shares" refer to Jazz Pharmaceuticals plc's ordinary shares.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our subsidiaries and intercompany transactions and balances have been eliminated. We record noncontrolling interests in our consolidated financial statements which represent the ownership interest of minority shareholders in the equity of Gentium. The results of operations of the acquired Azur Pharma, EUSA Pharma and Gentium 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, the EUSA Acquisition and the Gentium Acquisition, respectively.

Reclassifications

Certain prior period amounts presented in these consolidated financial statements and the accompanying footnotes have been reclassified to conform to the current period presentation. Upfront license fees, previously classified as research and development expense in 2013, have been reclassified to acquired in-process research and development, or IPR&D, in the consolidated statements of income and reclassified from operating activities to investing activities in the consolidated

statements of cash flows to conform to the current period presentation. Inventories of $1.4 million, previously classified as raw materials as of December 31, 2013, have been reclassified to work-in-process to conform to the current period presentation.

Significant Risks and Uncertainties

Our financial results are significantly influenced by sales of Xyrem. In 2014, net product sales of Xyrem were $778.6 million, which represented 67.0% of total net product sales. Our ability to maintain or increase 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. Five abbreviated new drug applications, or ANDAs, have been filed with the U.S. Food and Drug Administration, or FDA, by third parties seeking to market generic versions of Xyrem, including the most recent in the fourth quarter of 2014. We have initiated lawsuits against all five third parties, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. Although no trial date has been set in any of the ANDA suits, we anticipate that trial on some of the patents in the case against the first ANDA filer, Roxane Laboratories, Inc., or Roxane, could occur as early as the third quarter of 2015. In addition, certain of the ANDA filers have sought to challenge the validity of our patents covering the distribution system for Xyrem by filing petitions for covered business method, or CBM, post-grant patent review and/or inter partes review, or IPR, by the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO. The PTAB has issued decisions denying institution of CBM review for all of the CBM petitions and has not yet determined whether to institute proceedings with respect to the petitions for IPR. We cannot predict whether PTAB will institute any of the petitioned IPR proceedings, whether additional post-grant patent review challenges will be filed, the outcome of any IPR or other proceeding if instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings. We expect that the approval of an ANDA that results in the launch of a generic version of Xyrem, or the approval and launch of other sodium oxybate products that compete with Xyrem, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are continuing our efforts on various regulatory matters, including updating documents that we have submitted to the FDA on our risk management and controlled distribution system for Xyrem, which we refer to as the Xyrem Risk Management Program. We are engaged in ongoing communications with respect to our risk evaluation and mitigation strategies, or REMS, documents for Xyrem, but have not reached agreement with the FDA on certain significant terms. In late 2013, the FDA notified us that it would exercise its claimed authority to modify our REMS and that it would finalize the REMS as modified by the FDA unless we initiated dispute resolution procedures with respect to the modification of the Xyrem deemed REMS. Among other things, we disagree with the FDA's position in the late 2013 notice 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, be sufficient to ensure that the REMS includes only those elements necessary to ensure that the benefits of Xyrem outweigh its risks, and that would, in the FDA's view, reduce the burden on the healthcare system. Given these circumstances, we initiated dispute resolution procedures with the FDA at the end of February 2014. We received the FDA's denial of our initial dispute resolution submission in the second quarter of 2014, and our dispute is currently subject to further supervisory review at the next administrative level of the FDA. We have received interim responses from the FDA, but the FDA has not yet communicated a decision on our further appeal to us. We expect to receive the FDA's decision in the first quarter of 2015. We cannot predict whether, or on what terms, we will reach agreement with the FDA on final REMS documents for Xyrem, the outcome or timing of the current dispute resolution procedure, whether we will initiate additional dispute resolution proceedings with the FDA or other legal proceedings prior to finalizing the REMS documents, or the outcome or timing of any such proceedings. We expect that final REMS documents for Xyrem will include modifications to, and/or requirements that are not currently implemented in, the Xyrem Risk Management Program. Any such modifications or additional requirements could potentially make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of

Xyrem.

We also expect to face pressure to license or share our Xyrem Risk Management Program, which is the subject of multiple issued patents, or elements of it, with generic competitors. In January 2014, the FDA held an initial meeting with us and the then-current Xyrem ANDA applicants to facilitate the development of a single shared system REMS for Xyrem (sodium oxybate). The parties have had numerous interactions with respect to a single shared system REMS since the initial meeting, and we expect the interactions to continue. In addition, 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, elements to assure safe use. Similarly, it is possible that, consistent with the

position that the FDA articulated in its December 2012 response denying a Citizen Petition we filed in July 2012, the FDA could approve an 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 cannot predict the outcome or impact on our business of any future action that we may take with respect to the development of a single shared system REMS for Xyrem (sodium oxybate), licensing or sharing our REMS, or the FDA's response to a certification that a third party had been unable to obtain a license.

Sales of our second largest product, Erwinaze, continue to grow. In 2014, net product sales of Erwinaze/Erwinase were $199.7 million, which represented 17.2% of net product sales in 2014. We seek to maintain and increase sales of Erwinaze, as well as to make Erwinaze more widely available, through ongoing research and development activities. However, our ability to successfully and sustainably maintain or grow sales of Erwinaze is subject to a number of risks and uncertainties, including the limited population of patients with acute lymphoblastic leukemia, or ALL, and the incidence of hypersensitivity reactions to E. coli-derived asparaginase within that population, our ability to obtain clinical data on the use of Erwinaze in young adults age 18 to 39 with ALL who are hypersensitive to E. coli-derived asparaginase, as well as our need to apply for and receive marketing authorizations, through the European Union's, or EU's, mutual recognition procedure or otherwise, in certain additional countries so we can launch promotional efforts in those countries. Another significant challenge to our ability to maintain current sales levels and to increase sales is our need to avoid supply interruptions of Erwinaze due to capacity constraints, production delays, quality challenges or other manufacturing difficulties. We have limited inventory of Erwinaze, which puts us at significant risk of not being able to meet product demand. The current manufacturing capacity for Erwinaze is nearly completely absorbed by demand for the product. As a consequence of constrained manufacturing capacity, we have had an extremely limited ability to build an excess level of product inventory that could be used to absorb disruptions to supply resulting from any quality or other issues. If we continue to be subject to capacity constraints or experience quality or other manufacturing challenges in the future, we may be unable to build a desired excess level of product inventory, and our ability to supply the market may be compromised. Although we are taking steps to improve the Erwinaze manufacturing process, if our ongoing efforts are not successful, we could experience additional 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 expand production capacity to increase the supply of Erwinaze over the longer term to address worldwide demand, our ability to maintain or increase sales of Erwinaze may be limited by our ability to obtain a sufficient supply of the product.

In furtherance of our growth strategy, we have made a significant investment in Defitelio. We added the product to our portfolio as a result of the Gentium Acquisition and secured worldwide rights to the product by acquiring rights to defibrotide in the Americas in August 2014. Our ability to realize the anticipated benefits from this investment is subject to a number of risks and uncertainties, including our ability to successfully maintain or grow sales of Defitelio in Europe, or obtain marketing approval in other countries, including the United States, so that we can launch promotional efforts in those countries. During 2014, Defitelio was launched in a number of European countries. We expect to continue to launch Defitelio in additional European countries on a rolling basis in 2015. A key challenge to our success in maintaining or growing sales of Defitelio in Europe is our ability to obtain appropriate pricing and reimbursement approvals in those European countries where Defitelio is not yet launched. If we experience delays or unforeseen difficulties in obtaining favorable pricing and reimbursement approvals, planned launches in the affected countries would be delayed, or, if we are unable to ultimately obtain favorable pricing and reimbursement approvals in countries that represent significant markets, especially where a country's reimbursed price influences other countries, our growth prospects in Europe could be negatively affected.

We are also engaged in activities related to the potential approval of defibrotide in the United States. We initiated a rolling submission of a new drug application, or NDA, to the FDA for defibrotide for the treatment of severe hepatic veno-occlusive disease, or VOD, in December 2014 and expect to complete the submission in mid-2015. We do not expect to be required to complete any additional clinical trials prior to completion of the NDA submission. However,

we may be unable to acquire and remediate key information to be included in the data package for the NDA in a timely manner or our analysis of such information may not support submission, which would delay or preclude the completion of our NDA submission, and we may be unable to otherwise obtain regulatory approval of defibrotide in the United States in a timely manner, if at all. We also face other challenges that could impact the anticipated value of Defitelio/defibrotide, including the limited size of the population of patients who undergo hematopoietic stem cell transplantation, or HSCT, therapy and develop severe VOD, the need to establish U.S. pricing and reimbursement support for the product in the event we are able to obtain U.S. marketing approval for defibrotide, the possibility that we may be required to conduct time-consuming and costly clinical trials as a condition of any U.S. marketing approval for the product, the lack of experience of U.S. physicians in diagnosing and treating VOD, and challenges to our ability to develop the product for indications in addition to the treatment of severe VOD. If sales of Defitelio/defibrotide do not reach the levels we expect, our anticipated revenue from the product would be negatively

affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to risks specifically related to Xyrem, Erwinaze and Defitelio/defibrotide, 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 and enhancing our intellectual property rights; delays or problems in the supply or manufacture of our products, particularly with respect to certain products as to which we maintain limited inventories, including products for which our supply demands are growing, and our dependence on single source suppliers to continue to meet our ongoing commercial demand or our requirements for clinical trial supplies; the need to obtain and maintain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the United States and worldwide, including the need to obtain and maintain reimbursement for Xyrem in the United States in an environment in which we are subject to increasingly restrictive conditions for reimbursement required by third party payors; and the challenges of compliance with the requirements of 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.

Other risks and uncertainties related to our ability to execute on our strategy include: the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors; the risks associated with business combination or product or product candidate acquisition transactions, such as the challenges inherent in the integration of acquired businesses with our historic business, the increase in geographic dispersion among our centers of operation, taking on the operation of a manufacturing plant as a result of the Gentium Acquisition, and the risks that we may acquire unanticipated liabilities along with acquired businesses or otherwise fail to realize the anticipated benefits (commercial or otherwise) from such transactions; the difficulty and uncertainty of pharmaceutical product development, including the timing thereof, and the uncertainty of clinical success, such as the risk that results from preclinical studies and/or early clinical trials may not be predictive of results obtained in later and larger clinical trials planned or anticipated to be conducted for our product candidates; the inherent uncertainty associated with the regulatory approval process, 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 increased significantly in 2014.

Business Acquisitions

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

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, 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 pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the United States, and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We

monitor deteriorating economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of December 31, 2014, five customers accounted for 86% of gross accounts receivable including Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or Express Scripts, which accounted for 66% of gross accounts receivable and IDIS Limited, which accounted for 11% of gross accounts receivable. As of December 31, 2013, five customers accounted for 85% of gross accounts receivable including Express Scripts which accounted for 69% of gross accounts receivable and Accredo Health Group, Inc. which accounted for 9% of gross accounts receivable.

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

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 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 (loss) 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 our estimate of future demand changes, we consider the impact on the reserve for excess inventory and adjust the reserve as required. Increases in the reserve are recorded as charges in 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 no step-up in the value of inventories and $0.2 million step-up in the value of inventories as of December 31, 2014 and 2013, 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 leases 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.

Acquired In-Process Research and Development

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

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 16 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. Such assets 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 an asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

Revenue Recognition

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

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 2014 and 2013 included $10.5 million and $3.8 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 $122.6 million, $78.8 million and $65.1 million in 2014, 2013 and 2012, 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 services performed by clinical research organizations, clinical studies performed at clinical sites, 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. 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 2014, 2013 and 2012 were $1.0 million, $1.0 million and $0.7 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 (loss) in shareholders’ equity.

Transactions in foreign currencies are translated into the functional currency of the relevant subsidiary at the rate of exchange prevailing at the date of the transaction. 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 gain (loss) in our consolidated statements of

income.

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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 reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.
Net Income per Ordinary Share
Basic net income per ordinary share attributable to Jazz Pharmaceuticals plc is based on the weighted-average number of ordinary shares outstanding. Diluted net income per ordinary share attributable to Jazz Pharmaceuticals plc is based on the weighted-average number of ordinary shares outstanding and potentially dilutive ordinary shares outstanding.

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Basic and diluted net income per ordinary share attributable to Jazz Pharmaceuticals plc were computed as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2014	2013	2012
Numerator:			
Income from continuing operations	$57,326	$216,312	$261,149
Loss from continuing operations attributable to noncontrolling interests, net of tax	(1,061)	—	—
Income from continuing operations attributable to Jazz Pharmaceuticals plc	58,387	216,312	261,149
Income from discontinued operations	—	—	27,437
Net income attributable to Jazz Pharmaceuticals plc	$58,387	$216,312	$288,586
Denominator:			
Weighted-average ordinary shares used in calculating net income per ordinary share attributable to Jazz Pharmaceuticals plc - basic	59,746	58,298	56,643
Dilutive effect of employee equity incentive and purchase plans	2,402	1,772	1,536
Dilutive effect of warrants	466	1,499	2,016
Weighted-average ordinary shares used in calculating net income per ordinary share attributable to Jazz Pharmaceuticals plc - diluted	62,614	61,569	60,195
Net income per ordinary share attributable to Jazz Pharmaceuticals plc:			
Basic:			
Income from continuing operations	$0.98	$3.71	$4.61
Income from discontinued operations	—	—	0.48
Net income attributable to Jazz Pharmaceuticals plc	$0.98	$3.71	$5.09
Diluted:			
Income from continuing operations	$0.93	$3.51	$4.34
Income from discontinued operations	—	—	0.45
Net income attributable to Jazz Pharmaceuticals plc	$0.93	$3.51	$4.79

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans, warrants and exchangeable senior notes are determined by applying the treasury stock method to the assumed exercise of share options and warrants, the assumed vesting of outstanding restricted stock units, or RSUs, the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP, and the assumed issuance of ordinary shares upon exchange of our exchangeable senior notes. The approximately 2.9 million ordinary shares issuable upon exchange of our exchangeable senior notes had no effect on diluted net income per ordinary share attributable to Jazz Pharmaceuticals plc because the average price of our ordinary shares for the year ended December 31, 2014 did not exceed the effective exchange price of $199.77 per ordinary share. For additional information relating to our exchangeable senior notes, see Note 9.

The following table represents the weighted-average ordinary shares that were excluded from the computation of diluted net income per ordinary share attributable to Jazz Pharmaceuticals plc for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Options to purchase ordinary shares and RSUs	819	1,584	1,506
1.875% exchangeable senior notes due 2021	1,112	—	—

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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2014-09, "Revenue from Contracts with Customers", or ASU No. 2014-09, which states that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this, an entity will need to identify the contract with a customer; identify the separate performance obligations in the contract; determine the transaction price; allocate the transaction price to the separate performance obligations in the contract; and recognize revenue when (or as) the entity satisfies each performance obligation. ASU No. 2014-09 will be effective for us beginning January 1, 2017 and can be adopted on a full retrospective basis or on a modified retrospective basis. We are currently assessing our approach to the adoption of this standard and the impact on our results of operations and financial position.

In April 2014, the FASB issued ASU No. 2014-08, "Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity", or ASU 2014-08. Under ASU 2014-08, only disposals representing a strategic shift in operations should be presented as discontinued operations. Those strategic shifts should have a major effect on the organization's operations and financial results. Additionally, ASU 2014-08 requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. ASU 2014-08 is effective for fiscal and interim periods beginning on or after December 15, 2014, with early adoption permitted. We early adopted ASU 2014-08 in 2014. Please see Note 18 for additional information.

3. Business Combination and Asset Acquisitions

Gentium Acquisition

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

Upon payment for the properly tendered ordinary shares and ADSs on January 23, 2014, we became the indirect majority shareholder of Gentium and acquired control of Gentium. Following the expiration of the initial offering period, and in accordance with the terms of the Gentium tender offer agreement, we commenced a subsequent offering period to acquire all remaining untendered ordinary shares and ADSs. The subsequent offering period expired on February 20, 2014. In total, pursuant to the tender offer agreement, we purchased approximately 98% of Gentium's fully diluted ordinary shares and ADSs. Later in 2014, we acquired additional Gentium ordinary shares, representing a further 1.8% interest in Gentium, for aggregate cash consideration of $17.8 million. As of December 31, 2014, the aggregate acquisition cost of the Gentium ordinary shares and ADSs was $994.1 million, comprising cash payments of $1,011.2 million, offset by proceeds from the exercise of Gentium share options of $17.1 million. $857.1 million of the acquisition consideration is attributable to the 12,244,156 Gentium ordinary shares and ADSs purchased on the closing date of the Gentium Acquisition, 1,345,023 ADSs committed to tender in accordance with the guaranteed delivery procedures contemplated by the tender offer and options to acquire 1,666,608 ordinary shares of Gentium subject to support agreements requiring that such options be exercised and the underlying ordinary shares be tendered in a subsequent offering period. These ADSs and ordinary shares represented in the aggregate approximately 86% of

the fully diluted number of ordinary shares and ADSs of Gentium. The remaining $137.0 million of the acquisition cost is attributable to the acquisition of an additional 12% of the fully diluted Gentium ordinary shares and ADSs during the subsequent offering period of the tender offer and the acquisition of an additional 1.8% interest in Gentium later in 2014, which are accounted for as an acquisition of noncontrolling interests.

We believe the Gentium Acquisition provided 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.

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The Gentium Acquisition was accounted for using the acquisition method of accounting under which assets and liabilities of Gentium were recorded at their respective estimated fair values as of the closing date of the Gentium Acquisition and added to the assets and liabilities of Jazz Pharmaceuticals plc, including an amount for goodwill representing the difference between the acquisition consideration and the estimated fair value of the identifiable net assets. The results of operations of Gentium and the estimated fair values of the assets acquired and liabilities assumed have been included in our consolidated financial statements since the closing of the Gentium Acquisition on January 23, 2014.

In 2014, we incurred $11.9 million in acquisition-related costs related to the Gentium Acquisition, which primarily consisted of banking, legal, accounting and valuation-related expenses. In addition, we incurred $5.4 million related to change in control obligations associated with the Gentium Acquisition. These expenses were recorded in selling, general and administrative expense in the accompanying consolidated statements of income. In 2014, our consolidated statements of income included revenues of $78.2 million from the acquired Gentium business, as measured from the closing date of the Gentium Acquisition. The portion of total expenses and net income associated with the acquired Gentium business was not separately identifiable due to the integration of Gentium operations with our historic operations.

The acquisition consideration (not including the acquisition cost of $119.2 million to acquire the 12% noncontrolling interests in the subsequent offering period of the tender offer and the acquisition cost of $17.8 million to acquire the 1.8% noncontrolling interests later in 2014) was comprised of (in thousands):

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

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

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

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

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

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

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

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

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

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

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

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Pro Forma Financial Information (Unaudited)

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

- An increase in amortization expense related to the fair value of acquired identifiable intangible assets of $2.7 million in 2014 and $48.9 million in 2013.
- The exclusion of acquisition-related expenses of $43.0 million in 2014 and $4.8 million in 2013.
- An increase in interest expense of $1.3 million in 2014 and $22.5 million in 2013, incurred on additional borrowings made to fund the Gentium Acquisition as if the borrowings had occurred on January 1, 2013.
- The exclusion of other non-recurring expenses of $40.7 million in 2014 and the inclusion of $18.6 million in 2013 primarily related to Gentium transaction bonus costs, the fair value step-up to acquired inventory, costs of change in control obligations and share-based compensation incurred from the acceleration of stock option vesting upon the closing date of the Gentium Acquisition.

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

	Year Ended December 31,	
	2014	2013
Revenues	$1,176,178	$925,185
Net income attributable to Jazz Pharmaceuticals plc	$82,802	$181,318
Net income per ordinary share attributable to Jazz Pharmaceuticals plc - basic	$1.39	$3.11
Net income per ordinary share attributable to Jazz Pharmaceuticals plc - diluted	$1.32	$2.94

Acquisition of Rights to Defibrotide in the Americas

As a result of the Gentium Acquisition, we acquired defibrotide, which is marketed under the name Defitelio in Europe. In 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 March 2014, we commenced the launch of Defitelio on a rolling basis in Europe. At the time of the Gentium Acquisition, Gentium had licensed to Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, the rights to defibrotide for the treatment and prevention of VOD in North America, Central America and South America. In July 2014, we entered into a definitive agreement to acquire the rights to defibrotide in the Americas from Sigma-Tau. Pursuant to the agreement, upon the closing of the transaction in August 2014, we paid Sigma-Tau an upfront payment of $75.0 million. This transaction was accounted for as a purchase of IPR&D assets with no alternative future use. Accordingly, the $75.0 million upfront payment was charged to acquired IPR&D expense upon closing of the transaction. Sigma-Tau is also eligible to receive milestone payments of $25.0 million upon the acceptance for filing by the FDA of the first NDA for defibrotide for VOD and up to an additional $150.0 million based on the timing of potential FDA approval of defibrotide for VOD. We funded the upfront payment with cash on hand.

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

On January 13, 2014, we entered into a definitive agreement with Aerial BioPharma, LLC, or Aerial, under which we acquired certain assets related to JZP-110, a novel compound in clinical development for the treatment of excessive daytime sleepiness in patients with narcolepsy. Under the agreement, and in exchange for an upfront initial payment from us totaling $125.0 million, we acquired worldwide development, manufacturing and commercial rights to JZP-110, other than in certain jurisdictions in Asia where SK Biopharmaceuticals Co., Ltd, or SK, retains rights. Aerial and SK are eligible to receive milestone payments, in an aggregate amount of up $270.0 million, based on development, regulatory and sales milestones and tiered royalties from high single digits to mid-teens based on potential future sales. This acquisition was accounted for as a purchase of IPR&D assets with no alternative future use. Accordingly, the $125.0 million upfront payment was charged to acquired IPR&D expense in the year ended December 31, 2014. The assignment of the JZP-110 rights from Aerial to us triggered a milestone payment of $2.0

million to SK, which was also charged to acquired IPR&D expense in the year ended December 31, 2014.

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4. Fair Value Measurement

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

	December 31, 2014				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents
Cash	$338,262	$—	$—	$338,262	$338,262
Time deposits	345,780	—	—	345,780	345,780
Totals	$684,042	$—	$—	$684,042	$684,042

	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

Cash equivalents are considered available-for-sale securities. 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.

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

	December 31, 2014		December 31, 2013	
	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:				
Available-for-sale securities				
Time deposits	$345,780	$345,780	$140,514	$140,514
Liabilities:				
Contingent consideration	$—	$—	$50,000	$50,000

As of December 31, 2014, 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. 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. There were no transfers between the different levels of the fair value hierarchy in 2014 or in 2013.

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

As of December 31, 2014, the estimated fair value of the $895.4 million principal amount of our term loans was $881.9 million and the carrying amount was $890.5 million. The fair value was determined using quotes from the administrative agent of our credit facility that are based on the bid/ask prices of our term loans (Level 2). As of December 31, 2014, the estimated fair value of our exchangeable senior notes was $653.8 million. The fair value of

the exchangeable senior notes was estimated using quoted market prices obtained from brokers (Level 2). The fair value of other borrowings approximates book value based on the borrowing rates currently available for variable rate loans (Level 2).

As of December 31, 2014, assets measured at fair value on a non-recurring basis subsequent to initial recognition included assets classified as held for sale on the consolidated balance sheet. These assets are associated with certain products

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we acquired as part of the EUSA Acquisition that we expect to sell in the first half of 2015. See Note 18 for additional information. The carrying amount of $32.8 million for assets held for sale is equal to estimated fair value,which is based on the sales price agreed less costs to sell, and represents a Level 3 input.

5. Inventories

Inventories consisted of the following (in thousands):

	December 31,	
	2014	2013
Raw materials	$3,570	$3,506
Work in process	9,870	10,301
Finished goods	16,597	14,862
Total inventories	$30,037	$28,669

Inventories included no step-up in fair value and $0.2 million in acquisition accounting inventory fair value step-ups as of December 31, 2014 and 2013, respectively.

6. Property and Equipment

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

	December 31,	
	2014	2013
Construction-in-progress	$37,145	$4,388
Computer software	10,634	7,960
Leasehold improvements	7,931	4,587
Computer equipment	7,670	5,610
Machinery and equipment	6,408	417
Furniture and fixtures	2,220	1,897
Land and buildings	1,547	—
Subtotal	73,555	24,859
Less accumulated depreciation and amortization	(15,192)	(10,613)
Property and equipment, net	$58,363	$14,246

7. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2014	2013
Rebates and other sales deductions	$51,899	$38,772
Employee compensation and benefits	46,143	31,829
Sales returns reserve	14,039	21,110
Accrued interest	10,327	4,150
Royalties	7,964	6,082
Accrued construction-in-progress	4,931	450
Professional fees	3,295	5,225
Other	25,493	12,100
Total accrued liabilities	$164,091	$119,718

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8. Goodwill and Intangible Assets

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

Balance at December 31, 2013	$450,456
Goodwill arising from the Gentium Acquisition	308,642
Goodwill allocated to assets held for sale (1)	(1,686)
Foreign exchange	(54,699)
Balance at December 31, 2014	$702,713

(1) In December 2014, we entered into a definitive agreement to sell certain products and related assets. See Note 18 for information regarding assets held for sale.

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

	December 31, 2014				December 31, 2013		
	Remaining Weighted-Average Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies	12.9	$1,450,606	$ (259,889)	$1,190,717	$957,089	$ (179,225)	$777,864
Manufacturing contracts	3.1	13,012	(3,060)	9,952	—	—	—
Trademarks	0.1	2,914	(2,896)	18	2,600	(2,327)	273
Total finite-lived intangible assets		1,466,532	(265,845)	1,200,687	959,689	(181,552)	778,137
Acquired IPR&D assets		236,748	—	236,748	34,259	—	34,259
Total intangible assets		$1,703,280	$ (265,845)	$1,437,435	$993,948	$ (181,552)	$812,396

The increase in the gross carrying amount of intangible assets as of December 31, 2014 compared to December 31, 2013 reflected the acquisition of the Gentium intangible assets as described in Note 3, offset by the negative impact of foreign currency exchange which was primarily due to the strengthening of the U.S. dollar against the Euro, the impairment charge discussed below and the reclassification of certain intangible assets to assets held for sale as described in Note 18.

The assumptions and estimates used to determine future cash flows and remaining useful lives of our intangible and other long-lived assets are complex and subjective. They can be affected by various factors, including external factors, such as industry and economic trends, and internal factors such as changes in our business strategy and our forecasts for specific product lines.

In the second quarter of 2014, we recorded an impairment charge of $32.8 million on acquired developed technologies related to certain products we acquired as part of the EUSA Acquisition in June 2012. We report sales of these products under “Other” products. The impairment charge resulted from the reorganization of our operations in Europe to focus on our hematology/oncology therapeutic area following the Gentium Acquisition. In the fourth quarter of 2014, we entered into a definitive agreement to sell these products and the related business, and reclassified intangible assets associated with these products with a net book value of $27.5 million as assets held for sale. See Note 18 for information regarding assets held for sale.

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Based on finite-lived intangible assets recorded as of December 31, 2014, and assuming the underlying assets will not be further impaired and that we will not change the expected lives of the assets, future amortization expenses were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2015	$102,508
2016	99,167
2017	99,167
2018	95,313
2019	95,071
Thereafter	709,461
Total	$1,200,687

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 20 for information regarding discontinued operations.

9. Debt

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

	December 31, 2014	2013
1.875% exchangeable senior notes due 2021	$575,000	$—
Unamortized discount on 1.875% exchangeable senior notes due 2021	(124,735)	—
1.875% exchangeable senior notes due 2021, net	450,265	—
Term loans	890,479	549,976
Other borrowings	1,684	—
Total debt	1,342,428	549,976
Less current portion	9,428	5,572
Total long-term debt	$1,333,000	$544,404

Exchangeable Senior Notes

In August 2014, we completed a private placement of $575.0 million principal amount of 1.875% exchangeable senior notes due 2021, or the 2021 Notes, resulting in net proceeds to us, after debt issuance costs, of $558.9 million. Interest on the 2021 Notes is payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2015, at a rate of 1.875% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2021 Notes. The 2021 Notes mature on August 15, 2021, unless earlier exchanged, repurchased or redeemed.

The holders of the 2021 Notes have the ability to require us to repurchase all or a portion of their 2021 Notes for cash in the event Jazz Pharmaceuticals plc undergoes certain fundamental changes. Prior to August 15, 2021, we may redeem the 2021 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2021 Note additional amounts as a result of certain tax-related events. We also may redeem the 2021 Notes on or after August 20, 2018, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2021 Notes are exchangeable at an initial exchange rate of 5.0057 ordinary shares per $1,000 principal amount of 2021 Notes, which is equivalent to an initial exchange price of approximately $199.77 per ordinary share. Upon exchange, the 2021 Notes may be settled in cash, ordinary shares or a combination of cash and ordinary shares, at our election. Our intent and policy is to settle the principal amount of the 2021 Notes in cash upon exchange. The

exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-

whole fundamental changes occurring prior to the maturity date of the 2021 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2021 Notes who elect to exchange their 2021 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to February 15, 2021, the 2021 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

The 2021 Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of Jazz Pharmaceuticals plc. The Issuer's obligations under the 2021 Notes are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. No subsidiary of Jazz Pharmaceuticals plc guaranteed the 2021 Notes. Subject to certain local law restrictions on payment of dividends, among other things, and potential negative tax consequences, we are not aware of any significant restrictions on the ability of Jazz Pharmaceuticals plc to obtain funds from the Issuer or Jazz Pharmaceuticals plc's other subsidiaries by dividend or loan, or any legal or economic restrictions on the ability of the Issuer or Jazz Pharmaceuticals plc's other subsidiaries to transfer funds to Jazz Pharmaceuticals plc in the form of cash dividends, loans or advances. There is no assurance that in the future such restrictions will not be adopted.

In accounting for the issuance of the 2021 Notes, we separated the 2021 Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the estimated fair value of a similar liability that does not have an associated exchange feature. The carrying amount of the equity component representing the exchange option was determined by deducting the fair value of the liability component from the face value of the 2021 Notes as a whole. The excess of the principal amount of the liability component over its carrying amount will be amortized to interest expense over the expected life of the 2021 Notes using the effective interest method with an effective interest rate of 6.4% per annum. We have determined the expected life of the 2021 Notes to be equal to the original seven-year term. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. As of December 31, 2014, the "if-converted value" did not exceed the principal amount of the 2021 Notes.

We allocated the total issuance costs incurred of $16.1 million to the liability and equity components based on their relative values. Issuance costs attributable to the liability component will be amortized to expense over the term of the 2021 Notes, and issuance costs attributable to the equity component were included with the equity component in our shareholders' equity.

For the year ended December 31, 2014, we recognized $9.9 million in interest expense related to the contractual coupon rate and amortization of the debt discount on the 2021 Notes.

As of December 31, 2014, the carrying value of the equity component related to the 2021 Notes, net of equity issuance costs, was $126.9 million.

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 that provided 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 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 the term loans to refinance in full the $457.2 million principal amount of term loans outstanding under the credit agreement prior to the amendment. As a result of the June 2013 amendment, interest rate margins on the term loans and the revolving loans were reduced by 150 basis points.

On January 23, 2014, we entered into a second amendment to the credit agreement to provide for (i) a tranche of incremental term loans in the aggregate principal amount of $350.0 million, (ii) a tranche of term loans that refinanced the $554.4 million principal amount of term loans previously outstanding under the amended credit agreement, or the prior term loans, in their entirety, and (iii) a $425.0 million revolving credit facility that replaced the $200.0 million revolving credit facility. We used the proceeds from the incremental term loans and $300.0 million of loans under the revolving credit facility, together with cash on hand, to purchase the Gentium ordinary shares and ADSs properly

tendered and accepted for payment on the January 22, 2014 expiration of the initial tender offer period relating to the Gentium Acquisition. The January 2014 amendment also reduced the interest rate margins on the terms loans by 25 basis points. In August 2014, we used a portion of the net proceeds from the issuance of the 2021 Notes to repay all outstanding borrowings under the revolving credit facility.

The term loans under the credit agreement 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 current

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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 and any hedging or cash management obligations entered into with a lender or an affiliate of a lender are guaranteed on a senior secured basis by Jazz Pharmaceuticals plc and certain of its subsidiaries (including the Issuer) and are secured by substantially all of Jazz Pharmaceuticals plc's, the borrowers' and the subsidiary guarantors' assets.

We may make voluntary prepayments of principal at any time without payment of a premium. 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) 50% of our excess cash flow as defined in the current credit agreement (subject to decrease to 25% if our total 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 total leverage ratio is equal to or less than 1.25 to 1.00), and (4) casualty proceeds and condemnation awards (subject to reinvestment rights and other exceptions).

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

The credit agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to Jazz Pharmaceuticals plc and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. The credit agreement 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, 2014, and are currently in compliance with this financial covenant.

The refinancing of the term loans involved multiple lenders who were considered members of a loan syndicate. In determining whether the refinancing was to be accounted for as a debt extinguishment or modification, we considered whether the lenders remained the same or changed and whether the change in debt terms was substantial. The debt terms would be considered substantially different if the present value of the cash inflows and outflows of the new term loans, including all principal increases and lender fees on the refinancing date, was at least 10% different from the present value of the remaining cash inflows and outflows of the original term loans, or the 10% Test. We performed a separate 10% Test for each individual lender participating in the loan syndication. For existing lenders who participated in the new term loans as part of the new loan syndicate, the refinancing was accounted for as a modification as the change in debt terms was determined to not be substantial using the 10% Test.

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

As the borrowing capacity relating to each creditor under the revolving credit facility was greater than that under the original revolving credit facility, deferred financing costs totaling $5.4 million were associated with the new arrangement and are being amortized to interest expense on a straight-line basis over the life of the facility. As of December 31, 2014, there were no borrowings outstanding under the revolving credit facility.

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

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2015	$9,428
2016	9,433
2017	9,438
2018	868,479

2019	114
Thereafter	575,150
Total	$1,472,042

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10. Deferred Revenue

We have an agreement with UCB Pharma Limited, or 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 2014, 2013, and 2012 relating to two upfront payments received from UCB in 2006 totaling $15.0 million. As of December 31, 2014, $5.6 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.

11. 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, 2014 and December 31, 2013. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

We have noncancelable operating leases for our office buildings and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force.

Lease expense under our operating leases was as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Lease expense	$10,678	$9,114	$5,303

Future minimum lease payments under our noncancelable operating leases at December 31, 2014, were as follows (in thousands):

Year ending December 31,	Lease Payments
2015	$10,165
2016	7,852
2017	4,915
2018	1,443
2019	671
Thereafter	—
Total	$25,046

In January 2015, we entered into an agreement to lease approximately 100,000 square feet of office space in Palo Alto, California. We expect to occupy this office space by the end of 2017. This lease has a term of 12 years from commencement and we have an option to extend the term of the lease twice for a period of five years each. As a result, we are obligated to make lease payments over the initial term of the lease totaling approximately $96 million in addition to estimated operating expenses totaling $25 million. We also have an option to terminate this lease 10 years

from commencement, with no less than

one year prior written notice and the payment of a termination fee. The costs associated with this lease are not included in the above table.

As of December 31, 2014, we had $34.6 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 notice of Paragraph IV Patent Certification, or Paragraph IV Certification, from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem (sodium oxybate) oral solution. Roxane's initial notice 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 notice 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 initial notice in the U.S. District Court for the District of New Jersey, or the District Court, seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, as a result of our having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA was stayed for 30 months, or until April 18, 2013. That stay has expired. Additional patents covering Xyrem were issued between December 2010 and December 2012, and, after receiving Paragraph IV Certification notices from Roxane, we filed additional lawsuits against Roxane on February 4, 2011, May 2, 2011, October 26, 2012 and December 5, 2012 to include these additional patents in the litigation. All of the lawsuits filed against Roxane between 2010 and 2012 have been consolidated by the District Court into a single case, or the Roxane consolidated case, alleging that 10 of our patents covering Xyrem are or will be infringed by Roxane's ANDA and seeking a permanent injunction to prevent Roxane from launching a generic version of Xyrem that would infringe these patents.

In December 2013, the District Court permitted Roxane to amend its answer in the Roxane consolidated case to allege additional equitable defenses, and the parties were given additional time for discovery on those new defenses. In addition, in March 2014, the District Court granted our motion to bifurcate and stay the portion of the Roxane consolidated case regarding patents related to the distribution system for Xyrem. Although no trial date has been scheduled, based on the District Court's current schedule, we anticipate that trial on the patents in the Roxane consolidated case that are not subject to the stay could occur as early as the third quarter of 2015. We do not have any estimate of a possible trial date for trial on the patents in the Roxane consolidated case that are currently subject to the stay. The actual timing of events in this litigation may be significantly earlier or later than we currently anticipate, and we cannot predict the specific timing or outcome of events in this litigation.

On April 1, 2014 and January 15, 2015, we received additional notices of Paragraph IV Certification from Roxane regarding newly issued patents for Xyrem listed in the Orange Book. On February 20, 2015, we filed a new lawsuit against Roxane in the District Court, alleging that three of our patents covering Xyrem are infringed or will be infringed by Roxane's ANDA and seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in this matter or its impact on the Roxane consolidated case.

On December 10, 2012, December 12, 2012 and August 8, 2013, we received notices of 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. On January 18, 2013 and September 12, 2013, we filed lawsuits against Amneal in the District Court, alleging that nine of our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. These lawsuits against Amneal were consolidated by the District Court on November 6, 2013.

On November 21, 2013 and November 24, 2013, we received notices of 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. On December 27, 2013, we filed a lawsuit against Par in the District Court, alleging that 13 of our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents.

In April 2014, Amneal asked the District Court to consolidate its case with the Par case, stating that both cases would proceed on the schedule for the Par case. The District Court granted this request in May 2014. The order consolidating the cases provides that Amneal's 30-month stay period will be extended to coincide with the date of Par's 30-month stay period. As a result, FDA's approval of both Amneal's and Par's ANDAs is stayed until the earlier of (i) May 20, 2016, or (ii) a District

Court decision finding that the identified patents are invalid, unenforceable or not infringed. We cannot predict the timing or outcome of events in the Amneal/Par consolidated case or their impact on other ongoing proceedings with Amneal or Par.

On April 7, 2014 and January 19, 2015, we received additional notices of Paragraph IV Certification from Amneal regarding newly issued patents for Xyrem listed in the Orange Book. On May 20, 2014 and February 6, 2015, we filed additional lawsuits against Amneal in the District Court, alleging that four of our patents covering Xyrem are infringed or will be infringed by Amneal's ANDA and seeking a permanent injunction to prevent Amneal from introducing a generic version of Xyrem that would infringe these patents. These additional lawsuits have not been consolidated with the Amneal/Par consolidated case. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Amneal.

On July 3, 2014, August 6, 2014 and November 25, 2014, we received additional notices of Paragraph IV Certification from Par regarding newly issued patents for Xyrem listed in the Orange Book. We filed additional lawsuits against Par in the District Court on August 15, 2014, October 2, 2014 and January 8, 2015, alleging that three of our patents covering Xyrem are infringed or will be infringed by Par's ANDA and seeking a permanent injunction to prevent Par from introducing a generic version of Xyrem that would infringe these patents. These additional lawsuits have not been consolidated with the Amneal/Par consolidated case. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Par.

On June 4, 2014, we received a notice of Paragraph IV Certification from Ranbaxy Laboratories Limited, or Ranbaxy, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On June 6, 2014, we received a notice of an amended Paragraph IV Certification from Ranbaxy. On July 15, 2014, we filed a lawsuit against Ranbaxy in the District Court, alleging that 14 of our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that will infringe these patents. On August 20, 2014 and December 1, 2014, we received additional notices of Paragraph IV Certification from Ranbaxy regarding newly issued patents for Xyrem listed in the Orange Book. On October 2, 2014 and January 9, 2015, we filed additional lawsuits against Ranbaxy in the District Court, alleging that two of our patents covering Xyrem are infringed or will be infringed by Ranbaxy's ANDA and seeking a permanent injunction to prevent Ranbaxy from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in these matters or their impact on other ongoing proceedings with Ranbaxy.

On October 30, 2014, we received a notice of Paragraph IV Certification from Watson Laboratories, Inc., or Watson, that it has submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem. On December 11, 2014, we filed a lawsuit against Watson in the District Court, alleging that 15 of our patents covering Xyrem are or will be infringed by Watson's ANDA and seeking a permanent injunction to prevent Watson from introducing a generic version of Xyrem that would infringe these patents. We cannot predict the timing or outcome of events in this litigation.

In January 2015, Amneal, Ranbaxy and Watson proposed the consolidation of their respective cases and a consolidated schedule to the District Court. Under the proposed consolidated schedule, the District Court would hold a Markman hearing no earlier than January 2016. Par is currently seeking its own proposed schedule. Under Par's proposed schedule, the District Court would hold a Markman hearing in the Par case no earlier than September 2015. We cannot predict the timing or outcome of events in these proceedings, including what cases, if any, the District Court will consolidate and what cases, if any, the District Court will permit to go forward separately.

Between June and August 2014, petitions seeking covered business method, or CBM, post-grant patent review by the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, or USPTO, were filed by certain of the ANDA filers with respect to the validity of six of our patents related to the distribution system for Xyrem. In the fall of 2014, we filed preliminary responses to the petitions in which, among other things, we asserted that the challenged patents should not be subject to CBM review. In early 2015, the PTAB issued decisions denying institution of CBM review for all of these petitions.

In January 2015, petitions for IPR were filed by certain of the ANDA filers with respect to the validity of six of our patents related to the distribution system for Xyrem. The PTAB has not yet determined whether to institute proceedings with respect to these petitions for IPR. We cannot predict whether PTAB will institute any of the petitioned IPR proceedings, whether additional post-grant patent review challenges will be filed, the outcome of any IPR or other proceeding if instituted, or the impact any IPR or other proceeding might have on ongoing ANDA litigation proceedings.

FazaClo ANDA Matters: Azur Pharma received notices of 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

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Limited, or Teva, our licensor and the entity whose drug-delivery technology is incorporated into FazaClo LD, filed a lawsuit in response to each certification claiming infringement based on such certification against Barr on August 21, 2008, against Novel on November 25, 2008 and against Mylan on July 23, 2010. Each case was filed in the U.S. District Court for the District of Delaware, or the Delaware Court. On July 6, 2011, CIMA, Azur Pharma and Teva, which had acquired Barr, entered into an agreement settling the patent litigation and Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicense for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015. 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. Teva has also exercised its option for supply of an authorized generic product for FazaClo HD. The Novel and Mylan matters had been stayed pending reexamination of the patents in the lawsuits. In September 2013 and January 2014, reexamination certificates were issued for the two patents-in-suit, and the patentability of the claims of the patents confirmed. The Delaware Court lifted the stay of litigation in the two cases in March 2014. On December 19, 2014, we and CIMA entered into an agreement with Novel settling the patent litigation against Novel and we granted Novel a sublicense to manufacture, market and sell a generic version of FazaClo LD and, if applicable, FazaClo HD. The sublicense will commence on May 1, 2017, or earlier upon the occurrence of certain events. Trial in the Mylan case is currently set for the third quarter of 2015, but we cannot predict the specific timing or outcome of this litigation.

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in the California Superior Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to a $10.5 million and an additional $25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. In March 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. In July 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. That ruling was affirmed by the California Court of Appeal in January 2014, and the case was remanded to Superior Court for discovery and trial. Trial has been scheduled for October 2015. We cannot predict the specific timing or outcome of this litigation.

Shareholder Litigation Matter: In January 2014, we became aware of a purported class action lawsuit filed in the U.S. District Court for the Southern District of New York in connection with the Gentium Acquisition. The lawsuit named Gentium, each of the Gentium's directors, us and our Italian subsidiary as defendants. The lawsuit alleged, among other things, that Gentium's directors breached their fiduciary duties to Gentium's shareholders in connection with the Gentium tender offer agreement that Gentium entered into with us and our Italian subsidiary valuing Gentium ordinary shares and ADSs at $57.00 per share, and that we and our Italian subsidiary violated Sections 14(e) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, by allegedly overseeing Gentium's preparation of an allegedly false and misleading Section 14D-9 Solicitation/Recommendation Statement. On November 19, 2014, the plaintiff dismissed us and our Italian subsidiary from the lawsuit. On January 22, 2015, the entire lawsuit was dismissed with prejudice by the court.

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 two radiopharmaceutical products, ProstaScint® (capromab pendetide) and Quadramet® (samarium sm 153 lexidronam injection), for Medicaid and the Public Health Service's

340B drug pricing discount program. We 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 issues guidance on any requirements and reporting methodologies. 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 potential contingent loss. Any material liability resulting from radiopharmaceutical price reporting would negatively impact our financial results.

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12. 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 our 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 2014, we spent a total of $42.2 million to repurchase 0.3 million of our ordinary shares under the share repurchase program at an average total purchase price, including brokerage commissions, of $138.64 per share. All ordinary shares repurchased were canceled. As of December 31, 2014, the remaining amount authorized under the share repurchase program was $21.3 million.

Authorized But Unissued Ordinary Shares

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

	December 31, 2014
2011 Equity Incentive Plan	10,143
2007 Equity Incentive Plan	962
2007 Employee Stock Purchase Plan	587
Amended and Restated 2007 Non-Employee Directors Stock Option Plan	419
Amended and Restated Directors Deferred Compensation Plan	178
Total	12,289

13. Comprehensive Income (Loss)

Comprehensive income (loss) 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 (Loss)

The components of accumulated other comprehensive income (loss) attributable to Jazz Pharmaceuticals plc at December 31, 2014 and December 31, 2013 were as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2013	$56,153	$56,153
Other comprehensive loss	(178,250)	(178,250)
Balance at December 31, 2014	$(122,097)	$(122,097)

In 2014, other comprehensive loss included foreign currency translation adjustments which were primarily due to the strengthening of the U.S. dollar against the Euro.

14. 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 four years and expire no more than 10 years after the date of grant. As of December 31, 2014, a total of 13,549,336 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, 2015, the share reserve under the 2011 Plan automatically increased by 2,728,927 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, 2014, 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, 2015.

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, or the Internal Revenue Code, in connection with the Azur Merger. Accordingly, all future stock option grants under the 2007 Directors Option Plan will be at the discretion of our board of directors. Since the Azur Merger, all of the new grants under the 2007 Directors Option 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. 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, 2014, a total of 837,713 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, 2015, the share reserve under the 2007 Directors Option Plan automatically increased by 32,075 ordinary shares pursuant to this provision.

Amended and Restated Directors Deferred Compensation Plan

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

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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 2014, 2013 and 2012 related to retainer fees earned and deferred. As of December 31, 2014, 14,499 of our ordinary shares that 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,		
	2014	2013	2012
Grant date fair value	$60.29	$29.09	$25.28
Volatility	45%	58%	64%
Expected term (years)	4.3	4.4	4.6
Range of risk-free rates	1.1-1.4%	0.5-1.4%	0.5-1.1%
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. 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.

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

	Year Ended December 31,		
	2014	2013	2012
Selling, general and administrative	$55,083	$35,674	$18,950
Research and development	12,179	6,673	2,640
Cost of product sales	2,376	2,204	1,416
Total share-based compensation expense, pre-tax	69,638	44,551	23,006
Tax benefit from share-based compensation expense	(20,795)	(13,822)	(7,499)
Total share-based compensation expense, net of tax	$48,843	$30,729	$15,507

We realized tax benefits related to share option exercises of $11.8 million, $6.7 million and $18.3 million in 2014, 2013 and 2012, respectively.

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Share Options

The following table summarizes information as of December 31, 2014 and activity during 2014 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, 2014	4,306	$42.54		
Options granted	1,000	160.40		
Options exercised	(1,185)	36.33		
Options forfeited	(251)	75.08		
Options expired	—	—		
Outstanding at December 31, 2014	3,870	72.77	7.6	$354,050
Vested and expected to vest at December 31, 2014	3,632	70.29	7.5	341,118
Exercisable at December 31, 2014	1,639	36.61	6.5	208,339

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 $138.2 million, $46.0 million and $106.5 million, during 2014, 2013 and 2012, respectively. We issued new ordinary shares upon exercise of share options.

As of December 31, 2014, total compensation cost not yet recognized related to unvested share options was $68.8 million, which is expected to be recognized over a weighted-average period of 2.3 years.

As of December 31, 2014, total compensation cost not yet recognized related to grants under the ESPP was $2.3 million, which is expected to be recognized over a weighted-average period of less than one year.

Restricted Stock Units

In 2014, we granted RSUs covering an equal number of our ordinary shares to employees with a weighted-average grant date fair value of $160.45. 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 2014, 344,000 RSUs were released with 222,000 ordinary shares issued and 122,000 ordinary shares withheld for tax purposes. The total fair value of shares vested was $50.9 million, $16.1 million and none during 2014, 2013 and 2012, respectively.

As of December 31, 2014, total compensation cost not yet recognized related to unvested RSUs was $74.1 million, which is expected to be recognized over a weighted-average period of 2.4 years.

The following table summarizes information as of December 31, 2014 and activity during 2014 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, 2014	1,164	$55.28		
RSUs granted	488	160.45		
RSUs released	(344)	55.30		
RSUs forfeited	(120)	75.43		
RSUs expired	—	—		

Outstanding at December 31, 2014	1,188	96.41	1.3	$194,546

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15. 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 meaningful products that address unmet medical needs. The following table presents a summary of total revenues (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Xyrem	$778,584	$569,113	$378,663
Erwinaze/Erwinase	199,665	174,251	72,083
Defitelio/defibrotide	70,537	—	—
Prialt® (ziconotide) intrathecal infusion	26,421	27,103	26,360
Psychiatry	40,879	49,226	76,489
Other	46,630	45,705	26,932
Product sales, net	1,162,716	865,398	580,527
Royalties and contract revenues	10,159	7,025	5,452
Total revenues	$1,172,875	$872,423	$585,979

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

	Year Ended December 31,		
	2014	2013	2012
United States	$1,007,396	$792,518	$538,219
Europe	126,715	61,843	38,590
All other	38,764	18,062	9,170
Total revenues	$1,172,875	$872,423	$585,979

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,		
	2014	2013	2012
Express Scripts	66 %	65 %	64 %
Accredo	14 %	16 %	N/A

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

	December 31,	
	2014	2013
Ireland	$37,775	$5,799
United States	9,795	7,734
Italy	8,462	—
Other	2,331	713
Total long-lived assets	$58,363	$14,246

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

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16. Income Taxes

The components of income from continuing operations before the income tax provision (benefit) were as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Republic of Ireland	$238,351	$186,903	$(73,949)
United States	222,328	132,855	250,348
Other	(309,122)	(11,808)	956
Total	$151,557	$307,950	$177,355

The following table sets forth the details of the income tax provision (benefit) (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Current			
Republic of Ireland	$23,506	$17,089	$(10,733)
United States	97,679	71,964	33,387
Other	16,469	12,682	7,414
Total current income tax	137,654	101,735	30,068
Deferred			
Republic of Ireland	2,323	8,353	(315)
United States	(15,003)	(3,513)	(103,932)
Other	(30,743)	(14,937)	(9,615)
Total deferred income tax benefit	(43,423)	(10,097)	(113,862)
Total income tax provision (benefit)	$94,231	$91,638	$(83,794)

During 2014, we recognized an income tax provision of $94.2 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 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.

The effective tax rate for 2014 was 62.2%. After adjusting the income before income tax provision for the year ended December 31, 2014 by excluding a total of $202.0 million in upfront and milestone payments for rights to JZP-110 and to defibrotide in the Americas, which were acquired by our subsidiaries in a non-taxable jurisdiction, the effective tax rate on the resulting income before income tax provision for 2014 was 26.7%. The effective tax rate for 2014 was higher than the Irish statutory rate of 12.5%, primarily due to income taxable at a rate higher than the Irish statutory rate, uncertain tax positions, current year losses in some jurisdictions for which no tax benefit is available and various expenses not deductible for tax purposes, partially offset by changes in U.S. state valuation allowances and benefits from certain originating income tax credits. 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 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 net operating losses, 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

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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, after excluding the upfront and milestone payments, for 2014 compared to 2013 was primarily due to changes in income mix among the various jurisdictions in which we operate, changes in U.S. state valuation allowances and benefits from certain originating income tax credits. 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,		
	2014	2013	2012
Statutory income tax rate	12.5 %	12.5 %	12.5 %
Income tax provision at statutory rate	$18,945	$38,494	$22,169
Acquisition-related costs	4,703	—	763
Research and other tax credits	(14,234)	(5,957)	(100)
Non-deductible share-based compensation	4,203	2,497	873
Foreign income tax rate differential	75,780	31,651	52,066
Change in unrecognized tax benefits	9,447	8,685	2,249
Prior period adjustments	(5,522)	3,375	(2,524)
Change in valuation allowance	9,006	3,220	(159,158)
Non-deductible contingent consideration	—	5,320	—
Non-deductible financing costs	1,088	—	—
Deduction on subsidiary equity	(11,403)	—	—
Non-deductible officers' compensation	2,715	1,528	—
Other	(497)	2,825	(132)
Income tax provision (benefit)	$94,231	$91,638	$(83,794)
Effective income tax rate	62.2 %	29.8 %	(47.2)%

In 2014, the change in valuation allowance was $9.0 million. 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.

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.

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Significant components of our net deferred tax assets/(liabilities) were as follows (in thousands):

	December 31, 2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$74,057	$71,364
Tax credit carryforwards	23,946	11,374
Intangible assets	19,507	10,733
Share-based compensation	14,033	8,116
Accruals	36,157	30,730
Deferred revenue and other	5,038	9,252
Total deferred tax assets	172,738	141,569
Valuation allowance	(29,697)	(20,691)
Net deferred tax assets	143,041	120,878
Deferred tax liabilities:		
Acquired intangible assets	(395,651)	(176,576)
Other	(7,940)	(10,848)
Total deferred tax liabilities	(403,591)	(187,424)
Net deferred tax liabilities	$(260,550)	$(66,546)

The following table presents the breakdown between current and non-current deferred tax assets/(liabilities) (in thousands):

	Year Ended December 31, 2014	2013
Current deferred tax assets	$48,440	$33,613
Current deferred tax liabilities	(9,430)	(6,259)
Non-current deferred tax assets	75,494	74,597
Non-current deferred tax liabilities	(375,054)	(168,497)
Net deferred tax liabilities	$(260,550)	$(66,546)

As of December 31, 2014, we had NOL carryforwards and tax credit carryforwards for U.S. federal income tax purposes of approximately $264.9 million and $29.2 million, respectively, available to reduce future income subject to income taxes. The NOL carryforwards are inclusive of $117.2 million from the EUSA Acquisition in 2012. The federal NOL carryforwards will expire, if not utilized, in the tax years 2016 to 2034, and the federal tax credits will expire, if not utilized, in the tax years 2016 to 2034. In addition, we had approximately $267.4 million of NOL carryforwards and $4.2 million of tax credit carryforwards as of December 31, 2014 available to reduce future taxable income for state income tax purposes. The state NOL carryforwards will expire, if not utilized, in the tax years 2015 to 2033. The state tax credits have no expiration date. In addition, as of December 31, 2014, there were NOL carryforwards for income tax purposes of approximately $56.1 million and $74.2 million available to reduce future income subject to income taxes in the United Kingdom and Italy, respectively. The NOLs generated in the United Kingdom and Italy have no expiration period. We also had excess foreign tax credits, as of December 31, 2014, of $4.7 million, which may only be utilized against certain sources of income. The excess foreign tax credits have no expiration period.

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 $28.8 million for 2015, $28.9 million for 2016, $15.0 million for 2017, $1.4 million for 2018 and a combined total of $4.9 million for 2019 to 2026. In addition, as a result of the Azur Merger, until 2022 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.

Approximately $191.7 million of both the U.S. federal and state NOL carryforwards as of December 31, 2014 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 $29.7 million and $20.7 million as of December 31, 2014 and 2013, respectively, for certain U.S. state and foreign deferred tax assets which we maintain until sufficient positive evidence exists to support reversal. During 2014, as part of the overall change in valuation allowance, we recognized an income tax benefit of $7.7 million relating to the net reversal of a valuation allowance against certain deferred tax assets associated with NOLs and tax credit carryforwards. During 2013, as part of the overall change in valuation allowance, we recognized an income tax expense of $2.3 million relating to the creation of a valuation allowance against certain U.S. state deferred tax assets associated with tax credit carryforwards. 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. Realization of substantially all the deferred tax assets are dependent on future book income.

Temporary differences related to investments in foreign subsidiaries totaled approximately $736.9 million and $664.3 million as of December 31, 2014 and 2013, 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, 2014, 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,		
	2014	2013	2012
Balance at the beginning of the year	$21,637	$7,288	$3,764
Increases related to current year tax positions	19,837	14,308	3,492
Increases related to prior year tax positions	—	183	40
Decreases related to prior year tax positions	(672)	(142)	(8)
Balance at the end of the year	$40,802	$21,637	$7,288

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, 2014 and 2013, 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 $29.7 million and $16.3 million at December 31, 2014 and 2013, 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 most significant tax jurisdictions are Ireland, the United States, Italy and France. Because of our NOL and tax credit carryforwards, substantially all of our tax positions remain open to federal and state examination in the United States. In France, tax periods open to examination include all periods from 2012. In Ireland, tax periods open to examination include all periods from 2010. As of December 31, 2014, certain of our subsidiaries were under examination by the U.S. Internal Revenue Service, or IRS, for 2010. However, we subsequently received written confirmation from the IRS that no adjustment would be made for that year and the audit is now closed. As of December 31, 2014, certain of our subsidiaries were under examination by the French tax authorities for 2012 and 2013. Subsequent to December 31, 2014, certain of our Italian subsidiaries were notified of the commencement of an examination by the Italian tax authorities for 2012.

17. Related Party Transactions

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

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. 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.

18. Assets Held for Sale

In 2014, we reorganized our operations in Europe to focus our commercial efforts on our hematology/oncology therapeutic area following the Gentium Acquisition. As a result, we are selling certain products acquired as part of the EUSA Acquisition. In the fourth quarter of 2014, we entered into a definitive agreement to sell these products and the related business for approximately $34 million in cash, subject to certain working capital adjustments. The sale, subject to certain closing conditions, is expected to close in the first half of 2015. The related assets met the assets held for sale criteria and were reclassified to assets held for sale as of December 31, 2014. Goodwill was allocated to these assets using the relative fair value method.

In the fourth quarter of 2014, we adjusted the carrying value of the held for sale assets to fair value less costs to sell which resulted in a $6.6 million impairment charge. The impairment charge was recorded in impairment charges on the consolidated statements of income. This charge was in addition to the $32.8 million intangible asset impairment charge recorded during the second quarter of 2014 related to the assets now classified as held for sale.

We have determined that the expected disposition of these assets does not qualify for reporting as a discontinued operation since the expected sale does not represent a strategic shift that has or will have a major effect on our operations and financial results.

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The following assets were segregated and classified as assets held for sale in the consolidated balance sheet as of December 31, 2014 (in thousands):

	December 31, 2014
Inventories	$4,693
Accounts receivable	4,880
Intangible assets, net	27,479
Goodwill	1,686
Other	654
Valuation allowance	(6,559)
Assets held for sale	$32,833

19. Restructuring

In the fourth quarter of 2014, we incurred severance costs for terminated employees in connection with our decision to discontinue sales representative-led promotion of our psychiatry products starting in 2015. In addition, we initiated a restructuring plan related to the consolidation of our UK office locations and incurred costs of severance for terminated employees and facility closure costs in connection with this plan. 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 $1.8 million in the year ended December 31, 2014 within selling, general and administrative expenses in our consolidated statements of income. We expect to incur additional one-time termination benefit costs of $0.3 million in 2015. Facility closure costs of $0.1 million incurred in the year ended December 31, 2014 were recorded within selling, general and administrative expenses in our consolidated statements of income. We expect to incur additional facility closure costs of $0.1 million in 2015.

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 plan, we incurred restructuring costs of $1.5 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. We do not expect to incur any additional restructuring costs in connection with this plan.

The following table summarizes the amounts related to restructuring through December 31, 2014 (in thousands):

	Termination Benefits	Facility Closure Costs	Total
Balance at December 31, 2011	$—	$—	$—
Costs incurred during the period	2,789	—	2,789
Cash payments	(1,562)	—	(1,562)
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
Costs incurred during the period	1,823	118	1,941
Cash payments	—	(252)	(252)
Balance at December 31, 2014	$1,823	$118	$1,941

The balances as of December 31, 2014, 2013 and 2012 were included within accrued liabilities in our consolidated balance sheets.

20. 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. In 2012, we recorded a non-recurring gain on the sale of $35.2 million.

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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. 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 related to profits generated by the women's health business in 2012 which were 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.

21. 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 $2.0 million, $1.1 million and $0.3 million in the years ended December 31, 2014, 2013 and 2012, respectively. 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 $0.5 million and $0.3 million in the years ended December 31, 2014 and 2013, respectively, and none in 2012 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 $1.0 million and $0.4 million in the years ended December 31, 2014 and 2013, respectively. 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 $0.5 million, $0.4 million and $0.2 million in the years ended December 31, 2014, 2013 and 2012, respectively, 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 for France was $0.4 million, $0.3 million and $0.3 million as of December 31, 2014, 2013 and 2012, respectively. In Italy, we accrue for a potential liability which is payable if an employee leaves employment. The accrued liability for Italy was $0.4 million as of December 31, 2014.

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22. Quarterly Financial Data (Unaudited)

The following interim financial information presents our 2014 and 2013 results of operations on a quarterly basis (in thousands, except per share amounts):

	2014			
	March 31	June 30	September 30	December 31
Revenues	$246,919	$291,230	$306,584	$328,142
Gross margin (1)	214,062	258,408	277,413	295,415
Net income (loss) attributable to Jazz Pharmaceuticals plc	(92,650)	43,659	25,766	81,612
Net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc, basic	(1.58)	0.73	0.43	1.35
Net income (loss) per ordinary share attributable to Jazz Pharmaceuticals plc, diluted	(1.58)	0.70	0.41	1.30

	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

(1) Gross margin excludes amortization of acquired developed technology of $30.3 million, $31.7 million, $29.6 million and $31.0 million in the first, second, third and fourth quarters of 2014, respectively, and $19.5 million, $19.3 million, $19.5 million and $20.5 million in the first, second, third and fourth quarters of 2013, respectively.

The tables above include the following unusual or infrequently occurring items:

- Upfront and milestone payments of $127.0 million, $75.0 million and $0.6 million in the first, third and fourth quarters of 2014, respectively, and $4.0 million and $1.0 million in the first and third quarters of 2013, respectively.
- Impairment charges of $32.8 million and $6.6 million in the second and fourth quarters of 2014, respectively, associated with certain products and related assets acquired as part of the EUSA Acquisition. We report sales of these products under “Other” products. The second quarter impairment charge resulted from the reorganization of our operations in Europe to focus on our hematology/oncology therapeutic area following the Gentium Acquisition. The fourth quarter impairment charge represented the adjustment made to reduce the carrying value of the assets held for sale to fair value less cost to sell;
- Revenues of $13.5 million, $22.4 million, $21.1 million and $21.2 million in the first, second, third and fourth quarters of 2014, respectively, resulting from the Gentium Acquisition as measured from the date of acquisition of January 24, 2014. The portion of gross margin and net income associated with the acquired Gentium business was not separately identifiable due to the integration with our operations.
- Acquisition accounting inventory value step-up adjustments of $8.0 million and $2.5 million in the first and second quarters of 2014, respectively, and $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 $17.1 million, $4.4 million, $0.7 million and $5.2 million in the first, second, third and fourth quarters of 2014, respectively, and $0.4 million and $4.4 million in the second and fourth quarters of 2013, respectively;
- The change in fair value of the contingent consideration payable of $4.5 million, $3.4 million, $5.0 million and $2.3 million in the first, second, third and fourth quarters of 2013, respectively, for an additional contingent payment of $50.0 million in cash that we agreed to make as part of the EUSA Acquisition 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 made the payment of $50.0 million in the first quarter of 2014; and

- A loss on extinguishment and modification of debt of $3.7 million in the second quarter of 2013.

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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, 2014						
Allowance for doubtful accounts	(1)	$594	$—	$—	$(64)	$530
Allowance for sales discounts	(1)	378	3,794	—	(3,934)	238
Allowance for chargebacks	(1)	2,708	28,614	—	(28,607)	2,715
Deferred tax asset valuation allowance	(2)(4)	20,691	18,971	—	(9,965)	29,697
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

(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.

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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).
2.8†	Assignment Agreement, dated July 1, 2014, by and among Jazz Pharmaceuticals International II Limited, Sigma-Tau Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Gentium S.p.A. (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 August 5, 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	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).
4.2B	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).
4.3A	Indenture, dated as of August 13, 2014, by and among Jazz Pharmaceuticals plc, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.3B	Form of 1.875% Exchangeable Senior Note due 2021 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
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).

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Exhibit Number	Description of Document
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 Public Health England (formerly 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) for the period ended June 30, 2012, as filed with the SEC on August 9, 2012).
10.6A	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).
10.6B	Amendment No. 1, dated as of June 13, 2013, to the 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).
10.6C	Amendment No. 2, dated as of January 23, 2014, to the Credit Agreement, dated as of June 12, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Financing I Limited and Jazz Pharmaceuticals Ireland Limited, as borrowers, Jazz Pharmaceuticals Public Limited Company, as guarantor, the Lenders thereto and Barclays Bank PLC, as Administrative Agent, Collateral Agent, L/C Issuer and Swing Line Lender (incorporated herein by reference to Exhibit 10.32 in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).
10.7	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).
10.8A	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).

10.8B	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).
10.8C	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).
10.9	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.10	Commercial Lease, dated as of January 7, 2015, by and between The Board of Trustees of the Leland Stanford Junior University and Jazz Pharmaceuticals, Inc.
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).

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Exhibit Number	Description of Document
10.12+	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) for the period ended September 30, 2011, as filed with the SEC on November 8, 2011).
10.13+	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) for the period ended March 31, 2012, as filed with the SEC on May 8, 2012).
10.14+	Offer Letter from Jazz Pharmaceuticals, Inc. to Matthew Young (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 March 31, 2014, as filed with the SEC on May 8, 2014).
10.15A+	Employment Agreement by and between EUSA Pharma Inc. and Iain McGill (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2014, as filed with the SEC on November 4, 2014).
10.15B+	Amendment to Employment Agreement by and between Iain McGill and EUSA Pharma (Europe) Limited.
10.16+	Offer Letter from Jazz Pharmaceuticals, Inc. to Michael Miller (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2014, as filed with the SEC on November 4, 2014).
10.17A+	Employment Agreement by and between Jazz Pharmaceuticals Ireland Limited and Paul Treacy (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 September 30, 2014, as filed with the SEC on November 4, 2014).
10.17B+	Amendment to Employment Agreement by and between Jazz Pharmaceuticals Ireland Limited and Paul Treacy.
10.18A+	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).
10.18B+	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).
10.18C+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.18D+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.18E+	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).
10.18F+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.18G+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.18H+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.19A+	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).

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Exhibit Number	Description of Document
10.19B+	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).
10.19C+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19D+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19E+	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) for the period ended December 31, 2012, 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 (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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19G+	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) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).
10.19H+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.19I+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.19J+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.19K+	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 10.5 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.19L+	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) for the period ended September 30, 2013, as filed with the SEC on

	November 5, 2013).
10.20+	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).
10.21A+	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).
10.21B+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.21C+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).

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Exhibit Number	Description of Document
10.22A+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.22B+	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 10.14C 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 May 8, 2012).
10.23A+	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) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).
10.23B+	Jazz Pharmaceuticals Cash Bonus Plan for International Affiliates (2014) (incorporated herein by reference to Exhibit 10.24D in Jazz Pharmaceuticals plc's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2013, as filed with the SEC on February 25, 2014).
10.24+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.25A+	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).
10.25B+	Jazz Pharmaceuticals plc 2014 Executive Officer Compensation Arrangements (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2014, as filed with the SEC on May 8, 2014).
10.26A+	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) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).
10.26B+	Jazz Pharmaceuticals plc Non-Employee Director Compensation Policy (approved May 1, 2014) (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, 2014, as filed with the SEC on May 8, 2014).
10.27+	Named Officer 2015 Target Bonus Opportunity (incorporated herein by reference to Exhibit 10.1 in JazzPharmaceuticals plc's current report on Form 8-K (File No. 001-33500), as filed with the SEC on February 18, 2015).
21.1	Subsidiaries of Jazz Pharmaceuticals plc.
23.1	Consent of KPMG, 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

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+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.

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* 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.