Jazz Pharmaceuticals plc
Form 10-K
February 26, 2013
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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, 2012

or

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

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

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

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

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No ý
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of June 29, 2012, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $1,948,413,000 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 14,246,377 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 20, 2013, a total of 58,037,532 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 2013 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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JAZZ PHARMACEUTICALS PLC
2012 ANNUAL REPORT ON 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 non-U.S. countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Xyrem Success Program®, FazaClo® (clozapine, USP), Luvox CR® (fluvoxamine maleate) Extended-Release Capsules, Luvox® (fluvoxamine maleate), Versacloz™ (clozapine, USP) oral suspension, Prialt® (ziconotide) intrathecal infusion, Niravam® (orally disintegrating tablet presentation of alprazolam), Parcopa® (orally disintegrating tablet presentation of carbidopa/levodopa), Erwinaze® (asparaginase Erwinia chrysanthemi), Erwinase®, Asparec® (mPEG-r-crisantaspase), Leukotac® (inolimomab), ProstaScint® (capromab pendetide),

Quadramet® (samarium sm 153 lexidronam injection), Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (Escherichia coli L-asparaginase), Xenazine® (tetrabenazine), Custodiol® (solution HTK) and NAVIGATOR Reimbursement and Access Program™. This report also includes trademarks, service marks, and trade names of other companies.

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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," "intend," "potential" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, or the Azur Merger, in connection with which Azur Pharma was re-named Jazz Pharmaceuticals plc and we became the parent company of and successor to Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. becoming our wholly-owned subsidiary. Jazz Pharmaceuticals, Inc. was treated as the acquiring company in the Azur Merger for accounting purposes, and as a result, the historical consolidated financial statements of Jazz Pharmaceuticals, Inc. became our consolidated financial statements. Accordingly, the operating results of Jazz Pharmaceuticals, Inc. are included in our consolidated financial statements for all periods being presented, whereas the operating results of Azur Pharma are included only since January 18, 2012. In addition, on June 12, 2012, Jazz Pharmaceuticals plc completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, referred to as the EUSA Acquisition.

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

PART I

Item 1. Business

Overview

We are a specialty biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing products that address unmet medical needs. Our marketed products address medical needs in the following therapeutic areas and include the following products:

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

narcolepsy;
Oncology: Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in markets outside of the United States, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed sensitivity to E. coli-derived asparaginase, and other products, including products for oncology supportive care;
Pain: Prialt® (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for the management of severe chronic pain for patients who are intolerant of or refractory to other treatments; and
Psychiatry & Other: A portfolio of products, including FazaClo® (clozapine, USP) LD and FazaClo HD, orally disintegrating clozapine tablets indicated for treatment-resistant schizophrenia, and Luvox CR® (fluvoxamine maleate)

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Extended-Release Capsules marketed for the treatment of obsessive compulsive disorder. In addition, in February 2013 the FDA approved a new drug application for Versacloz™ (clozapine, USP) oral suspension for treatment-resistant schizophrenia, which we have exclusive rights to market in the United States.

Our international division, based in Europe, commercializes Erwinase as well as a portfolio of other products outside of the United States. These products are primarily in the oncology, critical care and oncology supportive care therapeutic areas and include Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (Escherichia coli L-asparaginase) and Xenazine® (tetrabenazine).

Our development pipeline projects currently include line extensions for existing products, the generation of additional clinical data for existing products and clinical development of new product candidates. These projects include two clinical trials involving Erwinaze, as well as the development of two product candidates: Asparec® (mPEG-r-crisantaspase), a pegylated recombinant Erwinia asparaginase for the treatment of patients with ALL with E. coli asparaginase hypersensitivity, and Leukotac® (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease.

Our strategy is to continue to create shareholder value by:

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

Significant Business Transactions in 2012

On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc., our predecessor company, and Azur Pharma Public Limited Company, or Azur Pharma, were combined in a merger transaction, the Azur Merger, which was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company for accounting purposes. As part of the Azur Merger, Azur Pharma changed its name to Jazz Pharmaceuticals plc, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as our wholly-owned subsidiary, and 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. The total acquisition consideration of $576.5 million was determined based on the market value of our ordinary shares that were held by the historic Azur Pharma shareholders immediately following the closing of the Azur Merger. Immediately after giving effect to the issuance of our ordinary shares in the Azur Merger, approximately 78% of our ordinary shares were held by the former Jazz Pharmaceuticals, Inc. stockholders and approximately 22% were held by the persons who acquired Azur Pharma ordinary shares prior to the Azur Merger. Prior to the Azur Merger, Jazz Pharmaceuticals, Inc. marketed its two products, Xyrem and Luvox CR, through its experienced specialty sales force. Prior to the Azur Merger, Azur Pharma was a specialty pharmaceutical company engaged in the acquisition, development and commercialization of therapeutic products for the central nervous system and women's health areas. Azur Pharma's lead marketed products were FazaClo LD, FazaClo HD and Prialt. Azur Pharma also marketed a portfolio of women's health and other products. As a result of the Azur Merger, we transitioned from being a standalone public Delaware corporation to being a public limited company organized in, and a tax resident of, Ireland, and the ultimate parent company of the Jazz Pharmaceuticals group of companies.

On June 12, 2012, we completed the acquisition of EUSA Pharma Inc., or EUSA Pharma, referred 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, which we acquired in the EUSA Acquisition, achieves U.S. net sales of $124.5 million or more in 2013. As part of the EUSA Acquisition, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as our indirect wholly-owned subsidiary. In connection with the EUSA Acquisition, we entered into a $575.0 million credit agreement consisting of a $475.0 million term loan and a $100.0 million revolving credit facility. We used all of the proceeds of the term loan, together with cash on hand, to finance the EUSA Acquisition.

Prior to the EUSA Acquisition, EUSA Pharma was a specialty pharmaceutical company with a portfolio of marketed products in therapeutic areas that included oncology, critical care and oncology supportive care products. EUSA Pharma's lead marketed product was Erwinaze, marketed directly in the United States and Europe and via distributors in other countries.

On October 15, 2012, we completed the sale of our women's health business, including six products, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl for $95.0 million, plus $2.6 million for certain inventory transferred upon the closing of the sale.

With the completion of the EUSA Acquisition and the Azur Merger in 2012, we gained not only an expanded portfolio of specialty pharmaceutical products and product candidates, but also an enhanced commercial platform and a strengthened management team, adding EUSA Pharma's specialty commercial infrastructure in the United States and Europe and its

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international distribution network to our existing U.S. specialty product platform. Our international footprint now includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 610 employees in 11 countries. We intend that our operations will function as an efficient platform for further growth, leveraging our commercial, medical and scientific experience to seek to maximize the potential of our existing products and expand our product portfolio through a combination of internal development, acquisition and in-licensing.

Marketed Products

Xyrem® (sodium oxybate) oral solution

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

Narcolepsy is a chronic neurologic disorder caused by targeted loss of neurons that produce the neurotransmitter hypocretin (also known as orexin), which is hypothesized to stabilize sleep-wake states. The primary symptoms of narcolepsy include excessive daytime sleepiness, cataplexy, sleep paralysis, hypnogogic hallucinations and disrupted nighttime sleep. Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. Excessive daytime sleepiness is characterized by chronic, pervasive sleepiness as well as sudden irresistible and overwhelming urges to sleep (inadvertent naps and sleep attacks). Cataplexy, the sudden loss of muscle tone, can be one of the most debilitating symptoms of narcolepsy. Cataplexy is present in approximately 70% of patients with narcolepsy. Cataplexy can range from slight weakness or a drooping of the face to the complete loss of muscle tone resulting in 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, with patients experiencing marked impairment of activities, such as limitations on education and employment opportunities, 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, obstructive sleep apnea, obesity, bipolar disorder, depression, hypercholesterolaemia, diseases of the digestive system, cardiovascular diseases, upper respiratory tract diseases and hypertension.

It is estimated that narcolepsy affects approximately 1 in 2,000 people in the United States, or approximately 157,000 people. Less than half of those people have been definitively diagnosed with narcolepsy. Xyrem is currently being used to treat more than 10,000 patients in the United States, and we believe that there are significantly more patients with narcolepsy and cataplexy and/or excessive daytime sleepiness who might benefit from treatment with Xyrem. In an effort to reach more patients, we are seeking to expand the base of physicians who prescribe Xyrem through a number of initiatives, including increased outreach to prescribers who treat narcolepsy, enhanced physician education and the launch of web-based pilot programs.

In 2012, net product sales of Xyrem were $378.7 million, which represented 65.2% of total net product sales.

We promote Xyrem in the United States through a specialty sales force of approximately 80 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, that was required in conjunction with Xyrem’s approval by the FDA to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. The Xyrem Risk Management Program is not in the form that is now required for a risk evaluation and mitigation strategy, or REMS. We have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documentation. We have had communications

with the FDA with respect to our submitted REMS documents. These communications are ongoing, and we cannot predict the timing of finalization, or the final terms, of our updated REMS documents.

Under our current Xyrem Risk Management Program, all of the Xyrem sold in the United States must be shipped directly to patients through a single central pharmacy, Express Scripts Specialty Distribution Services and its affiliate CuraScript, Inc., or ESSDS, through which Xyrem is distributed exclusively. Xyrem may not be stocked in retail pharmacies. Physicians and patients must enroll in the Xyrem Success Program®, which is part of our Xyrem Risk Management Program, prior to fulfillment of Xyrem prescriptions. Each physician and patient receives materials concerning the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and must speak with the patient before each shipment of Xyrem is sent to the patient. The central pharmacy ships the product directly to the patient by a courier service, and the patient or his/her designee signs for the package. The initial shipment may only be for up to a one-month supply and up to a three-month supply

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for refills. ESSDS also provides reimbursement support to patients by coordinating insurance coverage for Xyrem, and as applicable, referring qualified patients to various patient savings or assistance programs.

Pursuant to our agreement, ESSDS exclusively distributes Xyrem in the United States and provides customer support services related to the sales and marketing of Xyrem in the United States. Our agreement, which has been in effect since July 2002, expires on June 30, 2015, subject to automatic two-year extensions unless either party provides notice to the other of its intent to terminate the agreement not less than 120 days before the end of the then current term. Under the agreement, we own all of the standard operating procedures, business rules and intellectual property, and the agreement provides for ESSDS to assist in the orderly transfer of the services that ESSDS provides to us and the related intellectual property, including intellectual property related to the patient database, to any new pharmacy that we may we engage.

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

Outside of the United States, we have licensed to UCB Pharma Limited, or UCB, the exclusive right to market Xyrem for the treatment of narcolepsy in 54 countries in exchange for milestone and royalty payments to us. UCB currently markets the product in 18 countries in Europe. We have licensed to Valeant Canada Limited, or Valeant, the Canadian marketing rights to Xyrem for the treatment of narcolepsy. We supply Xyrem to UCB and Valeant.

We have eleven U.S. patents covering Xyrem, which expire at various times from December 2019 to June 2024. Our issued patents relate to Xyrem's stable and microbially resistant formulation, its manufacturing process and its method of use, including its restricted distribution system. Two 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 are currently involved in litigation with both companies. For a description of these matters, please see Item 3. "Legal Proceedings."

Erwinaze® (asparaginase Erwinia chrysanthemi)

Erwinaze, a biologic product, is used in conjunction with chemotherapy to treat patients with ALL who have developed hypersensitivity to E. coli-derived asparaginase. Erwinaze is an asparaginase, a type of enzyme that can deprive leukemic cells of an amino acid essential for their growth. It is derived from a rare bacterium (Erwinia chrysanthemi) and is therefore immunologically distinct from E. coli-derived asparaginase and suitable for patients with hypersensitivity to E. coli-derived treatments. For ALL patients with hypersensitivity to E. coli-derived asparaginase, Erwinaze is a crucial component of their therapeutic regimen. Erwinaze is currently delivered via intramuscular injection in conjunction with chemotherapy. Erwinaze was originally discovered by the U.K. Health Protection Agency, or the HPA, a non-departmental public body. Erwinaze was approved by the FDA under a biological license application, or BLA, in November 2011.

ALL is the most common childhood cancer. According to the U.S. National Cancer Institute, approximately 60% of ALL patients were diagnosed under age 20. The American Cancer Society estimated that approximately 6,000 new cases of ALL were diagnosed in the United States in 2012, of which approximately 3,600 were pediatric. Data reported in two papers published in Pediatric Blood & Cancer and Journal of Clinical Oncology suggest that approximately 20% of ALL patients develop hypersensitivity to E. coli-derived asparaginase. Current treatment guidelines and protocols recommend switching a patient receiving E. coli-derived asparaginase to treatment with Erwinaze if the patient's hypersensitivity reaction to the E. coli-derived asparaginase is Grade 2-4, indicating that the hypersensitivity reaction has resulted in an intervention or interruption in infusion occurring in the patient's treatment regimen. While pediatric treatment protocols commonly include asparaginase, adult protocols do not. A retrospective comparison to determine whether the outcome for adolescent and young adult ALL patients differed depending on their enrollment in pediatric compared with adult cooperative group trials showed that the seven-year overall survival rate among the adolescent and young adult ALL patients treated on pediatric protocols was 67% compared to 46% for those patients treated on adult protocols. As more adolescent and young adult patients are treated with asparaginase-based regimens, we expect to see increased use of Erwinaze in this population. In addition, we believe that Erwinaze could be used in patients with silent hypersensitivity, a situation in which E. coli-derived asparaginase

may induce antibodies that can neutralize the enzyme or increase its clearance, thereby depriving patients of its therapeutic benefits, without manifesting the clinical symptoms of hypersensitivity. In February 2013, a third party introduced an assay to determine the enzyme activity of asparaginase in patients who have been treated with any E. coli-derived asparaginase or Erwinaze. With this new assay, physicians will be able to monitor asparaginase levels to identify patients with silent hypersensitivity and maintain asparaginase activity by switching asparaginase preparations.

Erwinaze was launched in the U.S. market in November 2011. We promote Erwinaze in the United States through a specialty sales force of approximately 20 sales professionals. We provide reimbursement support through our Community Access Patient Program, a dedicated Erwinaze call center. Our field-based and internal reimbursement team provides additional reimbursement support, dealing specifically with the more complex needs of physicians and payors.

Outside of the United States, Erwinaze is sold under the name Erwinase pursuant to marketing authorizations, named

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patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere. Our international division employs approximately 30 sales professionals to promote Erwinase in a number of European countries where Erwinase is fully registered. In addition, our medical science liaison managers provide information consistent with local treatment protocols to healthcare professionals and/or respond to medical information requests.

Erwinaze is exclusively licensed to us for worldwide marketing, sales and distribution, and is manufactured for us, by the HPA. The HPA is our sole supplier for Erwinaze. We are obligated to make tiered royalty payments to the HPA based on worldwide net sales of Erwinaze and Erwinase.

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

Prialt® (ziconotide) intrathecal infusion

Prialt is an intrathecally administered infusion of ziconotide, approved by the FDA in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. Intrathecal therapy is the delivery of the drug into the intrathecal space in the spine through an infusion system comprised of a programmable infusion pump and catheter. Ziconotide is a synthetic neuroactive peptide known as conotoxin and is the synthetic equivalent of a naturally-occurring conopeptide found in the piscivorous marine snail, Conus Magus. Ziconotide is thought to inhibit pain signals transmitted via N-type calcium channels, most densely located in the dorsal horn of the spinal cord, although the precise mechanism of action in humans is unknown. For most patients who achieve good pain relief and tolerability with Prialt, pain relief can be maintained over time without dose increases or cumulative toxicity. Prialt is the only FDA-approved non-opioid intrathecal analgesic. Treatment with Prialt can be interrupted or discontinued without evidence of withdrawal effects. Prialt is approved for use with Medtronic Inc.'s SynchroMed® II programmable implantable pumps.

Azur Pharma acquired the rights to Prialt from Elan Pharmaceuticals, Inc., or Elan, in May 2010. Pursuant to an asset purchase agreement executed between Azur Pharma and Elan in April 2010, Azur Pharma acquired worldwide rights to Prialt excluding those territories licensed by Elan to Eisai Co. Limited, or Eisai, which consist of 34 countries outside of the United States, mainly in Europe. We supply Prialt to Eisai. Azur Pharma paid Elan $5 million on the closing of the transaction, with an additional $12 million in deferred payments, which we paid to Elan in 2012. We are also obligated to pay up to a maximum aggregate amount of $120 million in tiered contingent payments, with the first such payment becoming due if net sales of at least $75 million are achieved in a calendar year, as well as a tiered royalty payment in the teens based on net sales.

We promote Prialt through a specialty sales force of approximately 30 sales professionals. In the fourth quarter of 2012, we began the roll-out of a new centralized distribution system for Prialt, the NAVIGATOR Reimbursement and Access Program™. Through this new distribution system, we provide a simplified single point of access to Prialt, offering reimbursement and insurance support that is intended to reduce the burden on physicians and patients and providing information and support through a dedicated Prialt call center outsourced to a third party vendor. Our field-based reimbursement team provides additional support, dealing specifically with the more complex needs of physicians and payors.

We have four U.S. patents covering Prialt, the last to expire of which expires in December 2016, and six U.S. patents on a formulation containing Prialt and other active ingredients and methods for their use, which will expire in October 2024. The finished product and active pharmaceutical ingredient are each manufactured for us by a single source contract manufacturer.

Psychiatry Products

FazaClo® LD (clozapine, USP) Orally Disintegrating Tablet, FazaClo® HD (clozapine, USP) Orally Disintegrating Tablet and Versacloz™ (clozapine, USP) oral suspension

We market FazaClo LD and FazaClo HD, each of which is an orally disintegrating tablet formulation of clozapine that is indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard drug

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

In February 2013, the FDA approved a new drug application, or NDA, for Versacloz for treatment-resistant schizophrenia. Versacloz is an oral suspension formulation of clozapine currently approved and marketed by other companies in Europe and in other territories outside of the United States. In February 2010, Azur Pharma entered into a license and supply agreement with Douglas Pharmaceuticals America Limited, or Douglas Pharmaceuticals, and obtained an exclusive license to market, distribute and sell Versacloz in the United States and Mexico from Douglas Pharmaceuticals. The initial term of the

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license and supply agreement expires 10 years after the first commercial sale of Versacloz in the United States, subject to automatic extension for additional five-year terms unless terminated by either party subject to certain conditions. We expect to commence marketing Versacloz in 2013.

According to IMS Health Inc., or IMS, the U.S. clozapine market is dominated by generics, which accounted for approximately 92.6% of clozapine prescription volumes in 2012. Our FazaClo LD and FazaClo HD products accounted for approximately 4.9% and 2.6%, respectively, of clozapine prescription volumes in 2012. An authorized generic version of FazaClo LD launched in August 2012. Other generics are referenced to Clozaril, a standard immediate release tablet formulation of clozapine from Novartis. FazaClo LD and FazaClo HD incorporate the DuraSolv® orally disintegrating tablet technology that we license from CIMA Labs Inc., or CIMA, now a subsidiary of Teva Pharmaceutical Industries Limited, or Teva, which enables the products to dissolve without the need to chew or to swallow with water. FazaClo LD (including its authorized generic version) and FazaClo HD are currently the only orally disintegrating tablet formulations of clozapine available in the United States. Versacloz is currently the only oral suspension formulation of clozapine approved by the FDA.

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

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

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

The two formulation patents covering FazaClo LD and FazaClo HD, which we license from CIMA, are under re-examination by the U.S. Patent and Trademark Office, or the USPTO, and both of the re-examination proceedings have proceeded to appeal at the USPTO. It is currently not possible to predict whether these re-examination proceedings will result in one or both of the patents being fully or partly invalidated and, if so, whether any appeal will be successful. Versacloz is covered by a U.S. formulation patent and a pending U.S. patent application that we license from Douglas Pharmaceuticals. The patent expires in May 2028.

Three generic manufacturers have filed ANDAs requesting approval to market generic versions of FazaClo LD, and one of them, Teva, has also submitted an ANDA requesting approval to market a generic version of FazaClo HD. Azur Pharma brought lawsuits against each of them and settled the lawsuit with Teva in 2011. In the settlement agreement, Azur Pharma granted a sublicense to an affiliate of Teva of Azur Pharma's rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD, as well as an option for supply of authorized generic product. The sublicenses for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events. Teva exercised its option for supply of an authorized generic product for FazaClo LD and launched the authorized generic product in August 2012.

Luvox CR® (fluvoxamine maleate) Extended-Release Capsules

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

Obsessive compulsive disorder is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health,

obsessive compulsive disorder affects approximately 2.2 million adults in the United States. According to an article published in the International Journal of Clinical Practice, it is estimated that 60% of patients with obsessive compulsive disorder worldwide receive no treatment for their disorder. Patients with obsessive compulsive disorder often use rituals to help control anxiety related to their obsessive thoughts, and these rituals can become disruptive to their daily lives.

We acquired the rights to market Luvox CR in the United States from Solvay Pharmaceuticals, Inc., or Solvay, which was subsequently acquired by Abbott Laboratories. Solvay assigned to us its rights and obligations under its license and supply agreement with Alkermes, and we sublicensed back to Solvay the rights under that agreement outside of the United States.

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Luvox CR is not currently marketed outside of the United States.

Three companies have filed ANDAs requesting FDA approval to market a generic version of Luvox CR, and we brought lawsuits against each of them. In August 2010, we and Alkermes settled the lawsuit against one of the companies, Anchen Pharmaceuticals, Inc. (now owned by Par Pharmaceutical Companies, Inc.), or Anchen, and granted a sublicense to Anchen of our rights to have manufactured, market and sell a generic version of Luvox CR, which sublicense commenced in February 2013. As of a result of this settlement, a generic version of Luvox CR could be introduced as soon as Anchen obtains FDA approval of its ANDA. In April 2012, we and Alkermes entered into settlement agreements with the other two companies, Actavis Elizabeth, LLC, or Actavis, and Torrent Pharma Limited, or Torrent, respectively, and granted a sublicense to each of Actavis and Torrent of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The sublicenses will commence on April 15, 2014, or earlier if a generic version of Luvox CR receives FDA approval.

Other Products

The other products that we sell in the United States include:

- Caphosol® (supersaturated calcium phosphate rinse), indicated for the treatment of oral mucositis, a common and debilitating side-effect of radiation therapy and high dose chemotherapy;
- Quadramet® (samarium sm 153 lexidronam injection), indicated for the treatment of pain in patients whose cancer has spread to the bones;
- ProstaScint® (capromab pendetide), indicated for imaging the extent and spread of prostate cancer;
- Niravam® (alprazolam orally disintegrating tablets), indicated for the treatment of generalized anxiety disorder and also indicated for the treatment of panic disorder, with or without agoraphobia; and
- Parcopa® (carbidopa and levodopa orally disintegrating tablets), indicated for the treatment of symptoms associated with idiopathic Parkinson's disease.

In addition, our international division commercializes a portfolio of other products in oncology, critical care and oncology supportive care outside of the United States, including:

- Caphosol;
- Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), a surgical implant impregnated with the antibiotic gentamicin;
- Fomepizole® (fomepizole), indicated for the treatment of ethylene glycol poisoning;
- Kidrolase® (Escherichia coli L-asparaginase), indicated in the treatment of ALL, Leukaemic meningitis and Non-Hodgkin's lymphoma;
- Xenazine® (tetrabenazine), indicated for the treatment of movement disorders associated with Huntington's chorea and hemiballismus; and
- Custodiol® (solution HTK), a ready to use solution used in organ transplantation for rinsing and hypothermic storage for preservation of organs (heart, kidney, liver and pancreas) since their removal from the donor to the graft in the recipient.

Research and Development Projects

Our development pipeline projects currently include line extensions for existing products, the generation of additional clinical data for existing products, and clinical development of new product candidates. These projects include two clinical trials involving Erwinaze: an ongoing pharmacokinetic clinical trial of the intravenous administration of Erwinaze in North America; and a planned clinical trial including pharmacokinetic efficacy measures to evaluate Erwinaze in adolescents and young adults with ALL who are hypersensitive to E. coli-derived asparaginase, which is expected to begin in the second half of 2013. In addition, we are developing two product candidates, including a Phase I clinical trial in Europe of Asparec® (mPEG-r-crisantaspase), a pegylated recombinant Erwinia asparaginase for the treatment of patients with ALL with E. coli asparaginase hypersensitivity; and a Phase III clinical trial in Europe of Leukotac® (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease. Worldwide rights to develop and commercialize Asparec were licensed by EUSA Pharma from Alizé Pharma II, or Alizé, in 2009. Under our license agreement with Alizé, we are subject to contractual obligations to meet certain development milestones within certain timeframes. We submitted an investigational new drug

application, or IND, to conduct studies relating to Asparec to the FDA in November 2012, and we received FDA confirmation in December 2012 that we may proceed with the studies. EUSA Pharma acquired the rights for Leukotac from Biotest AG in 2003.

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Sales and Marketing

As of February 20, 2013, our commercial activities in the United States were dedicated to our marketed products Xyrem, Erwinaze, Prialt and our psychiatry products (FazaClo LD, FazaClo HD and Luvox CR), as well as preparing for the launch of Versacloz and providing support for sales of certain of our other products. We have approximately 170 trained, experienced sales professionals who detail our marketed products to physicians in specialties appropriate for each marketed product in the United States. In addition, our international division employs approximately 30 sales professionals to promote Erwinase in a number of European countries where Erwinase is fully registered. Our international division also sells products in oncology, oncology supportive care and critical care outside of the United States through a network of local distributors and wholesalers in more than 80 countries.

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

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

Competition

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

Our ability to continue to grow requires that we compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. Some of these competitors include Valeant, Shire Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., Forest Laboratories, Inc., Sigma-Tau Pharmaceuticals Inc. and Teva. These established companies may have a competitive advantage over us due to their size and financial resources.

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

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

- Xyrem® (sodium oxybate) oral solution. Xyrem is the only product approved for the treatment of both cataplexy and excessive daytime sleepiness 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 excessive daytime sleepiness in patients with narcolepsy are Provigil® (modafinil) and Nuvigil® (armodafinil), which are marketed by Teva, and the generic versions of Provigil. Provigil, its generic equivalents and Nuvigil are also approved for the treatment of

excessive daytime sleepiness in patients with obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder. Xyrem is often used in conjunction with stimulants and wakefulness promoting drugs, which are administered during the day.

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

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used in the 1950s. The use of these drugs can often result in somnolence, which exacerbates the excessive daytime sleepiness already experienced by all patients with narcolepsy. SSRIs and SNRIs are compounds typically used for the treatment of clinical depression. Somnolence and insomnia are commonly reported side effects with SSRIs while loss of sleep is a commonly reported side effect with SNRIs. These side effects may be problematic for patients with narcolepsy.

- Erwinaze® (asparaginase Erwinia chrysanthemi). Erwinaze is a biologic product used in conjunction with chemotherapy and is indicated for patients with ALL who have developed hypersensitivity to E. coli-derived asparaginase. While there is currently no direct competition to Erwinaze to treat ALL patients with hypersensitivity to E. coli-derived asparaginase, other companies are developing new treatments for ALL, including new asparaginase treatments that could reduce the rate of hypersensitivity in patients with ALL and new treatment protocols for ALL that may not include asparaginase-containing regimens. Any of these potential new treatments could compete with, or reduce the market for, Erwinaze. As a biologic product, Erwinaze also faces potential competition from biosimilar products.
- Prialt® (ziconotide) intrathecal infusion. Prialt is the only FDA-approved non-opioid intrathecal analgesic. It competes with intrathecally administered morphine, which is the only other product approved by the FDA for the intrathecal treatment of severe chronic pain. Other drugs are also used intrathecally by physicians, including hydromorphone, clonidine, baclofen and sufentanil.
- FazaClo® LD (clozapine, USP) Orally Disintegrating Tablet, FazaClo® HD (clozapine, USP) Orally Disintegrating Tablet and Versacloz™ (clozapine, USP) oral suspension. FazaClo LD, the authorized generic version of FazaClo LD launched in 2012 and FazaClo HD are the only orally disintegrating tablet formulations of clozapine available. FazaClo LD competes against the authorized generic. The bulk of prescriptions for clozapine are generic tablets, which compete with both FazaClo LD and FazaClo HD. In addition, prior to prescribing clozapine, most physicians choose other branded products as treatment options, including Seroquel®, marketed by AstraZeneca, Risperdal®, marketed by Janssen, and Zyprexa®, marketed by Eli Lilly. Versacloz is currently the only oral suspension formation of clozapine approved by the FDA.
- Luvox CR® (fluvoxamine maleate) Extended-Release Capsules. The market for drugs to treat obsessive compulsive disorder is very fragmented. We believe that, in addition to Luvox CR, a large number of branded and generic drugs are used for the treatment of this disorder. Seven branded products, including Luvox CR, and generic equivalents of many of these, have been approved by the FDA for the treatment of obsessive compulsive disorder, and we believe that other products are regularly used to treat this disorder. A generic version of Luvox CR could be introduced as soon as the FDA approves Anchen's ANDA.

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

- the existence of competing or alternative products in the marketplace, including generic competition, and the relative price of those products;
- the efficacy, safety and reliability of our products and product candidates compared to competing or alternative products;
- product acceptance by physicians, other health care providers and patients;
- protection of our proprietary rights;
- obtaining reimbursement for our products in approved indications;
- our ability to complete clinical development and obtain regulatory approvals for our product candidates, and the timing and scope of regulatory approvals;
- our ability to supply commercial quantities of a product to the market; and
- our ability to recruit and retain skilled employees.

Customers and Information About Geographic Areas

In the United States, Xyrem is sold to one specialty pharmacy, ESSDS, which ships Xyrem directly to patients. Erwinaze is sold through an exclusive wholesaler and distributor, Accredo Health Group, Inc., to hospitals in the United States. The other products that we sell in the United States are sold primarily to distributors who distribute the

product to pharmacies and hospitals. In 2012, the principal distributors for our products in the United States were Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation and its subsidiary, Integrated Commercialization Solutions Inc. We have standard industry agreements made in the ordinary course of business with these distributors, which include prompt payment discounts and various standard fee or rebate arrangements. Purchases are made on a purchase order basis.

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Outside of the United States, UCB has rights to market Xyrem in 54 countries, and Valeant has rights for Canada. Xyrem is currently sold in 18 countries by UCB and in Canada by Valeant. Our international division distributes Erwinase through Durbin PLC, a U.K.-based wholesaler and distributor, to hospitals and local wholesalers in Europe where it markets Erwinase directly and, in markets where it does not market Erwinase directly, to local distributors and wholesalers in Europe and elsewhere in the world. Our international division also sells other products both directly and through local distributors and wholesalers in Europe and elsewhere in the world in accordance with local regulatory approval status. We do not have rights outside of the United States to our psychiatry products. 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 U.S. and non-U.S. sources and customers who represented at least 10% of total revenues in each of 2012, 2011 and 2010, as well as the location of our long-lived assets, is included in Note 15 to our consolidated financial statements.

With the completion of the EUSA Acquisition and the Azur Merger in 2012, our international footprint now includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 610 employees in 11 countries. 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 O Financial Condition” in Item 1A, “Government Regulation—Ex-U.S. Regulations” in this Item 1, and “Quantitative and Qualitative Disclosure about Market Risk” in Item 7A.

Manufacturing

We do not have our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. We have engaged third parties for these activities. Currently, we have a single source of supply for each of our marketed products and for the active pharmaceutical ingredients used in these products. Our ability to develop and deliver products in a timely and competitive manner depends on our third party suppliers and manufacturers being able to continue to meet our ongoing commercial needs. 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. 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., 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 became our only supplier of sodium oxybate in 2012, we have the right to purchase a portion of our worldwide requirements of sodium oxybate from other suppliers. Under the 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 2015, subject to automatic three-year extensions until either party provides notice to the other of its intent to terminate the agreement at least 18 months before the end of the then-current term. Either party has the right to terminate the agreement in the event of the other party’s uncured material breach or insolvency. During the term of the agreement and, under certain circumstances for 18 months after the agreement terminates, Siegfried is not permitted to manufacture sodium oxybate for any other company.

We have an exclusive agreement with Patheon Pharmaceuticals, or Patheon, which became effective in 2008, under which we have agreed to purchase exclusively from Patheon (except in very limited circumstances), and Patheon has agreed to manufacture, supply and package, our worldwide supply of Xyrem. The current term of the agreement with Patheon, which is our sole supplier of Xyrem, extends until July 2014 and may be extended, at our option, for additional two-year terms with written notice at least twelve months before the end of the then current term. Either party has the right to terminate the agreement in the event of the other party’s uncured material breach or insolvency.

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

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

We have an agreement with the HPA under which Erwinaze is exclusively licensed to us for worldwide marketing, sales and distribution, and is manufactured for us, by the HPA. The HPA is our sole supplier for Erwinaze. The agreement with the HPA expires in December 2020, subject to automatic extension for additional five-year periods unless terminated by either party in writing at least a fixed period before the end of the then-current term. Either party has the right to terminate the

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agreement in the event of the other party's uncured material breach or insolvency. We provide periodic rolling forecasts to the HPA, and a portion of each rolling forecast constitutes a firm purchase order. We are obligated to make tiered royalty payments to the HPA based on worldwide net sales of Erwinaze and Erwinase. During the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma agreed to a number of post-marketing commitments related to the manufacture of Erwinaze by the HPA. In the past, there has been a disruption of supply of Erwinase in the European market due to manufacturing challenges. We have limited inventory of Erwinaze. If the HPA experiences a disruption in supply or capacity constraints as a result of increased demand, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach by the HPA or the cessation of HPA's business. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinaze.

We are in the process of changing our supplier for ziconotide, the active ingredient in Prialt, and have commenced the transfer to the new supplier. We believe that we have sufficient supply of ziconotide to meet our commercial requirements for finished product for a number of years, which we expect to be sufficient time to complete the transfer to the new supplier. We are also in the process of changing our finished product manufacturer for Prialt. We believe that we have sufficient supply to meet commercial requirements for Prialt through the end of 2013. Our new manufacturer of finished product was approved by the FDA in December 2012 but has not yet needed to manufacture commercial supplies of Prialt for us.

For FazaClo LD, FazaClo HD and Luvox CR, we have single sources of supply for both the active pharmaceutical ingredient and finished product, and should it become necessary to change suppliers, the process could take two years or longer. Pursuant to our agreement, Douglas Pharmaceuticals has agreed to supply Versacloz finished product to us. Our active pharmaceutical ingredient and finished product manufacturers may not be able to continue to meet our requirements for quality, quantity and timeliness. In addition, our manufacturers and suppliers are subject to the FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and other rules and regulations prescribed by non-U.S. regulatory authorities. We depend on our third party suppliers and manufacturers for continued compliance with these requirements, and they may not be able to do so.

Government Regulation

The research, testing, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, sale, distribution, recordkeeping, importing and exporting of pharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities, and regulations differ from country to country. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, regulates the review, approval, manufacturing and marketing of pharmaceutical products. We are not permitted to market medicines in the United States or countries in Europe until we receive approval from the FDA or the competent European authorities, respectively, generally of an NDA or a BLA, or their non-U.S. equivalent. The application must contain information on the proposed product, including data from preclinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability.

Xyrem is also regulated as a controlled substance and is subject to additional regulation by the DEA under the Controlled Substances Act, or CSA, and its implementing regulations.

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

U.S. Regulations

Drug and Biologic Approval Process

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

The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The steps required before a drug or biologic product 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

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efficacy of the drug product for each indication; the submission to the FDA of a marketing application; satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made, analyzed and stored to assess compliance with cGMP; potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the application; and FDA review and approval of the application.

The FDA reviews all applications submitted before it accepts them for filing and may request additional information rather than, or before, accepting an NDA or BLA for filing. Once the 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 in which to complete its initial review of a standard application and respond to the applicant, and eight months for a priority application. The FDA does not always meet its PDUFA goal dates, and in certain circumstances the PDUFA goal date may be extended. The FDA may not act quickly or favorably in reviewing applications, and we may encounter significant difficulties or costs in any efforts to obtain FDA approvals, which could delay or preclude us from marketing our product candidates.

If the FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include, as part of the application or after approval, a proposed REMS, which may include a patient package insert or a medication guide to provide information to consumers about the product's risks and benefits, a plan for communication to healthcare providers, and restrictions on the product's distribution referred to as "elements to assure safe use," or ETASU. For example, Xyrem is required to have a REMS. While elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or FDAAA, the program is not in the form that is now required for REMS. FDAAA, which amended FDCA, requires that certain products' risk management programs and related documents that existed prior to the adoption of FDAAA, including the Xyrem Risk Management Program, be updated to comply with the current requirements for REMS documents. We have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documentation. We have had communications with the FDA with respect to our submitted REMS documents. These communications are ongoing, and we cannot predict the timing of finalization, or the final terms, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could make it more difficult or expensive for us to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem. See the discussion below regarding REMS in the context of potential generic competition under "The Hatch-Waxman Act" and in the risk factor in Item 1A entitled "The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem."

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

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

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

Post-Approval Regulation

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

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changes, or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted.

Often, even after a drug or biologic has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies and trials. If such post-approval conditions are not satisfied, the FDA may impose civil money penalties, declare the product misbranded or prohibit the introduction of the drug in interstate commerce. In addition, holders of an approved NDA or BLA are required to: report certain adverse reactions to the FDA; comply with certain requirements concerning advertising and promotional labeling for their products; submit drug safety or adverse event reports; and continue to have quality control and manufacturing procedures conform to cGMP after approval. For example, during the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma agreed to a number of post-marketing commitments related to the manufacture of Erwinaze by the HPA.

We monitor adverse events resulting from the use of our commercial products, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The authorities review these events and reports, and if they determine that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing and/or require or conduct other actions. From time to time, the FDA issues drug safety communications on its adverse event reporting system based on its review of reported adverse events. In December 2012, the FDA issued a drug safety communication reminding physicians and patients that the use of Xyrem with alcohol or central nervous system depressants can impair consciousness and lead to severe breathing problems. Also in December 2012, we agreed with the FDA on a change to our label that included a new contraindication for the use of alcohol with Xyrem. See also the risk factor in Item 1A entitled “The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.”

The FDA also periodically inspects the sponsor’s records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved product, including withdrawal of the product from the market.

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

The Hatch-Waxman Act

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

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

The second path established under the Hatch-Waxman Act is for the approval of generic drugs. Section 505(j) of the FDCA permits the submission of an abbreviated new drug application, or ANDA, for a generic version of an approved, brand-name drug. Generally, an ANDA must contain data and information showing that the proposed generic product and the approved, brand-name drug, which is referred to as the "referenced drug," (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This data and information are provided instead of independently demonstrating the proposed generic product's safety and effectiveness, which are inferred from the fact that the generic product is the same as the referenced drug, which the FDA previously found to be safe and effective. On October 18, 2010, we received notice from Roxane Laboratories, Inc., or Roxane, that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem, and, on December 10, 2012, we received notice from Amneal Pharmaceuticals, LLC , or Amneal, that it had submitted an ANDA to the

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FDA seeking regulatory approval to market a generic version of Xyrem. ANDAs have been filed in the past seeking approval to market generic versions of certain of our other products, and additional ANDAs may be filed in the future seeking approval to market generic forms of Xyrem and/or other products.

To the extent that an ANDA or a Section 505(b)(2) NDA applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify that there are no patents listed for that product in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, or that for each Orange-Book-listed patent the listed patent has expired, or will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product. A certification that the new product will not infringe the referenced product's Orange-Book-listed patents or that such patents are invalid is called a Paragraph IV Certification. If the applicant does not challenge the listed patents, the ANDA or the Section 505(b)(2) NDA will not be approved until all the listed patents claiming the referenced product have expired, as well as any additional period of exclusivity that might be obtained for completing pediatric studies pursuant to the FDA's written request. The ANDA or the Section 505(b)(2) NDA may also be subject to delay in review or approval based on applicable non-patent exclusivities, such as exclusivity that results from obtaining approval of a new chemical entity or of a new use of a previously approved active ingredient.

If the applicant has provided a Paragraph IV Certification to the FDA, the applicant must also send notice of the Paragraph IV Certification to the holder of the NDA and the relevant patent holders once the ANDA or the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the proposed generic product for infringing the patent. The filing of a patent infringement lawsuit within 45 days of receipt of a Paragraph IV Certification automatically prevents the FDA from approving the ANDA or the Section 505(b)(2) NDA until the earliest of 30 months after the NDA holder's receipt of the notice of the Paragraph IV Certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA sponsor. The 30-month stay period may also be shortened or lengthened upon order of the court in the infringement lawsuit. For drugs with five-year exclusivity, if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the reference drug NDA. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant will not be subject to the 30-month stay. The FDA may issue tentative approval of an ANDA if the generic applicant meets all conditions for approval but cannot receive effective approval because the 30-month stay or a period of statutory exclusivity has not expired.

We intend to submit for Orange Book listing all relevant patents for our products and product candidates, and to vigorously defend any patents for our approved products, including Orange Book-listed patents. In November 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification relating to Xyrem in connection with Roxane's ANDA filing. In January 2013, we filed a lawsuit against Amneal in response to Amneal's Paragraph IV Certification relating to Xyrem in connection with Amneal's ANDA filing. For a description of these matters, please see Item 3. "Legal Proceedings." If an ANDA is approved after the 30-month stay and before conclusion of any relevant patent litigation at the district, and potentially appellate, court, a generic manufacturer could nonetheless choose to commercialize the generic product. In the event of such commercialization, the generic manufacturer generally would be liable to the NDA holder for damages in the event the NDA holder ultimately prevails in the patent litigation.

Section 505-1(i)(1) of the FDCA provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same or comparable elements as the referenced drug, such as a medication guide, a patient package insert and other ETASU, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and permit the ANDA holder to submit a separate but comparable REMS if the FDA determines that the burden of creating such a 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 entitled to protection. 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. 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, from time to time we may face pressure to license or share our Xyrem Risk Management Program, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that may be taken by a third party to seek to license or share our REMS program. Furthermore, if we do not share our REMS with a generic competitor, the FDA may grant the generic competitor a waiver and allow the generic competitor to market a generic drug with a comparable REMS.

On July 10, 2012, we submitted a Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, which

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did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. In the FDA's response, the FDA stated that when the NDA holder has a deemed REMS, the FDA directs the ANDA applicant to work with the NDA holder to create a single shared system to implement the ETASU that will be approved as a final REMS. We cannot predict the outcome or impact on our business of any discussions with any ANDA applicant with respect to the potential creation of a single shared system. See the risk factor in Item 1A entitled "We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products."

It is also possible that the FDA may take the position that a potential generic competitor does not need to share or license aspects of our deemed REMS program in order to obtain approval of its ANDA. In the December 13, 2012 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 to have adequate risk management elements in place for the ANDA until the final REMS is approved. Thus, it is possible that the FDA may rely on this position as a basis to grant approval or tentative approval of an ANDA without a final REMS.

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 regulatory review period, that represents the first commercial marketing of that drug, is eligible for the extension, and it must be applied for prior to expiration of the patent. The U.S. Patent and Trademark Office, or 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 and Europe, 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 for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product. In the United States, in order to obtain orphan drug designation, this designation

must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. If a product that has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years from the time of FDA approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.
The FDA designated and approved Xyrem as an orphan drug for treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. The period of orphan drug exclusivity for cataplexy in patients with narcolepsy expired in July 2009, and the period of orphan drug exclusivity for excessive daytime sleepiness in patients with narcolepsy expired in

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November 2012. In addition, Erwinaze has orphan drug exclusivity until November 2018, seven years from its FDA approval. Our product candidate Asparec was also granted orphan drug designation by the FDA, subject to certain conditions.

Separately, Erwinaze, as a biologic product approved under a BLA, is subject to the BPCIA. The BPCIA establishes a period of twelve years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a twelve-year period. The FDA is in the process of implementing the BPCIA and has not established final guidelines for administering the review and approval of applications for data exclusivity. We expect that Erwinaze would receive data exclusivity in the United States through 2023 under the BPCIA.

United States Healthcare Reform

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

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. The Healthcare Reform Act also makes changes to the Medicaid Drug Rebate Program, discussed in more detail below, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014 and thereafter, and their details will be shaped significantly by implementing regulations that have yet to be finalized. In 2012, the Supreme Court of the United States heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the Healthcare Reform Act. The Supreme Court's decision upheld most of the Healthcare Reform Act and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, the Supreme Court struck down a provision in the Healthcare Reform Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2014 than anticipated when Congress passed the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall, which could impact our sales, business and financial condition.

Other Regulatory Requirements

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, or FTC, the U.S. Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those non-U.S. countries in which we commercialize our products. In addition to the FDCA, other federal, state and non-U.S. statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical

testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government healthcare programs. Our partners, including our suppliers, manufacturers and distributors and the central pharmacy for Xyrem, are subject to many of the same requirements.

These requirements include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate and Xyrem. In addition to quota requirements, the DEA imposes various registration, recordkeeping and reporting requirements, labeling and packaging requirements, importing, exporting, security controls and a restriction on prescription refills on certain pharmaceutical products under the CSA. The states also impose similar requirements for handling controlled substances. A principal factor in determining the particular requirements, if any, applicable to a product is the actual or potential abuse profile. Sodium oxybate, in the form of an active pharmaceutical ingredient, is regulated by the DEA as a Schedule I controlled substance, a category reserved for products believed to present the highest risk of substance abuse and with no approved medicinal use. When contained in Xyrem, sodium oxybate is regulated as a Schedule III controlled substance. Controlled

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substances are subject to DEA and state regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of the scheduled substance that would be available for clinical trials and commercial distribution. As a Schedule III drug, Xyrem is subject to limitations on prescription refills. Sodium oxybate, as a Schedule I substance, is subject to additional controls, including quotas that limit the amount of product that can be manufactured each year. The DEA publishes an annual aggregate quota for the active pharmaceutical ingredient of Xyrem, and our supplier is required to request and justify allocation of sufficient annual manufacturing quota, as well as additional manufacturing quota if needed throughout the year. Until 2011, our active pharmaceutical ingredient supplier obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for each of 2012 and 2013, our supplier has been allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. As a result, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In addition, our supplier has been allocated only a portion of the requested quota for 2013 to make the active pharmaceutical ingredient of Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, we anticipate that both our active pharmaceutical ingredient supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013.

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.

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

Iran Related Disclosures

Section 219 of the Iran Threat Reduction and Syria Human Rights Act of 2012 added a new subsection (r) to Section 13 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that requires a public company to disclose in its annual or quarterly reports whether it or any of its affiliates have knowingly engaged in specified activities or transactions relating to Iran, including activities not prohibited by U.S. law and conducted outside the U.S. by non-U.S. affiliates in compliance with local law. The following disclosure is made pursuant to Section 13(r) of the Exchange Act.

On June 12, 2012, we completed the EUSA Acquisition. Prior to the completion of the EUSA Acquisition, a French subsidiary of EUSA Pharma entered into a contract to sell Kidrolase (Escherichia coli L-asparaginase), a life-saving cancer drug produced outside of the United States, to Medical Equipment and Pharmaceutical Holding Co., or MEPH, which we understand is an affiliate of the Iranian Ministry of Health. Following the completion of the EUSA Acquisition, the French subsidiary of EUSA Pharma shipped Kidrolase to MEPH pursuant to the pre-existing contract. The Kidrolase contract was entered into prior to our acquisition of EUSA Pharma, was performed entirely by the French subsidiary, and we believe that the post-acquisition shipment of Kidrolase was not prohibited by or sanctionable under applicable law at the time. Our anticipated gross revenue from this shipment of Kidrolase was approximately 92,000 Euros. The French subsidiary of EUSA Pharma, which is now our wholly-owned subsidiary, has sought payment from MEPH for this shipment. To date, no such payment has been received. No additional sales or shipments of Kidrolase to MEPH were made following the June 2012 shipment.

Our mission is to improve patients' lives by identifying, developing and commercializing products that address unmet medical needs. As part of fulfilling our mission, we intend to provide access to important and life-saving pharmaceutical products to patients wherever they may be located, including in Iran, to the extent permitted by applicable U.S. and non-U.S. laws and regulations. For that reason, we expect that we may make future sales of Kidrolase to MEPH in accordance with applicable law.

Ex-U.S. Regulations

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

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Most of the countries where we market our products have product authorization and post-authorization regulatory processes. In the European Union, or 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 European Medicines Agency, or EMA, which approves the application if it meets certain quality, safety, and efficacy requirements. A centralized marketing authorization is valid in all EU member states. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and advanced therapy medicinal products, and optional for certain other products. Unlike the centralized procedure, the national procedure requires a separate application to, and leads to separate approval by, each EU member state. The decentralized procedure allows applicants to file identical applications to several EU member states and receive simultaneous national approvals based on the recognition by EU member states of an assessment by a reference member state, and the mutual recognition procedure similarly is based on the acceptance by EU member states of the assessment and/or authorization of a medicinal product by a reference member state. The making available or placing on the EU market of unauthorized medicinal products is generally prohibited, but EU Member States may exceptionally and temporarily allow the making available of such products to individual patients or a group of patients. Clinical studies must be conducted in accordance with the requirements of the EU Clinical Trial Directive and applicable good clinical practice standards. The time needed to secure approval for medicinal products may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

Irrespective of the different marketing authorization tracks, various additional requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the EU Medicinal Products Directive, as amended by the EU Falsified Medicines Directive aimed at preventing falsified medicines from entering into the legal supply chain. These requirements include compliance with EU equivalent cGMP standards when manufacturing active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.

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

The United States is a party to the Convention on Psychotropic Substances (1971), the 1971 Convention. In October 2012, the World Health Organization, or WHO, sent a recommendation to the United Nations Commission on Narcotic Drugs, or CND, to reschedule gamma-hydroxybutyrate, or GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. 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, if GHB is rescheduled internationally, Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements. 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 sodium oxybate and Xyrem are already subject to more restrictive regulations in the United States than required under the 1971 Convention, a decision by the CND to reschedule GHB would result in sodium oxybate and Xyrem being

subject to more restrictive registration, recordkeeping, importing, exporting, reporting and other requirements in Europe and certain other countries than are currently in place given GHB's Schedule IV status under the 1971 Convention. The CND is expected to review the WHO recommendation at its annual meeting in March 2013. If GHB is rescheduled as a Schedule II substance under the 1971 Convention, we will likely be subject to additional regulatory requirements outside of the United States and may be subject to additional regulatory requirements in the United States.

Our international business activities face a variety of additional legal and compliance requirements. For example, our interactions with health care professionals are subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise 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 corporation and to devise and maintain an adequate system of internal accounting controls. We are also subject to applicable anti-bribery laws in

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the countries in which we operate, such as the U.K. Bribery Act of 2010, or the UK Bribery Act, which became effective on July 1, 2011. The UK Bribery Act prohibits companies which do business with the United Kingdom and their employees and representatives from giving, offering, or promising bribes to any person, including non-UK government officials, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies may be held liable for failing to prevent employees and persons associated with the company from violating the Act. Other countries in which we operate have enacted similar laws. We have ongoing efforts that are designed to ensure our compliance with these laws, including 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. Any violation of these laws may result in civil and criminal penalties, and could have a material adverse impact on our business.

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. 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

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. Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than other products, and third party payors may not provide coverage and reimbursement for our products or any of our product candidates that we commercialize, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. We anticipate that the 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.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and the Centers for Medicare and Medicare Services, or CMS, the federal agency that administers the Medicaid Drug Rebate program, has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products.

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

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

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

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

Outside of the United States, political, economic and regulatory developments are also subjecting the healthcare industry to fundamental changes and challenges. Pressure by governments and other stakeholders on prices and reimbursement levels continue to exist. In various European countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. In the EU, our products are marketed through various channels and within different legal frameworks. In certain EU Member States, reimbursement is provided for unauthorized products provided through national named patient or compassionate use programs. Such reimbursement may no longer be available if authorization for named patient or compassionate use programs expire or are terminated. 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.

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

Patents and Proprietary Rights

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products, inventions and improvements that we consider important to our business. We own a portfolio of 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

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patent applications cover formulations of our products and product candidates, uses of our products and product candidates to treat particular conditions, drug delivery technologies and delivery profiles relating to our products and product candidates and methods for producing our products and product candidates. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. The patents and patent applications that relate to our products and product candidates include the following:

- Xyrem® (sodium oxybate) oral solution. Xyrem is covered by eleven U.S. patents that expire at various times from December 2019 to June 2024. These patents relate to Xyrem's stable and microbially resistant formulation, its manufacturing process, and its method of use, including its restricted distribution system. Nine of these eleven patents are listed in the Orange Book. Of the patents listed in the Orange Book, two are formulation patents expiring in July 2020; four are method of use patents covering the distribution of Xyrem, three of which expire in June 2024 and one of which expires in December 2022; two are method of use patents covering Xyrem's use in narcolepsy, both of which expire in December 2019; and one is formulation and method of use patent expiring in December 2019. A process patent and a distribution system patent not listed in the Orange Book also cover the product and expire in December 2019 and June 2024, respectively. A Xyrem formulation patent has issued in 19 other countries and will expire in December 2019. This formulation patent is currently pending in two additional countries. In addition to our issued patents, we have patent applications relating to Xyrem pending in the United States. The patent laws of non-U.S. countries differ from those in United States, and the degree of protection afforded by non-U.S. patents may be different from the protection offered by U.S. patents. Two 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 are currently involved in litigation with both companies.
- Prialt® (ziconotide) intrathecal infusion. Prialt is covered by a portfolio of four U.S. patents for a formulation and methods of use. Two of these patents are listed in the Orange Book. These patents will expire from June 2015 to December 2016. Also, there are four non-U.S. patents that will expire in June 2016. There are also six additional U.S. patents issued on a formulation containing Prialt and other active ingredients and methods for their use. These U.S. patents will expire in October 2024. We also have equivalent non-U.S. applications to these additional patents pending in Canada and Japan that, if issued, would expire in October 2024.
- FazaClo® LD (clozapine, USP) Orally Disintegrating Tablet and FazaClo® HD (clozapine, USP) Orally Disintegrating Tablet. FazaClo LD and FazaClo HD are covered by three U.S. formulation patents. All are licensed by us, one from Ethypharm, expiring in December 2017, and the other two from CIMA, expiring April 2018. The three patents are listed in the Orange Book. The two patents licensed from CIMA are subject to ongoing re-examination proceedings at the USPTO, as described in "Marketed Products" in this Item 1. As part of its settlement with Teva in 2011, Azur Pharma granted a sublicense to an affiliate of Teva of its rights to have manufactured, market and sell a generic version of both FazaClo LD and FazaClo HD. The sublicenses for FazaClo LD commenced in July 2012, and the sublicense for FazaClo HD will commence in May 2015, or earlier upon the occurrence of certain events.
- Versacloz™ (clozapine, USP) oral suspension. Versacloz is covered by a U.S. formulation patent and a pending U.S. patent application that we license from Douglas Pharmaceuticals. The patent expires in May 2028.
- Luvox CR® (fluvoxamine maleate) Extended-Release Capsules. Luvox CR is covered by a U.S. formulation patent owned by Alkermes that is listed in the Orange Book and will expire in 2020. A continuation application is pending in the United States. Pursuant to our settlement agreements with three companies, we granted a sublicense to each of these companies of our rights to have manufactured, market and sell a generic version of Luvox CR in the United States. The first of such sublicenses commenced in February 2013, and a generic version of Luvox CR could be introduced as soon as the FDA approves the generic company's ANDA. The other two sublicenses will commence in April 2014, or earlier if a generic version of Luvox CR receives FDA approval.
- Product candidate. Asparec® (mPEG-r-crisantaspase) is not yet covered by any issued patents. We have rights to patent applications for Asparec pending in the United States and many other countries that, if issued, would expire in July 2030.

Erwinaze® (asparaginase Erwinia chrysanthemi) has no patent protection, and we therefore rely on trade secrets and other unpatented proprietary information to protect our commercial position, which we may be unable to do.

We cannot be certain that any of our patent applications, or those of our licensors, will result in issued patents. Changes in patent laws could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, because the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions, the patents we own and license, or any additional patents we may

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own or license, may not prevent other companies from developing similar or therapeutically equivalent products. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful.

As reflected above, generic manufacturers have challenged our patents covering Xyrem, FazaClo LD, FazaClo HD and Luvox CR. Azur Pharma settled a suit against Teva relating to FazaClo LD and FazaClo HD, and we settled three suits against Anchen, Actavis and Torrent, relating to Luvox CR. Other suits are ongoing. See Item 3. “Legal Proceedings.” We cannot assure you that our patents will not be further challenged by third parties or that we will be successful in any defense we undertake. Failure to successfully defend a patent challenge could materially and adversely affect our business.

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

We have also applied for a number of trademarks and service marks to further protect the proprietary position of our products. We have approximately 80 registered trademarks and service marks in the United States and approximately 390 registered trademarks and service marks in other jurisdictions. We also have pending trademark and service mark applications in the United States. We also rely on our trade secrets and those of our licensors, as well as other unpatented proprietary information, to protect our products. To the extent that our products have a competitive edge as a result of our reliance on trade secrets and unpatented know-how, our competitive position may be compromised if others independently develop products using the same or similar technologies or trade secrets.

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

Employees

As of February 20, 2013, we had approximately 610 employees. We consider our employee relations to be good.

About Jazz Pharmaceuticals plc

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

a reverse acquisition under the acquisition method of accounting for business combinations. Our predecessor, Jazz Pharmaceuticals, Inc., was originally incorporated in California in March 2003 and was reincorporated in Delaware in January 2004. In the Azur Merger, all outstanding shares of Jazz Pharmaceuticals, Inc.'s common stock were canceled and converted into the right to receive, on a one-for-one basis, our ordinary shares. Our ordinary shares trade on the same exchange, The NASDAQ Global Select Market, and under the same trading symbol, "JAZZ," as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger.

Our principal offices are located at One Burlington Road, Dublin, 4 Ireland, and our telephone number is 353-1-634-7800. Our U.S. operations are located in Palo Alto, California and Philadelphia and Langhorne, Pennsylvania. Our international division is headquartered in Oxford, United Kingdom, with offices in Lyon, France and elsewhere in Europe. Our

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

Available Information

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

Item 1A. Risk Factors

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

Risks Relating to Xyrem and the Significant Impact of Xyrem Sales

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

Xyrem® is our largest selling product and our financial results are significantly influenced by sales of Xyrem, which accounted for 65% of our net product sales for the year ended December 31, 2012 and 88% of our net product sales for the year ended December 31, 2011, and our future plans assume that sales of Xyrem will increase. While Xyrem product sales grew from 2010 to 2011 and from 2011 to 2012, 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 2013, and we cannot assure you that price adjustments we have taken or may take in the future have not already negatively affected, or will not in the future negatively affect, Xyrem sales volumes.

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

- the potential introduction of a generic version of Xyrem;
- changed or increased regulatory restrictions, including changes to our risk management program, and the terms of the final REMS documents, for Xyrem, or regulatory actions by the FDA as a result of, or related to the matters raised in, the warning letter we received from the FDA in October 2011 or the Form FDA 483 we received in May 2012, as discussed in more detail in the risk factors below;
- our manufacturing partners' ability to obtain sufficient quota from the DEA to satisfy our needs for Xyrem;
- any supply, manufacturing or distribution problems arising with any of our manufacturing and distribution partners, all of whom are sole source providers for us;
- the availability of reimbursement from third party payors;
- changes in healthcare laws and policy, including changes in requirements for rebates, reimbursement and coverage by federal healthcare programs;
- continued acceptance of Xyrem as safe and effective by physicians and patients, even in the face of negative publicity that surfaces from time to time; and
- changes to our label, including new safety warnings or changes to our boxed warning, that further restrict how we market and sell Xyrem.

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

If sales of Xyrem were to decline significantly, we might need to reduce our operating expenses or to seek to raise

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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 products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected. Although Xyrem is covered by patents covering its formulation, distribution system and method of use, two third parties have filed ANDAs seeking FDA approval of generic versions of Xyrem, and additional third parties may also seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable.

On October 18, 2010, we received notice from Roxane that it had submitted an ANDA to the FDA requesting approval to market a generic version of Xyrem before expiration of the Orange-Book-listed patents relating to Xyrem. On December 10, 2012, we received notice from Amneal that Amneal has submitted an ANDA to the FDA seeking regulatory approval to market a generic version of Xyrem before expiration of the Orange-Book-listed patents relating to Xyrem. We have sued both Roxane and Amneal 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 forms of Xyrem. If an ANDA is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA is stayed until the earlier of (i) April 18, 2013 or (ii) a District Court decision finding that the patents that are the subject of our litigation with Roxane are invalid, unenforceable or not infringed. Our lawsuits with Roxane are ongoing. Although no trial date has been established, we do not expect a trial date or any decision by the District Court until after April 18, 2013. 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 before or at any time after the stay provided for under the Hatch-Waxman Act is lifted, 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.

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, which did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition.

We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's stated positions in its responses to the

Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem. See the next risk factor in this Item 1A entitled “The manufacture, distribution and sale of Xyrem are subject to significant regulatory oversight and restrictions and the requirements of a risk management program, and these restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Xyrem.”

A generic manufacturer would need to obtain quota from the DEA in order to manufacture both the active pharmaceutical ingredient and the finished product for a generic version of Xyrem. The DEA publishes an annual aggregate quota for the active pharmaceutical ingredient of Xyrem, and our supplier is required to request and justify allocation of sufficient annual manufacturing quota as well as additional manufacturing quota if needed throughout the year. Until 2011, our active pharmaceutical ingredient supplier obtained substantially all of the published annual aggregate quota for use in the manufacture of Xyrem. However, for each of 2012 and 2013, our supplier has been allocated only a portion of the published annual aggregate quota for the active pharmaceutical ingredient. As a result, a generic manufacturer may be able to obtain a portion of the annual aggregate active pharmaceutical ingredient quota. In addition, our supplier has been allocated only a portion of the

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requested quota for 2013 to make the active pharmaceutical ingredient of Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, we anticipate that both our active pharmaceutical ingredient supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013.

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

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

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management and controlled distribution system that was implemented at the time Xyrem was approved, which includes parts of the Xyrem Success Program, to ensure the safe distribution of Xyrem and minimize the risk of misuse, abuse and diversion of sodium oxybate. Our Xyrem Risk Management Program includes patient and physician education, a database of information so that we may track and report certain information and other elements. It also includes unique features that provide information about adverse events, including deaths, which is generally not available for other products that are not subject to similar risk management programs. As required by the FDA and other regulatory agencies, the adverse event information that we collect for Xyrem is regularly reported to the FDA and could result in the FDA requiring changes to the Xyrem label or taking or requiring us to take other actions that could have an adverse effect on Xyrem's commercial success.

While elements of the Xyrem Risk Management Program, adopted in 2002 before the FDA had authority to require REMS, are deemed to be an approved REMS pursuant to the Food and Drug Administration Amendments Act of 2007, or the FDAAA, the program is not in the form that is now required for REMS. FDAAA requires that certain products' risk management programs and related documents that existed prior to the adoption of FDAAA, including the Xyrem Risk Management Program, be updated to comply with the current requirements for REMS documents. We have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documents. We have had communications with the FDA with respect to our submitted REMS documents. These communications are ongoing, and we cannot predict the timing of finalization, or the final terms of, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could 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 addition, Section 505-1(i)(1) of the FDCA provides that (i) an ANDA with a referenced drug subject to the REMS requirements is required to have a REMS with the same or comparable elements as the referenced drug, such as a medication guide, a patient package insert and other "elements to assure safe use," or ETASU, and (ii) the ANDA drug and the referenced drug shall use a single shared system to assure safe use. However, the FDA may waive this requirement for a single shared system and permit the ANDA holder to submit a separate but comparable REMS if the FDA determines that the burden of creating such a 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 entitled to protection. 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. 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, from time to time we may be face pressure to license or share our Xyrem Risk Management Program, or elements of it, with generic competitors. We cannot predict the outcome or impact on our business of any future action that may be taken by a third party to seek to license or share our REMS program. Furthermore, if we do not share our REMS with a generic competitor, the FDA may grant the generic competitor a waiver and allow the generic competitor to market a generic drug with a comparable REMS. In addition, the FTC has been paying increasing attention to the use of REMS by companies selling branded products, in particular whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner.

On July 10, 2012, we submitted a Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product

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would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the Roxane ANDA, which did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. In the FDA's response, the FDA stated that when the NDA holder has a deemed REMS, the FDA directs the ANDA applicant to work with the NDA holder to create a single shared system to implement the ETASU that will be approved as a final REMS. We cannot predict the outcome or impact on our business of any discussions with any ANDA applicant with respect to the potential creation of a single shared system. See the risk factor in this Item 1A entitled "We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights, and we may be unable to protect our rights to, or commercialize, our products."

It is also possible that the FDA may take the position that a potential generic competitor does not need to share or license aspects of our deemed REMS program in order to obtain approval of its ANDA. In the December 13, 2012 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 to have adequate risk management elements in place for the ANDA until the final REMS is approved. Thus, it is possible that the FDA may rely on this position as a basis to grant approval or tentative approval of an ANDA without a final REMS. We expect that the approval or tentative approval of an ANDA resulting 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.

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

In April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us, as required. We 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 July 2012, we held a telephonic meeting with the FDA with respect to our analysis. Based in part on this meeting and our agreement with the FDA on a revised Xyrem label in December 2012, we believe that the FDA will not require any further data or analysis with respect to mortality during the historical period that was covered by our investigation and evaluation, and that no further action is required by us. However, there can be no assurance that the FDA will agree with our assessment, and the FDA may ultimately take, or require us to take, actions that may be costly or time consuming and/or that negatively affect the commercial success of Xyrem.

In October 2011, we received a warning letter from the FDA following a 2011 Form FDA 483 covering certain aspects of our adverse event reporting system for Xyrem and drug safety procedures related to the unreported deaths uncovered in April 2011. In May 2012, we received a Form FDA 483 at the conclusion of an FDA inspection conducted in May 2012, which noted the FDA investigators' observations with respect to our incomplete review of information from ESSDS related to potential Xyrem-related adverse events prior to 2011 and determination of

whether there are additional adverse events that are required to be reported to the FDA based on such review; our investigation of serious unexpected adverse drug experiences, including insufficient documentation to demonstrate the past investigation; and our lack of a written procedure relating to one administrative aspect of our current drug safety monitoring procedures. We have completed the actions that we believe are required to address the observations in the May 2012 Form FDA 483, and we believe that we have submitted all data and completed all actions that are necessary to fully address the matters raised in the warning letter. We have submitted a request to the FDA to close out the warning letter, but we do not know whether the FDA will require further information or actions. In any event, we expect that the FDA will conduct a re-inspection before closing out the warning letter. We cannot predict either the timing or the final outcome of the FDA's regulatory compliance review. We do not know whether the FDA will take further action, or require us to take further action, with respect to our adverse event reporting, or whether the FDA will ultimately conclude we have not taken all appropriate corrective actions with respect to the May 2012 Form FDA 483 or the warning letter.

Regulatory authorities in other countries where Xyrem is sold may take similar actions. Any failure to demonstrate our substantial compliance with applicable regulatory requirements to the FDA's or any other regulatory authority's satisfaction

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could have a material and adverse effect on Xyrem sales and therefore on our business, financial condition, results of operations and growth prospects.

The FDA has required that Xyrem's label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, or ads that mention the pharmaceutical brand name but not the indication or medical condition it treats. In addition, Xyrem's FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. We cannot predict whether the FDA will require additional warnings, including boxed warnings, to be included on Xyrem's label. For example, in December 2012, we updated our Xyrem label in conjunction with the FDA to include a new contraindication for the use of alcohol with Xyrem. 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 marketed products, and our inability to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to Xyrem®, we have a portfolio of marketed products, including Erwinaze® (called Erwinase® in ex-U.S. markets) and Prialt®. 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 the HPA and was approved by the FDA under a BLA, in November 2011 and launched in the U.S. market in the same month. It is also being sold under marketing authorizations, named patient programs, temporary use authorizations or similar authorizations in multiple countries in Europe and elsewhere.

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

Prialt, an intrathecally administered infusion of ziconotide, was approved by the FDA in December 2004 for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or intrathecal morphine. We face many challenges in maintaining and growing sales of Prialt, including acceptance of intrathecal administration by patients and physicians and challenges for physicians with timely reimbursement for use of Prialt. In addition, the FDA has required that Prialt's label include a boxed warning regarding the risk of psychiatric symptoms and neurological impairment. We cannot predict whether the FDA will require additional warnings, or place any additional limitations on our ability to advertise and promote Prialt, which could negatively impact Prialt sales. In the fourth quarter of 2012, we began the roll-out of the NAVIGATOR Reimbursement and Access Program™, a new centralized distribution system for Prialt. In connection with the implementation of the new distribution system, we could experience disruptions that could negatively affect product sales.

Failure to maintain or increase prescriptions and revenue from sales of our marketed products other than Xyrem, including Erwinaze and Prialt, could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We may choose to increase the price of our marketed 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 dosing requirements of treated patients and other factors, and it may be difficult for us or investors to estimate Erwinaze revenue until we have more experience selling the product. The market price of our ordinary shares may decline if the sales of our products do not continue or grow at the rates anticipated by financial analysts or investors.

In addition, if we fail to obtain approvals for certain of our existing products in new indications or formulations, we will be unable to commercialize our products in new indications or formulations, which could have a material adverse effect on our

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business, financial condition, results of operations and growth prospects.

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

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

We do not have our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. The availability of our products for commercial sale depends upon our ability to procure the ingredients, 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 very limited inventories of certain of our products, including Xyrem and Erwinaze, as well as the ingredients or raw materials used to make our products. Our limited inventory puts us at significant risk of not being able to meet product demand. If our suppliers and manufacturers, including any new suppliers without a track record of meeting our supply needs, for any reason do not continue to supply us with our products or product candidates in a timely fashion and in compliance with applicable quality and regulatory requirements, or otherwise fail or refuse to comply with their obligations to us under our supply and manufacturing arrangements, we may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates, which could adversely affect our business, financial condition, results of operations and growth prospects.

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

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 legal and other efforts to obtain the needed quotas after the original annual quotas had first been allocated. For 2013, our supplier has been allocated only a portion of the requested quota to make the active pharmaceutical ingredient of

Xyrem. Our finished product manufacturer for Xyrem was similarly allocated only a portion of the requested quota to make finished product. As a result, we anticipate that both our active pharmaceutical ingredient supplier and our finished product manufacturer will need to obtain increased quotas from the DEA for 2013. We cannot assure you sufficient quotas will be received from the DEA to meet our needs, and if we and our supplier and manufacturer cannot obtain the quotas that are needed on a timely basis, or at all, our business, financial condition, results of operations and growth prospects could be materially and adversely affected.

In addition, the FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. If there are delays in qualifying new manufacturers or facilities or a new manufacturer is unable to obtain a sufficient quota from the DEA, if required, or to otherwise meet FDA or similar international regulatory body's requirements for approval, there could be a shortage of the

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affected products for the marketplace or for use in clinical studies, or both, particularly since we do not have secondary sources for supply and manufacture of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates.

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

Erwinaze is licensed to us, and manufactured for us, by the HPA, which is our sole supplier for Erwinaze. During the review and approval process by the FDA of the BLA for Erwinaze, EUSA Pharma agreed to a number of post-marketing commitments related to the manufacture of Erwinaze by the HPA. In the past, there has been a disruption of supply of Erwinase in the European market due to manufacturing challenges. Failure by the HPA to comply with regulatory requirements, including post-marketing commitments, could adversely affect its ability to supply Erwinaze to us and could result in FDA approval being revoked or product recalls, 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. We cannot assure you that the HPA will be able to continue to supply our ongoing commercial needs of Erwinaze in a timely manner, or at all, especially if our demand for product continues to increase. We have limited inventory of Erwinaze. If the HPA experiences a disruption in supply or capacity constraints as a result of increased demand, we do not have the right to engage a backup supplier for Erwinaze except in very limited circumstances, such as following the termination of the agreement by us due to the uncured material breach by the HPA or the cessation of the HPA's business. If we are required to engage a backup or alternative supplier, the transfer of technical expertise and manufacturing process to the backup or alternative supplier would be difficult, costly and time-consuming and would increase the likelihood of a delay or interruption in manufacturing or a shortage of supply of Erwinaze. Any failure of the HPA to supply necessary quantities of Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, if the FDA or any 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 the HPA may charge us more to supply Erwinaze meeting such specifications, which may result in additional costs to us and may decrease any profit we would otherwise achieve with Erwinaze.

We are in the process of changing our supplier for ziconotide, the active ingredient in Prialt, and have commenced the transfer to the new supplier. We are also in the process of changing our finished product manufacturer for Prialt. There can be no assurance that the new supplier of ziconotide will be approved by the FDA or non-U.S. regulatory authorities or that the new manufacturer of Prialt will be approved by non-U.S. regulatory authorities, or that our commercial supplies of such products will be sufficient until such approvals have been obtained. Any failure to obtain and maintain sufficient commercial supplies could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

For FazaClo LD, FazaClo HD and Luvox CR, we have single sources of supply for both the active pharmaceutical ingredient and finished product, and should it become necessary to change suppliers, the process could take two years or longer. Pursuant to our agreement, Douglas Pharmaceuticals has agreed to supply Versacloz finished product to us.

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

possible legal or regulatory action, including shutdown, which may adversely affect their ability to supply us with the ingredients or finished products we need.

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

We may not 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

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

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

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

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

- the risk that our lack of experience in new markets, including the oncology market, will not allow us to achieve growth in, or maintain current levels of, sales of our products in such markets;
- the strain on, and need to expand, our existing operational, technical, financial and administrative infrastructure, including our financial controls and reporting systems and procedures and disaster recovery procedures, in connection with integrating three different businesses and operations;
- the challenges in controlling additional costs and expenses in connection with and as a result of the acquisitions, including professional fees to comply with corporate and tax laws and financial reporting requirements in a number of countries in Europe, costs and expenses incurred in connection with travel, and additional costs we may incur going forward as a result of our corporate structure that includes an increased number of subsidiaries in multiple additional countries;
- the diversion of our management's attention to integration of operations; and
- any unanticipated liabilities for activities of or related to Azur Pharma or EUSA Pharma or any of their operations, products or product candidates that occurred prior to the closing of the respective acquisitions or before adequate risk mitigation could be accomplished.

If any of these factors impairs our ability to integrate the acquired businesses successfully or on a timely basis, we may not be able to realize the anticipated financial and strategic benefits from combining the businesses. In addition, we may be required to spend additional time or money on integration activities that otherwise would be spent on the development and expansion of our business. If we fail to integrate or otherwise manage the acquired businesses successfully and in a timely manner, resulting operating inefficiencies could increase costs and expenses more than we planned, could negatively impact the market price of our ordinary shares and otherwise distract us from execution of our strategy. Failure to maintain effective financial controls and reporting systems and procedures could also impact our ability to produce timely and accurate financial statements.

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

may not provide meaningful guidance to form an assessment of the prospects or potential success of our future business operations.

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

We are headquartered in Dublin, Ireland and have multiple offices in the United States, the United Kingdom, and other countries in Europe. Our headcount has grown from approximately 260 employees at the end of 2011 to approximately 610 in

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February 2013. This includes employees in ten countries in Europe, a European commercial presence, and a complex distribution network for products in Europe and additional territories. In addition, we may expand our international operations into other countries in the future, either organically or by acquisition. While we have acquired significant management and other personnel with substantial international experience, because we are conducting a larger portion of our business outside of the United States, we are now subject to a variety of risks and complexities that may materially and adversely affect our business, results of operations and financial condition, including, among other things:

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

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. Continuing worldwide economic instability, including challenges faced by the Eurozone and certain of the countries in Europe, could adversely affect our revenues, financial condition or results of operations, if, for example, our customers in Europe fail to pay or delay payments owed to us for our products.

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

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

- the clinical indications for which a product is approved, including any restrictions placed upon the product in connection with its approval, such as a REMS, patient registry or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and the severity of side effects;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- perceived advantages over alternative treatments;
- relative convenience and ease of administration;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and
- the availability of adequate reimbursement by third parties.

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

We face substantial competition from other companies, including companies with greater resources, including larger sales organizations and more experience working with large and diverse product portfolios, than we have.
The commercial opportunities of our products or potential future products may be reduced or eliminated if our

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

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

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

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

We expect to increase our research and development organization to pursue targeted development activities in 2013. We have several development pipeline projects, including the development of two product candidates: Asparec®, which is in a Phase I clinical trial in Europe, and Leukotac®, which is in a Phase III clinical trial also in Europe. We also intend to pursue clinical development of other product candidates that we may acquire or in-license in the future. Significant clinical, development and financial resources will be required to progress these product candidates to obtain necessary regulatory approvals and to develop them into commercially viable products. We have not been successful in developing any product candidates that received FDA approval in the past. If a product candidate fails at any stage of development, it will not receive regulatory approval, we will not be able to commercialize it, or potentially even to continue to receive modest revenue being generated as a result of sales under a named patient program, such as in the case of Leukotac, and we will not receive any return on our investment from that product candidate.

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

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

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory

guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial;
- failure of our clinical trials and clinical investigators to be in compliance with the FDA's Good Clinical Practices;
- unforeseen safety issues, including negative results from ongoing preclinical studies and adverse events associated

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with product candidates;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- failure of our third-party clinical trial managers to satisfy their contractual duties, comply with regulations or meet expected deadlines; or
- insufficient funds to complete the trials.

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

We are currently undertaking a Phase 1 clinical trial of Asparec. Under our license agreement with Alizé under which we obtained rights to develop and commercialize Asparec, we are subject to contractual obligations to meet certain development milestones within certain timeframes. Our ability to meet each of these milestones is uncertain, and depends upon a number of factors, including our ability to obtain clinical material and to develop a clinical program meeting the development requirements of both the FDA and European regulatory authorities in a timely fashion. If our development activities are delayed for any reason and we fail to meet our licensing obligations to Alizé, we may lose our rights to develop and commercialize Asparec.

Our development pipeline projects include not only new product candidates, but also projects involving line extensions for existing products and the generation of additional clinical data for existing products. For example, we are conducting a pharmacokinetic clinical trial of the intravenous administration of Erwinaze in the North America, to generate support for approval for the intravenous administration of Erwinaze, which is intended to provide more convenient dosing for patients. We also plan to conduct a clinical trial including pharmacokinetic efficacy measures to evaluate Erwinaze in adolescents and young adults with ALL who are hypersensitive to E. coli-derived asparaginase, which is expected to begin in the second half of 2013. These development efforts may not be successful, and any adverse events or other information generated during the course of our studies related to existing products could result in action by the FDA or any non-U.S. regulatory agency, which may restrict our ability to sell, or sales of, currently marketed products, or such events or other information could otherwise have a material adverse effect on a related commercial product. Any failure or delay in completing clinical trials for line extensions or the generation of additional clinical data could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

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 their highest priority, or in the manner in which we would prefer, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as FDA's and non-U.S. regulatory agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good

clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the United States. Our failure, or the failure of our product manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they

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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.

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 a few months' notice and without cause or good reason. Since the completion of the Azur Pharma and EUSA Pharma transactions, several members of the former management teams of those entities, as well as other employees, have left our company to pursue other opportunities. The resulting loss of institutional knowledge may negatively impact our achievement of the anticipated benefits of those transactions.

In addition, to grow our company we will need additional personnel. Competition for qualified personnel in the pharmaceutical industry is very intense. If we lose key personnel or are unable to attract, retain and motivate quality individuals, our business, financial condition, results of operations and growth prospects could be adversely affected. We also depend on the unique abilities, industry experience and institutional knowledge of the members of our board of directors to efficiently set company strategy and effectively guide our executive management team. We cannot be certain that future board turnover will not negatively affect our business in the future.

Risks Related to Our Intellectual Property

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

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

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. Although Xyrem® is covered by patents covering its formulation, distribution system and method of use, including a new formulation and method of use patent issued by the USPTO in September 2012 and a new patent for the treatment of narcolepsy issued by the USPTO in December 2012, third parties are seeking to introduce a generic equivalent of Xyrem, and additional third parties may also attempt to invalidate or design around the patents, or assert that they are invalid or otherwise unenforceable, and seek to introduce generic versions of Xyrem. If one or more companies receive FDA approval of an ANDA, it is possible that such company or companies could introduce generic versions of Xyrem before our patents expire if they do not infringe our patents or if it is determined that our patents are invalid or unenforceable.

On December 10, 2012, we received a Paragraph IV Certification from Amneal Pharmaceuticals, LLC, or Amneal, that it 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. Previously, on October 18, 2010, we received notice that Roxane filed an ANDA with the FDA requesting approval to market a generic version of Xyrem before the expiration of the

Orange-Book-listed patents relating to Xyrem. If either of these applications is approved, and a generic version of Xyrem is introduced, our sales of Xyrem would be adversely affected. Additional ANDAs could also be filed requesting approval to market generic forms of Xyrem; if those applications for generics were approved and the generics were launched, sales of Xyrem would decrease. We have sued both Roxane and Amneal to prevent either from introducing a generic version of Xyrem that would infringe our patents, but we cannot assure you that the lawsuit will prevent the introduction of a generic version of Xyrem for any particular length of time, or at all. See the risk factor in this Item 1A entitled “If generic products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected.”

Azur Pharma received Paragraph IV certifications from three generic manufacturers, two in 2008 and one in 2010,

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

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

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

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has issued some and is developing additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until March 2013. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;
- our issued patents and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

- our issued patents and the issued patents of our licensors or partners may be vulnerable to legal challenges as a result of changes in applicable law;
- we may not develop additional proprietary products that are patentable; or
- the patents of others may have an adverse effect on our business.

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

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

Certain of the products we sell have no patent protection and, as a result, potential competitors face fewer barriers in introducing competing products. For example, Erwinaze® has no patent protection, and we therefore must rely on trade secrets and other unpatented proprietary information in order to obtain a competitive advantage, which we may be unable to do. Erwinaze, as a biologic product approved under a BLA, is subject to the BPCIA. The BPCIA establishes a period of twelve years of data exclusivity for reference products in order to preserve incentives for future innovation, protecting data included by the applicant in a BLA by prohibiting others from gaining FDA approval based in part on reliance on, or reference to, the data in the BLA during a twelve-year period. The FDA is in the process of implementing the BPCIA and has not established final guidelines for administering the review and approval of applications for data exclusivity. We expect that Erwinaze would receive data exclusivity in the United States through 2023 under the BPCIA. While Erwinaze has orphan drug marketing exclusivity for a seven-year period from its FDA approval in the United States until November 2018, and is expected to receive data exclusivity in the United States through 2023 under the BPCIA, it is possible that a potential competitor might obtain earlier approval from the FDA based upon an approval application that does not rely on or refer to data in our BLA for Erwinaze. In the European Union, the regulatory data protection and thus regulatory exclusivity period for Erwinaze has lapsed. This also means that any new marketing authorizations for Erwinaze in other European Union member states will not receive any regulatory data protection. If a biosimilar product to Erwinaze is approved in the future in the United States or in other countries where it is sold, a significant percentage of the prescriptions written for Erwinaze may be filled with the biosimilar version, resulting in a loss in sales of Erwinaze, and there may be a decrease in the price at which Erwinaze can be sold. Competition from a biosimilar product to Erwinaze could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, although there are patent applications for Asparec pending in the United States and 28 other countries, Asparec is not yet covered by any issued patents. Asparec was granted orphan drug designation by the FDA subject to certain conditions. In addition, the FDA has not yet clarified whether Asparec is eligible to receive data exclusivity under the BPCIA. If we fail to obtain orphan drug marketing exclusivity and/or data exclusivity, and if we also fail to successfully execute on other strategies to protect our intellectual property with respect to Asparec, including protection by one or more issued patents, Asparec would be subject to competition from a biosimilar product, which could have a material adverse effect on our ability to recognize any return on our investment in the development of this product as well as on our future growth prospects.

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

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

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent

positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and non-U.S. counterparts, and may file additional U.S. and non-U.S. patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted. Moreover, in part because of prior research performed and patent applications submitted in the same manner or similar fields, there can be no assurance that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents, our licensed patents or our partners' patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these

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patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity. We are prosecuting lawsuits against the generic manufacturers who delivered Paragraph IV certifications to us with respect to Xyrem and FazaClo LD. See Item 3. "Legal Proceedings." We cannot assure you that these, or other lawsuits we may file in the future, will be successful in stopping the infringement of our patents, that any such litigation will be cost-effective, or that the litigation will have a satisfactory result for us.

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

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

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many non-U.S. jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors' or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors' patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the 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.

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

We own patents and trade secrets that cover elements of the Xyrem Risk Management Program. As a result of the implementation of the FDAAA, we have submitted updated REMS documents to the FDA, which are intended to conform the relevant elements of the Xyrem Risk Management Program to the current REMS formatting requirements, as well as to make other updates to the program and its documentation. We have had communications with the FDA with respect to our submitted REMS documents. These communications are ongoing, and we cannot predict the timing of finalization, or the final terms of, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could 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, if certain provisions of our Xyrem Risk Management Program that are currently protected by our patents are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced, as certain claims of our patents may not provide as much protection in a modified REMS structure. The interpretation of intellectual property protections and the effect of these protections are extremely complex, and we

cannot predict the impact of any changes to our REMS documents on our business.

Risks Related to Our Industry

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

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

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authorities, respectively, generally of a NDA or BLA. The application must contain information on the drug or biological candidate, including data from the preclinical and clinical trials, information pertaining to the preparation of the drug or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability. Submission of an application does not assure approval for marketing in any jurisdiction, 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.

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

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

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

Additional provisions of the Healthcare Reform Act, some of which became effective in 2011, may negatively affect our revenues in the future. For example, as part of the Healthcare Reform Act's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we are required to provide a 50% discount on branded prescription drugs dispensed to beneficiaries within this donut hole. The Healthcare Reform Act also makes changes to the Medicaid Drug Rebate Program, discussed further herein, including increasing the minimum rebate from 15.1% to 23.1% of the average manufacturer price for most innovator products and from 11% to 13% for non-innovator products.

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

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

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

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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.

To help patients afford our products, we have various programs to assist them, including patient assistance programs, a Xyrem free product voucher program and co-pay coupon programs for certain products. The co-pay coupon programs of other pharmaceutical manufacturers are the subject of ongoing class action lawsuits first filed in 2012 and challenging their legality under a variety of federal and state laws, and our co-pay coupon programs could become the target of similar lawsuits. In addition, co-pay coupon programs, including our program for Xyrem, have received some negative publicity related to their use to promote branded pharmaceutical products over other less costly alternatives. It is possible that the outcome of the pending litigation against other manufacturers and/or the introduction and enactment of new legislation could restrict or otherwise negatively affect these programs, which could result in fewer patients using affected products and therefore could have a material adverse effect on our sales, business and financial condition.

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

Oversight by FDA and Equivalent 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 or European and other non-U.S. regulatory authorities will be, subject to extensive and ongoing regulatory requirements. These requirements apply both to us and to third parties we contract with to perform services and supply us with products. Failure by us or any of our third party partners, including suppliers, manufacturers and distributors and our central pharmacy for Xyrem, 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, any of which could have a significant impact on our sales, business and financial condition.

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

The FDA approved the BLA for Erwinaze® in the United States in November 2011, subject to certain post marketing requirements, including developing and validating assays and conducting certain non-clinical studies. In addition, the BLA approval for Erwinaze is subject to compliance with numerous post marketing commitments, including certain

commitments which must be met by the HPA with respect to product manufacturing, which are outside of our control. While activities are underway to complete the post marketing requirements and to comply with the post marketing commitments, if we or the HPA fail to do so within the timeframe established by the FDA, or if the results of the non-clinical studies raise concerns or other issues for the FDA, our approval to market Erwinaze in the United States may be withdrawn or otherwise jeopardized.

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

In June 2009, the FDA posted an announcement regarding a potential safety signal associated with FazaClo®. The posting stated that FazaClo had been found to exhibit a higher proportion of adverse events with a fatal outcome versus total adverse events compared to other clozapine products. The posting also stated that the reported events in the cases with fatal outcome

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are similar for FazaClo and other clozapine products. Although Azur Pharma investigated and we believe that the difference in the cited ratio between FazaClo and other marketed clozapine products does not reflect an underlying adverse safety signal, we cannot assure you that additional information we may learn will not modify our current assessment, that the FDA will agree with this assessment or that the FDA will not take further actions related to the potential safety signal, any of which could have a material adverse effect on our results of operations.

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

The FDA requires advertising and promotional labeling to be truthful and not misleading, and that products be marketed only for the approved indications and in accordance with the provisions of the approved label. The FDA routinely provides its interpretations of that authority in informal communications and also in more formal communications such as untitled letters or warning letters, and although such communications are not final agency decisions, companies may decide not to contest the agency's interpretations so as to avoid disputes with the FDA, even if they believe the claims to be truthful, not misleading and otherwise lawful. For example, in September 2012, we received a warning letter from the FDA related to a direct-to-consumer patient brochure for FazaClo. We were no longer using the allegedly violative promotional materials at the time we received the letter, but reviewed all of our other promotional materials for FazaClo in accordance with the letter. We agreed with the FDA on plans for correcting the promotional materials and disseminating the corrective messages to healthcare providers, patients and consumers and began implementation of the corrective actions in accordance with the agreed-upon plans in February 2013. We believe that we have taken necessary actions required to fully address the agency's concerns. However, there can be no assurance that the FDA will agree with our assessment. The FDA could take further action, could require us to take further action, with respect to our FazaClo promotional materials, or could otherwise conclude we have not taken all appropriate corrective actions with respect to the warning letter. The FDA or other regulatory authorities may disagree with our response to the warning letter or challenge other of our promotional materials or activities in the future, through additional enforcement action, which may have a negative impact on our sales and/or may subject us to financial or other penalties.

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

Various state agencies oversee pharmaceutical compounding activities. Compounded drugs are made by certain pharmacies, typically by combining ingredients (prescription and/or over-the-counter) to make a formulation that is

not readily available to patients and/or approved by the FDA. A number of problems have been associated with the making and use of compounded drugs, including product contamination and product toxicity. Improperly compounded products can pose serious public health issues, as evidenced by the recent fungal meningitis outbreak in the United States which was traced to compounded drugs from the New England Compounding Center. Pharmaceutical products administered intrathecally, such as Prialt, are frequently compounded by pharmacies for off-label use, a process over which we have no control. If any of our products are used in compounded drugs, we may have exposure to claims by patients treated with compounded formulations containing our products and to regulatory action by relevant government agencies. Any such claims or regulatory actions could result in harm to our reputation and have a negative effect on our business.

Other Regulatory Authorities

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the Department of Justice, the FTC, the U.S. Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those non-U.S. countries in which we

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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 is a party to the 1971 Convention. In October 2012 , the WHO sent a recommendation to the United Nations Commission on Narcotic Drugs, or CND, to reschedule GHB, under the 1971 Convention from its current Schedule IV status to Schedule II status. 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, if GHB is rescheduled internationally, Xyrem and/or sodium oxybate may be subject to more restrictive registration, recordkeeping, reporting, importing, exporting and other requirements. 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 sodium oxybate and Xyrem are already subject to more restrictive regulations in the United States than required under the 1971 Convention, a decision by the CND to reschedule GHB would result in sodium oxybate and Xyrem being subject to more restrictive registration, recordkeeping, importing, exporting, reporting and other requirements in Europe and certain other countries than are currently in place given GHB's Schedule IV status under the 1971 Convention. The CND is expected to review the WHO recommendation at its annual meeting in March 2013. If GHB is rescheduled as a Schedule II substance under the 1971 Convention, we will likely be subject to additional regulatory requirements outside of the United States and may be subject to additional regulatory requirements in the United States. Failure by us or any of our partners, including suppliers, manufacturers and distributors, to comply with such requirements could result in, among other things, additional operating costs to us, delays in shipments outside or into the United States and adverse regulatory actions.

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

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

The Federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under 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 payment 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, and thus non-reimbursable, 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.

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

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prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes of conduct. Additional states are considering or recently have considered similar proposals. Non-U.S. governments often have similar regulations which we also will be subject to in those countries where we market and sell products.

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 generally prohibits the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise 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 corporation and to devise and maintain an adequate system of internal accounting controls. The UK Bribery Act prohibits companies which do business with the United Kingdom and their employees and representatives from giving, offering, or promising bribes to any person, including non-UK government officials, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the UK Bribery Act, companies may be held liable for failing to prevent employees and persons associated with the company from violating the Act. 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 are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. We have ongoing efforts that are designed to ensure our compliance with these laws, including 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. Any violation of these laws may result in civil and criminal penalties, and could have a material adverse impact on our business.

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from the different EU member states may interpret the legislation differently, which adds to its complexity, and guidance on implementation and compliance practices are often updated or otherwise revised. Fully understanding and implementing the legislation could be quite costly and timely, which could adversely affect our business. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. 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.

The number and complexity of both federal and state laws continue to increase, and additional governmental resources are being added to enforce these laws and to prosecute companies and individuals who are believed to be violating them. In particular, the Healthcare Reform Act includes a number of provisions aimed at strengthening the government’s ability to pursue anti-kickback and false claims cases against pharmaceutical manufacturers and other healthcare entities, including substantially increased funding for healthcare fraud enforcement activities, enhanced investigative powers, amendments to the False Claims Act that make it easier for the government and whistleblowers to pursue cases for alleged kickback and false claim violations and the Physician Payment Sunshine provisions. The Physician Payment Sunshine provisions will require extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. CMS recently issued a final rule implementing the Physician Payment Sunshine provisions and clarified the scope of the reporting obligations. The

final rule also provided that manufacturers must begin tracking on August 1, 2013 and must report payment data to CMS by March 31, 2014. While it is too early to predict what effect these changes will have on our business, we anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions. Responding to a government investigation or enforcement action would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Compliance with the various federal and state laws that apply to pharmaceutical manufacturers is difficult and time consuming, and companies that violate them may face substantial penalties. The potential sanctions include civil monetary penalties, exclusion of a company's products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and, in some cases, the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge under one or more of these laws. For example, the FTC has been paying increasing attention to the use of REMS by companies selling branded

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products, in particular whether REMS may be being deliberately used to reduce the risk of competition from generic drugs in a way that may be deemed to be anticompetitive. It is possible that the FTC or others could claim that our REMS or other practices are being used in an anticompetitive manner. Such a challenge or any challenge that we 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.

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

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

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program. Effective March 23, 2010, rebates are also due on the utilization of Medicaid managed care organizations. With regard to the amount of the rebates owed, the Healthcare Reform Act increased the minimum Medicaid rebate for all drugs; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. In addition, the 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 new branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer will pay a prorated share of the branded prescription drug fee of $2.8 billion in 2013 (and set to increase in ensuing years) based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

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

Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service’s 340B drug pricing discount program in order for federal funds to be available for the manufacturer’s

drugs under Medicaid and Medicare Part B. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under 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.

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 Healthcare Reform Act expanded the 340B program to include additional entity types: certain free-standing cancer hospitals,

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critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. The Healthcare Reform Act exempts "orphan drugs" – those designated under section 526 of the FDCA – from the ceiling price requirements for these newly-eligible entities. The Health Resources and Services Administration, or HRSA, which administers the 340B program, has issued proposed regulations to implement the orphan drug exception, but has not yet issued final regulations. The issuance of final regulations will continue to increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

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

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

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

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

The Healthcare Reform Act also obligates the Secretary of the Department of Health and Human Services to create regulations and processes to improve the integrity of the program and to update the agreement that manufacturers must sign to participate in the program to obligate manufacturers to sell to covered entities if they sell to any other purchaser and to report to the government the ceiling prices for its drugs. In addition, 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 requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule, or FSS, pricing program. To participate, we are required to enter into an FSS contract with the VA, under which we must make our innovator "covered drugs" available to the "Big Four" federal agencies – the VA, the Department of Defense, or DoD, the Public Health Service, and the

Coast Guard – at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, or VHCA. The FCP is based on a weighted average wholesaler price known as the "non-federal average manufacturer price," or Non-FAMP, which manufacturers are required to report on a quarterly and annual basis to the VA. If a company misstates Non-FAMPs or FCPs it must restate these figures. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing 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

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mandatory disclosure of the contractor's commercial "most favored customer" pricing. We offer one single FCP-based FSS contract price to all FSS purchasers for all products.

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

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

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

In both U.S. and 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. Third party payors decide which drugs they will pay for and establish reimbursement and co-pay levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement and co-pay policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than 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. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because some of our products compete in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts, or the lack of reimbursement, will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to effectively commercialize our products.

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and Actual Acquisition Cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and the CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payors to cover our products. Any failure to cover products appropriately under our DoD pricing agreements, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the Federal marketplace. As discussed

above, recent legislative changes to the 340B drug pricing program, the Medicaid Drug Rebate program, and the Medicare Part D prescription drug benefit also could impact our revenues. A significant portion of our revenue from sales of Erwinaze is obtained through government payors, including Medicaid, and any failure to qualify for reimbursement for Erwinaze under those programs would have a material adverse effect on revenues from sales of Erwinaze.

We expect to experience pricing pressure in the United States in connection with the sale of our products due to managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. In various European countries we expect to be subject to continuous cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. 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 2013, 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

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reimbursement coverage for our products, which could negatively impact our sales volumes.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologicals, will be reduced by up to 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, Pub. L. No. 112-25, or BCA, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240, or ATRA. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs, because Congress failed to enact legislation by January 15, 2012, to reduce federal deficits by $1.2 trillion over ten years. The BCA caps the cuts to Medicare payments or items and services at 2%, and requires the cuts to be implemented on the first day of the first month following the issuance of a sequestration order. The ATRA delayed implementation of sequestration from January 2, 2013, to March 1, 2013, and as a result, the Medicare cuts will take effect April 1, 2013, unless Congress enacts legislation to cancel or delay the cuts. If implemented, these cuts could adversely impact payment for our products and related procedures.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products are associated with significant risks of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. Some of our products, including Xyrem, have boxed warnings in their labels. Further, another product, Luvox CR, is a selective serotonin reuptake inhibitor, and other products in that class are currently involved in product liability litigation.

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

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

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

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an FDA investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs. An FDA investigation could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the indications for which they may be used, or suspension or withdrawal of approval. Similarly, any such regulatory action by the FDA could lead to product liability lawsuits as well.

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, 2012, we had approximately $463.1 million in secured debt outstanding, all of which was incurred under our credit agreement entered into in connection with the EUSA Acquisition. Our debt may:

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit our ability to use our cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry;

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- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

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

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

In June 2012, we entered into a credit agreement which provides for a six-year $475.0 million term loan and a five-year $100.0 million revolving credit facility. 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.

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

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

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

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

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

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

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

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

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

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

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

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

the Azur Merger at the closing, we could be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874.

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

It is possible that the IRS could disagree with the position that the ownership test is satisfied and assert that Section 7874 of the Code applies to treat us as a U.S. corporation following the Azur Merger. There is limited guidance regarding the Code Section 7874 provisions, including the application of the ownership test described above. The IRS continues to scrutinize

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transactions that are potentially subject to Section 7874, and issued new final and temporary regulations under Section 7874 in June 2012. These regulations apply only to acquisitions completed on or after June 7, 2012, and therefore should not apply to the Azur Merger. Nevertheless, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have retroactive application to us, Jazz Pharmaceuticals, Inc., our respective shareholders, and/or the Azur Merger.

Section 7874 of the Code likely will limit Jazz Pharmaceuticals, Inc. and its U.S. affiliates' ability to utilize their U.S. tax attributes to offset certain U.S. taxable income, if any, generated by taxable transactions following the Azur Merger for a period of time following the Azur Merger.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code limits the ability of the acquired U.S. corporation and its U.S. affiliates to utilize U.S. tax attributes such as net operating losses to offset U.S. taxable income resulting from certain transactions. Based on the limited guidance available, it is currently expected that this limitation should apply to us. As a result, it is not currently expected that Jazz Pharmaceuticals, Inc. or its U.S. affiliates will be able to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable transactions following the Azur Merger. Notwithstanding this limitation, we plan to fully utilize Jazz Pharmaceuticals, Inc.'s U.S. net operating losses, or NOLs, prior to their expiration. As a result of this limitation, however, it may take Jazz Pharmaceuticals, Inc. longer to use its NOLs. Moreover, contrary to these plans, it is possible that the limitation under Section 7874 of the Code on the utilization of U.S. tax attributes could prevent Jazz Pharmaceuticals, Inc. from fully utilizing its U.S. tax attributes prior to their expiration if Jazz Pharmaceuticals, Inc. does not generate sufficient taxable income.

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 Treasury Regulations. In this regard, we currently estimate that, as a result of these ownership change provisions, we have an annual limitation on the utilization of certain NOLs of $29 million for each of the years 2013 to 2016, $12 million for 2017, and a combined total of $3 million for 2018 to 2026. However, Sections 382 and 383 of the Code are extremely complex provisions with respect to which there are many uncertainties, and we have not requested a ruling from the IRS to confirm our analysis of the ownership change limitations related to the NOLs generated by our U.S. affiliates. Therefore, we have not established whether the IRS would agree with our analysis regarding the application of Sections 382 and 383 of the Code. If the IRS were to disagree with our analysis, or if our U.S. affiliates were to experience additional ownership changes in the future, our U.S. affiliates could be subject to further annual limitations on the use of the NOLs to offset potential taxable income and related income taxes that would otherwise be due.

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

As of December 31, 2012, we had recorded $1.3 billion of intangible assets and goodwill related to our past acquisitions. Intangible assets and goodwill are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually.

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

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

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

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

Risks Relating to Our Ordinary Shares

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

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

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

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

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

Sales of a substantial number of our ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. As of February 20, 2013, we had 58,037,532 ordinary shares outstanding, all of which shares are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale and other requirements under Rule 144.

As of February 20, 2013, the holders of up to approximately 6,549,000 ordinary shares, based on shares outstanding as of that date, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, or the Securities Act, under an amended and restated investor rights agreement that Jazz Pharmaceuticals, Inc. entered into with these holders in June 2007, which we assumed at the closing of the Azur Merger. If such holders, by exercising their registration rights or otherwise, sell a large number of shares, the sale could adversely affect the market price of our ordinary shares. If in the future we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights or otherwise, these sales may impair our ability to raise capital. In addition, we have filed a registration statement on Form S-8 under the Securities Act to register our ordinary shares reserved for issuance under our equity incentive and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

Pursuant to the terms of an investor rights agreement dated July 7, 2009 Jazz Pharmaceuticals, Inc. entered into in connection with a private placement completed on such date, which agreement we assumed at the closing of the Azur Merger, we agreed to file a registration statement under the Securities Act registering the resale of 1,584,092 ordinary

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

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

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

As of February 20, 2013, our executive officers and directors, together with the shareholders with which our executive officers and directors were affiliated or associated as of such date, beneficially owned approximately 23.4% of our ordinary shares. Accordingly, our executive officers and directors, together with their respective affiliates or associates, may be able to significantly influence matters subject to shareholder approval and will continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our ordinary shares, and may prevent attempts by our shareholders to replace or remove our board of directors or management.

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

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

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

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

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

- permit our board of directors to issue one or more series of preferred shares with rights and preferences designated by our board;
- impose advance notice requirements for shareholder proposals and nominations of directors to be considered at shareholder meetings;
- stagger the terms of our board of directors into three classes; and
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal our articles of association.

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

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

We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs. Even if we propose to pay dividends in the future, we may be unable to do so under Irish law. Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, "distributable reserves." In addition, our ability to pay cash dividends on our ordinary shares is restricted under the terms of our 2012 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. 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.

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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, European Union 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 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 2012 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 U.S. operations are located in Palo Alto, California, Philadelphia, Pennsylvania and Langhorne, Pennsylvania.

We occupy approximately 12,000 square feet of office space in Dublin, Ireland under a lease which expires in May 2022. We have an option to terminate this lease in May 2017, with no less than six months' prior written notice and the payment of a termination fee. In Palo Alto, California, we occupy a total of approximately 61,000 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, 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. We also occupy approximately 16,000 square feet of office space in Philadelphia, Pennsylvania under a lease that expires in February 2016 and approximately 8,000 square feet of office space in Langhorne, Pennsylvania under a lease that expires in October 2016.

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Our international division is headquartered in Oxford, United Kingdom, with offices in Lyon, France and elsewhere in Europe. We occupy approximately 5,000 square feet of office space in Oxford, United Kingdom under a lease that expires in March 2015. We also occupy approximately 9,000 square feet of office space in Lyon, France under a lease that expires January 2019. We have an option to terminate this lease in December 2015.

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

Item 3. Legal Proceedings

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

Xyrem® ANDA Matters: On October 18, 2010, we received a Paragraph IV Patent Certification notice, or Paragraph IV Certification, from Roxane Laboratories, Inc., or Roxane, that it had submitted an abbreviated new drug application, or ANDA, to the United States Food and Drug Administration, or FDA, requesting approval to market a generic version of Xyrem. Roxane's Paragraph IV Certification alleged that all five patents then listed for Xyrem in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, on the date of the Paragraph IV Certification are invalid, unenforceable or not infringed by Roxane's proposed generic product. On November 22, 2010, we filed a lawsuit against Roxane in response to Roxane's Paragraph IV Certification in the United States District Court for the District of New Jersey, or the District Court. We are seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe our patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) April 18, 2013, which is 30 months after our October 18, 2010 receipt of Roxane's Paragraph IV Certification, or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. Two additional method of use patents covering the distribution system for Xyrem were issued in December 2010 and February 2011, respectively, and were listed in the Orange Book, and we filed lawsuits against Roxane in February 2011 and again in May 2011 to include these additional patents in the litigation in response to Roxane's Paragraph IV Certifications against each of these patents, and also to include another issued patent in the litigation which is not listed in the Orange Book. These additional lawsuits were subsequently consolidated with the action filed on November 22, 2010. On April 26, 2012, the District Court held a Markman hearing, a pretrial hearing following which the trial judge construes the claims of the patents at issue in a lawsuit, and the District Court issued a Markman order construing the claims of the patents then involved in the litigation in September 2012. New patents, one covering a formulation of Xyrem and the other covering use of Xyrem for treatment of narcolepsy, were issued in September 2012 and December 2012, respectively, and were listed in the Orange Book. In October 2012, we filed a new lawsuit in the District Court against Roxane in response to Roxane's Paragraph IV Certification against the new formulation patent, and in December 2012, we filed a lawsuit in the District Court against Roxane alleging infringement of the new treatment patent. Our original lawsuit against Roxane has been temporarily stayed while the District Court determines whether to consolidate the three lawsuits, and no trial date has been scheduled. We cannot predict the timing or outcome of this matter.

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

On May 18, 2012, we submitted a Citizen Petition to the FDA that addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem. Among other actions requested of the FDA, this petition requested that the FDA (i) not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs and (ii) require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. On November 13, 2012, the FDA denied this Citizen Petition. On July 10, 2012, we submitted a second Citizen Petition to the FDA that addressed the requirements for submission of any ANDA referencing Xyrem. This petition focused on our view that any ANDA referencing Xyrem must contain a proposed risk management system at the time it was or is filed in order to demonstrate, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. Among other actions requested of the FDA, this petition asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing

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Xyrem, including the Roxane ANDA, that did not contain a proposed risk management system at the time it was accepted for review. On December 13, 2012, the FDA denied this Citizen Petition. We are evaluating the FDA's responses to both Citizen Petitions and potential further actions that we may take with respect to the issues raised in, and the FDA's denials of, the Citizen Petitions. The FDA's denial of the Citizen Petitions does not have a direct impact on the merits of our ongoing lawsuits with Roxane and Amneal. However, we cannot predict the effect of the denial of either of our Citizen Petitions, or the FDA's stated positions in its responses to the Citizen Petitions, on the timing of the potential introduction of a generic version of Xyrem.

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

Cutler Matter: On October 19, 2011, Dr. Neal Cutler, one of the original owners of FazaClo, filed a complaint against Azur Pharma and one of its subsidiaries, as well as Avanir Pharmaceuticals, Inc., or Avanir, in California Superior Court in the County of Los Angeles, or the Superior Court. The complaint alleges that Azur Pharma and its subsidiary breached certain contractual obligations. Azur Pharma acquired rights to FazaClo from Avanir in 2007. The complaint alleges that as part of the acquisition of FazaClo, Azur Pharma's subsidiary agreed to assume certain contingent payment obligations to Dr. Cutler. The complaint further alleges that certain contingent payments are due because revenue thresholds have been achieved, entitling Dr. Cutler to either a $10.5 million or $25.0 million contingent payment, plus unspecified punitive damages and attorneys' fees. On March 14, 2012, the Superior Court granted our petition to compel arbitration of the dispute in New York and stayed the Superior Court litigation. We submitted a complaint in arbitration alleging that Dr. Cutler's suit had been improperly filed in Los Angeles and seeking a declaratory judgment that we have complied with all contractual obligations to Dr. Cutler. On July 25, 2012, the arbitrator dismissed the arbitration on the grounds that the parties' dispute falls outside of the scope of the arbitration clause in the applicable contract. We have asked the Superior Court to vacate the arbitrator's dismissal of the arbitration and appealed the Superior Court's denial of our motion to the California Court of Appeal. In addition, on November 7, 2012, we filed challenges to the sufficiency of the complaint in the Superior Court, but the Superior Court case has been stayed pending the outcome of our appeal. This matter, like all litigation, carries certain risks, and there can be no assurance of the outcome.

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

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

	High	Low
Calendar Quarter—2011		
First Quarter	$33.83	$18.85
Second Quarter	$34.97	$23.50
Third Quarter	$47.88	$31.87
Fourth Quarter	$45.81	$34.02
Calendar Quarter—2012		
First Quarter	$53.10	$37.90
Second Quarter	$54.50	$40.38
Third Quarter	$58.94	$43.38
Fourth Quarter	$60.00	$47.37

On February 20, 2013, the last reported sales price per share of our ordinary shares was $57.67 per share.

Holders of Ordinary Shares

As of February 20, 2013, there were three holders of record of our ordinary shares. Because many of our ordinary shares are held by brokers, nominees and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Dividends

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 June 2012 credit agreement restrict our ability to make certain restricted payments, which include the payment of cash dividends, in excess of $30 million plus a formula-based amount that is based on our consolidated net income, provided that, in the case of paying cash dividends pursuant to this formula, our total leverage ratio (as defined in the credit agreement) does not exceed a certain amount. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of our credit agreement and other factors our board of directors deems relevant.

Unregistered Sales of Equity Securities

Except as previously reported in our quarterly reports on Form 10-Q filed with the SEC during the year ended December 31, 2012, there were no unregistered sales of equity securities by us during the year ended December 31, 2012.

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. The acquisition or disposal of interests in shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. At present the Financial Transfers Act, 1992 prohibits financial transfers involving the late Slobodan Milosevic and associated persons, Burma (Myanmar), Belarus, certain persons indicted by the International Criminal Tribunal for the former Yugoslavia, the late Osama bin Laden, Al-Qaida, the Taliban of Afghanistan, Democratic Republic of Congo, Democratic People's Republic of Korea (North Korea), Iran, Iraq, Côte d'Ivoire, Lebanon, Liberia, Zimbabwe, Sudan, Somalia, Republic of Guinea, Afghanistan, Egypt, Eritrea, Libya, Syria, Tunisia, certain known terrorists and terrorist groups, and countries that harbor certain terrorist groups, without the prior permission of the Central Bank of Ireland. Any transfer of, or payment in respect of, a share or interest in a share involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law.

Irish Taxes Applicable to U.S. Holders

Withholding 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 for the sale of the related book-entry interest or the ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party being contemplated.

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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, 2007 in (i) our ordinary shares; (ii) the NASDAQ Composite Index; and (iii) the NASDAQ Biotechnology Index through December 31, 2012. Information set forth in the graph below represents the performance of the Jazz Pharmaceuticals, Inc. common stock from December 31, 2007 until January 17, 2012, the day before the consummation of the Azur Merger, and the performance of our ordinary shares from January 18, 2012 through December 31, 2012. Our ordinary share trade on the same exchange, the NASDAQ Global Select Market, and under the same trading symbol, "JAZZ," as the Jazz Pharmaceuticals, Inc. common stock prior to the Azur Merger. Pursuant to applicable Securities and Exchange Commission 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 share 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)

*$100 invested on December 31, 2007 in stock or in index, including reinvestment of dividends.

Fiscal year ending December 31.

(1) This section is not "soliciting material", is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

(2) Information used in the graph was obtained from Research Data Group, Inc.

Item 6. Selected Financial Data

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

We derived the consolidated statements of operations data for the years ended December 31, 2012, 2011 and 2010 and the consolidated balance sheet data as of December 31, 2012 and 2011 from the audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2009 and 2008, and the selected consolidated balance sheet data as of December 31, 2010, 2009 and 2008 are derived from audited consolidated financial statements not included in this Annual Report on Form 10-K. The selected

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consolidated financial data for periods prior to the year ended December 31, 2012 is that of Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries, our predecessor, while the selected consolidated financial data as of and for the year ended December 31, 2012 is that of Jazz Pharmaceuticals plc and its consolidated subsidiaries.

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	Year Ended December 31,				
	2012 (1)	2011	2010	2009	2008
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net	$580,527	$266,518	$170,006	$115,108	$64,637
Royalties and contract revenues	5,452	5,759	3,775	13,341	2,877
Total revenues	585,979	272,277	173,781	128,449	67,514
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technologies and intangible asset impairment)	78,425	13,942	13,559	9,638	13,924
Selling, general and administrative	223,882	108,936	68,996	58,652	111,401
Research and development	20,477	14,120	25,612	36,561	69,963
Intangible asset amortization	65,351	7,448	7,825	7,668	12,828
Intangible asset impairment	—	—	—	—	29,763
Total operating expenses	388,135	144,446	115,992	112,519	237,879
Income (loss) from operations	197,844	127,831	57,789	15,930	(170,365)
Interest expense, net (including $570, $1,183 and $1,179 for the years ended December 31, 2010, 2009 and 2008, respectively, pertaining to a related party)	(16,869)	(1,600)	(12,724)	(22,766)	(17,892)
Foreign currency loss	(3,620)	—	—	—	—
Gain on sale of product rights	—	—	—	—	3,918
Loss on extinguishment of debt (including $701 for the year ended December 31, 2010 pertaining to a related party)	—	(1,247)	(12,287)	—	—
Income (loss) from continuing operations before income tax benefit	177,355	124,984	32,778	(6,836)	(184,339)
Income tax benefit	(83,794)	—	—	—	—
Income (loss) from continuing operations	261,149	124,984	32,778	(6,836)	(184,339)
Income from discontinued operations, net of taxes	27,437	—	—	—	—
Net income (loss)	$288,586	$124,984	$32,778	$(6,836)	$(184,339)
Basic income (loss) per ordinary share: (2)					
Income (loss) from continuing operations	$4.61	$3.01	$0.90	$(0.23)	$(7.19)
Income from discontinued operations	0.48	—	—	—	—
Net income (loss)	$5.09	$3.01	$0.90	$(0.23)	$(7.19)
Diluted income (loss) per ordinary share: (2)					
Income (loss) from continuing operations	$4.34	$2.67	$0.83	$(0.23)	$(7.19)
Income from discontinued operations	0.45	—	—	—	—
Net income (loss)	$4.79	$2.67	$0.83	$(0.23)	$(7.19)

Weighted-average number of ordinary shares outstanding: (2)					
Basic	56,643	41,499	36,343	30,018	25,646
Diluted	60,195	46,798	39,411	30,018	25,646

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	As of December 31, 2012 (1)	2011	2010	2009	2008
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$387,196	$157,898	$44,794	$15,595	$25,907
Working capital (deficit)	360,034	146,261	14,522	(22,287)	(129,492)
Total assets	1,966,493	253,573	135,729	107,396	117,498
Long-term debt, current and non-current (including $6,552 and $6,747 as of December 31, 2009 and 2008, respectively, held by a related party)	456,761	—	40,693	114,866	118,534
Accumulated deficit	(61,296)	(349,882)	(474,866)	(507,644)	(500,808)
Total shareholders' equity (deficit)	1,121,292	192,788	30,551	(72,830)	(92,878)

(1) On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in the Azur Merger pursuant to which all outstanding shares of Jazz Pharmaceuticals, Inc.'s common stock were canceled and converted into the right to receive, on a one-for-one basis, our ordinary shares. Jazz Pharmaceuticals, Inc. was treated as the acquiring company in the Azur Merger for accounting purposes, and as a result, the historical consolidated financial statements of Jazz Pharmaceuticals, Inc. became our consolidated financial statements. On June 12, 2012, we completed 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 achieves U.S. net sales of $124.5 million or more in 2013. In connection with the EUSA Acquisition, we entered into a $575.0 million credit agreement consisting of a $475.0 million term loan and a $100.0 million revolving credit facility. We used all of the proceeds of the term loan, together with cash on hand, to finance the EUSA Acquisition. 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. See Note 3 to the notes to our consolidated financial statements for more information on these transactions.

(2) All references to "ordinary shares" refer to Jazz Pharmaceuticals, Inc.'s common stock with respect to the comparative prior year periods and to our ordinary shares with respect to the year ended December 31, 2012. Our earnings per share in the comparative prior year periods were not impacted by the Azur Merger since each share of Jazz Pharmaceuticals, Inc. common stock issued and outstanding immediately prior to the effective time of the Azur Merger was canceled and 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 characterize our business. In particular, we encourage you to review the risks and uncertainties described in Part I Item 1A. "Risk Factors" included elsewhere in this report. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends.

Overview

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

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

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

Merger with Azur Pharma. On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in the Azur Merger, which was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations, with Jazz Pharmaceuticals, Inc. treated as the acquiring company in the Azur Merger for accounting purposes. The total acquisition consideration of $576.5 million was determined based on the market value of our ordinary shares that were held by the historic Azur Pharma shareholders immediately following the closing of the Azur Merger. Accordingly, the operating results of Jazz Pharmaceuticals, Inc. are included in our consolidated financial statements for all periods presented in this report, whereas the operating results of Azur Pharma are included only since January 18, 2012. As part of the Azur Merger, a wholly-owned subsidiary of Azur Pharma merged with and into Jazz Pharmaceuticals, Inc., with Jazz Pharmaceuticals, Inc. surviving the Azur Merger as a wholly-owned subsidiary of Jazz Pharmaceuticals plc. Prior to the Azur Merger, Jazz Pharmaceuticals, Inc. was an independent specialty pharmaceutical company incorporated in Delaware.

Acquisition of EUSA Pharma and Term Loan and Revolving Credit Facility. On June 12, 2012, we completed the acquisition of EUSA Pharma. As part of the EUSA Acquisition, an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc merged with and into EUSA Pharma, with EUSA Pharma continuing as the surviving corporation and as an indirect wholly-owned subsidiary of Jazz Pharmaceuticals plc. At the closing of the EUSA Acquisition, we paid $678.4 million in cash, and agreed to make an additional contingent payment of $50.0 million in cash if Erwinaze (asparaginase Erwinia chrysanthemi), a product acquired in the EUSA Acquisition, achieves U.S. net sales of $124.5 million or more in 2013. The operating results of EUSA Pharma are included in our consolidated financial statements since the effective date of the EUSA Acquisition on June 12, 2012. In connection with the EUSA Acquisition, we entered into a $575.0 million credit agreement with Barclays Bank PLC and certain other lenders. The credit agreement provides for a six-year $475.0 million term loan and a five-year $100.0 million revolving credit facility. The proceeds from the term loan were used to partially finance the EUSA Acquisition. Our obligations are secured by substantially all of the assets of certain of our subsidiaries. For a more detailed discussion, see "Liquidity and Capital Resources" below.

Sale of Women's Health Business. In October 2012, we completed the sale of our women's health business, which included six products and was acquired in the Azur Merger, to Meda Pharmaceuticals Inc. and Meda Pharma, Sàrl, or

collectively, Meda, for net cash proceeds of $93.9 million.

In 2012, we made substantial progress in the execution of our strategy. Sales of our lead product, Xyrem® (sodium oxybate) oral solution, increased 62% in 2012 compared to 2011. In addition, as a result of the EUSA Acquisition and Azur Merger, we significantly increased the number of products that we market and added products in therapeutic areas that are new to us, such as oncology and pain. Our marketed products address medical needs in the following therapeutic areas and include the following products:

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

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Oncology: Erwinaze® (asparaginase Erwinia chrysanthemi), called Erwinase® in ex-U.S. markets, a treatment for patients with acute lymphoblastic leukemia, or ALL, who have developed sensitivity to E. coli-derived asparaginase, and other products, including products for oncology supportive care;
Pain: Prialt® (ziconotide) intrathecal infusion, the only non-opioid intrathecal analgesic indicated for the management of severe chronic pain for patients who are intolerant of or refractory to other treatments; and
Psychiatry & Other: A portfolio of products, including FazaClo® (clozapine, USP) LD and FazaClo HD, orally disintegrating clozapine tablets indicated for treatment-resistant schizophrenia and Luvox CR® (fluvoxamine maleate) Extended-Release Capsules marketed for the treatment of obsessive compulsive disorder. In addition, in February 2013 the FDA approved a new drug application for Versacloz™ (clozapine, USP) oral suspension for treatment-resistant schizophrenia, which we have exclusive rights to market in the United States.

Our international division, based in Europe, commercializes Erwinase as well as a portfolio of other products outside of the United States. These products are primarily in the oncology, critical care and oncology supportive care therapeutic areas and include Caphosol® (supersaturated calcium phosphate rinse), Collatamp® (lyophilized collagen implant impregnated with the aminoglycoside antibiotic gentamicin), Fomepizole®, Kidrolase® (Escherichia coli L-asparaginase) and Xenazine® (tetrabenazine).

Our development pipeline projects currently include line extensions for existing products, the generation of additional clinical data for existing products and clinical development of new product candidates. These projects include two clinical trials involving Erwinaze: an ongoing pharmacokinetic clinical trial of the intravenous administration of Erwinaze in North America; and a planned clinical trial including pharmacokinetic efficacy measures to evaluate Erwinaze in adolescents and young adults with ALL who are hypersensitive to E. coli-derived asparaginase, which is expected to begin in the second half of 2013. In addition, we are developing two product candidates, including a Phase I clinical trial in Europe of Asparec® (mPEG-r-crisantaspase), a pegylated recombinant Erwinia asparaginase for the treatment of patients with ALL with E. coli asparaginase hypersensitivity; and a Phase III clinical trial in Europe of Leukotac® (inolimomab), an anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease. We expect that research and development expenses will be higher in 2013 compared to 2012 due to an expected increase in development activities and due to the inclusion of a full year of expense from the acquired Azur Pharma and EUSA Pharma businesses.

With the completion of the EUSA Acquisition and the Azur Merger in 2012, we gained not only an expanded portfolio of specialty pharmaceutical products and product candidates, but also an enhanced commercial platform and a strengthened management team, adding EUSA Pharma's specialty commercial infrastructure in the United States and Europe and its international distribution network to our existing U.S. specialty product platform. Our international footprint now includes headquarters in Dublin, Ireland and multiple offices in the United States, the United Kingdom and other countries in Europe, with approximately 610 employees in eleven countries. We intend that our operations will function as an efficient platform for further growth, leveraging our commercial, medical and scientific experience to seek to maximize the potential of our existing products and expand our product portfolio through a combination of internal development, acquisition and in-licensing.

In 2013, we plan to focus on executing on our strategy. We anticipate that we will continue to face a number of challenges and risks to our business and our ability to execute our strategy. For example, while we now have a more diversified product portfolio than in the past, our financial results remain significantly influenced by sales of Xyrem, which accounted for 65% of our net product sales for 2012. As a result, we continue to place a high priority on seeking to maintain and increase sales of Xyrem in its approved indications, while remaining focused on ensuring the safe and effective use of the product, and lifecycle management of the product including enhancing and enforcing our intellectual property rights.

Our ability to maintain or increase Xyrem product sales is subject to a number of risks and uncertainties, including those discussed in Part I, Item 1A of this Annual Report on Form 10-K. In particular, there are two abbreviated new drug applications, or ANDAs, submitted to the FDA by third parties seeking to market generic versions of Xyrem. We have sued both third parties for infringement of our patents, and the litigation proceedings are ongoing. We cannot predict the timing or outcome of these proceedings. We expect that the approval or tentative approval of an ANDA

resulting in the launch of a generic version of Xyrem would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are continuing our work on various regulatory matters, including our work with the FDA on updated documents that we have submitted to the FDA on our Xyrem Risk Management Program. The updated documents are intended to conform to current formatting requirements for risk evaluation and mitigation strategies, or REMS, required by law, as well as to make other updates to the program and its documentation. We cannot predict the timing of finalization, or the final terms, of our updated REMS documents. The FDA may impose new requirements for certain elements that we have implemented in our Xyrem Risk Management Program, or require us to modify our current practices. Any such requirements, depending on their substance and the extent of modifications required, could 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.

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

- the challenges of protecting our intellectual property rights;
- the need to obtain appropriate pricing and reimbursement for our products in an increasingly challenging environment due to, among other things, the attention being paid to health care cost containment and other austerity measures in the United States and worldwide;
- the ongoing regulation and oversight by the FDA, the U.S. Drug Enforcement Administration, or DEA, and non-U.S. regulatory agencies, including with respect to product labeling, requirements for distribution, obtaining sufficient DEA quotas where needed, marketing and promotional activities, adverse event reporting and product recalls or withdrawals;
- the challenges of achieving and maintaining commercial success of our products, such as obtaining sustained acceptance of our products by patients, physicians and payors;
- our dependence on sole source suppliers to continue to meet our ongoing commercial needs, especially when our supply demands are growing; and
- the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success and regulatory approval.

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

Results of Operations

The following discussions of our results of continuing operations exclude the results related to the women's health business. This business has been segregated from continuing operations and reflected as a discontinued operation. See "Income from Discontinued Operations, Net of Taxes" below. The following table presents revenues and expenses from continuing operations for the years ended December 31, 2012, 2011 and 2010 (amounts in thousands):

	2012	Change		2011	Change		2010
Product sales, net	$580,527	118	%	$266,518	57	%	$170,006
Royalties and contract revenues	5,452	(5	)%	5,759	53	%	3,775
Cost of product sales (excluding amortization of acquired developed technologies)	78,425	463	%	13,942	3	%	13,559
Selling, general and administrative	223,882	106	%	108,936	58	%	68,996
Research and development	20,477	45	%	14,120	(45	)%	25,612
Intangible asset amortization	65,351	777	%	7,448	(5	)%	7,825
Interest expense, net	16,869	954	%	1,600	(87	%)	12,724
Foreign currency loss	3,620	N/A(1)		—	N/A(1)		—
Loss on extinguishment of debt	—	N/A(1)		1,247	(90	%)	12,287
Income tax benefit	83,794	N/A(1)		—	N/A(1)		—

(1) Comparison to prior period is not meaningful.

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Product Sales, Net

The following table presents product sales for the years ended December 31, 2012, 2011 and 2010 (amounts in thousands):

	2012	Change		2011	Change		2010
Xyrem	$378,663	62	%	$233,348	64	%	$142,630
Erwinaze/Erwinase	72,083	N/A(1)		—	N/A(1)		—
Prialt	26,360	N/A(1)		—	N/A(1)		—
Psychiatry:							—
Luvox CR	42,419	28	%	33,170	21	%	27,376
FazaClo LD	22,023	N/A(1)		—	N/A(1)		—
FazaClo HD	12,047	N/A(1)		—	N/A(1)		—
Other	26,932	N/A(1)		—	N/A(1)		—
Product sales, net	580,527	118	%	266,518	57	%	170,006
Royalties and contract revenues	5,452	(5	%)	5,759	53	%	3,775
Total revenues	$585,979	115	%	$272,277	57	%	$173,781

(1) Comparison to prior period is not meaningful.

Xyrem product sales increased in 2012 and 2011 compared to the immediately preceding years, primarily due to higher average net selling prices in the 2012 and 2011 periods resulting from price increases that we instituted in those periods and, to a lesser extent, increases in sales volume of 11% in both 2012 and 2011. Price increases were instituted based on market analysis. Growth in sales volumes in the 2012 and 2011 periods were driven by an increase in the average number of patients on Xyrem. This increase was due primarily to 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. The sales volume increase in the 2012 period was also impacted by the deployment of a dedicated Xyrem sales force to increase physician awareness of narcolepsy and its diagnosis, and, more recently, by a higher number of prescriptions from new or previously infrequent physician prescribers. Sales of Erwinaze/Erwinase since the EUSA Acquisition on June 12, 2012 were $72.1 million in 2012. Prialt product sales included sales of $4.6 million in 2012 related to a supply agreement to provide Prialt to Eisai Co. Limited for distribution and sale in Europe. Luvox CR product sales increased in 2012 compared to 2011 due to price increases, partially offset by a decrease in sales volumes of 3%. Luvox CR product sales increased in 2011 compared to 2010, primarily due to price increases and to a lesser extent an increase in sales volume of 4%. In 2012, a generic version of FazaClo LD was launched, which has had a negative impact on sales of FazaClo LD and may have a negative impact on sales of FazaClo HD in future periods. We expect total product sales will increase in 2013 over 2012 primarily due to growth in sales of Xyrem, Erwinaze/Erwinase and Prialt, partially offset by decreases in sales of other products.

Royalties and Contract Revenues

Royalties and contract revenues in 2012 of $5.5 million is consistent with prior year levels. Royalties and contract revenues increased in 2011 compared to 2010, primarily due to the recognition of a $1.5 million milestone payment related to sales of Xyrem in Europe by UCB Pharma Limited, or UCB, under a license agreement. We expect royalties and contract revenues to increase slightly in 2013 as compared to 2012 primarily due to the inclusion of a full year of royalties from the acquired EUSA business.

Cost of Product Sales

Cost of product sales increased in 2012 compared to 2011, primarily due to cost of product sales in relation to products acquired in the Azur Merger and the EUSA Acquisition, including acquisition accounting inventory fair value step-up adjustments of $16.8 million in 2012. Cost of product sales increased slightly in 2011 compared to 2010. Gross margins as a percentage of product sales were 86.5%, 94.8% and 92.0% in 2012, 2011 and 2010, respectively. Our gross margin percentage in 2012 as compared to 2011 was lower primarily due to the effect of the

purchase accounting inventory fair value step-up adjustments recorded as cost of product sales and also due to the impact of our product mix in 2012. The gross margin on products acquired during 2012 is lower than the gross margins earned on our legacy products. Our gross margin percentage in 2011 as compared to 2010 was higher primarily due to increases in average selling prices. We expect our gross margin

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percentage to increase slightly in 2013 compared to 2012 primarily driven by a decrease in the amount of acquisition accounting inventory fair value step-up adjustments and also a change in product mix.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in 2012 compared to 2011 primarily due to an increase in salary and benefit related headcount expenses (including share-based compensation) of $49.0 million driven primarily by increased headcount following the Azur Merger in January 2012 and the EUSA Acquisition in June 2012. In addition, sales and promotional expenses in 2012 increased by $12.8 million compared to 2011 primarily due to the expansion of our organization, including our increased commercial presence. Transaction, integration and restructuring expenses were $10.4 million higher in 2012 compared to 2011 primarily due to expenses related to the Azur Merger and the EUSA Acquisition. In 2011 we incurred transaction and integration costs related to the Azur Merger only. Professional and service fees increased in 2012 by $15.2 million compared to 2011 due to the continuing operations of the larger entity. Travel, facility and maintenance expenses increased in 2012 by $15.5 million compared to 2011 primarily due to an increase in the number of facilities that we occupy in the United States and in Europe.

Selling, general and administrative expenses were higher in 2011 compared to 2010 primarily due to an increase in employee-related expenses of $15.9 million as a result of an increase in commercial activities, higher share-based compensation expense and higher legal and professional expenses of $11.2 million associated with the Azur Merger.

We expect that selling, general and administrative expenses will be higher in 2013 than in 2012 due to the inclusion of a full year of expense with respect to the acquired EUSA business, an increase in direct marketing spend on key products and increased headcount to support the larger, global corporate 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 clinical studies performed by clinical research organizations, materials and supplies, and other third-party fees. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. We do not track fully-burdened research and development expenses on a project-by-project basis. We manage our research and development expenses by identifying the research and development activities that we anticipate will be performed during a given period and then prioritizing efforts based on our assessment of what development activities are important to our business and have a reasonable probability of success, and by dynamically allocating resources accordingly. We also continually review our development pipeline projects and the status of their development and, as necessary, reallocate resources among our development pipeline projects that we believe will best support the future growth of our business.

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

	Year Ended December 31,		
	2012	2011	2010
Personnel expenses	$10,432	$10,581	$11,422
Clinical studies and outside services	8,566	2,145	12,320
Other	1,479	1,394	1,870
Total	$20,477	$14,120	$25,612

Research and development expenses increased by $6.4 million in 2012 compared to 2011 primarily due to increased clinical studies and outside services costs related to the generation of additional clinical data and the development of line extensions for existing products, and to a lesser extent, costs incurred to develop new product candidates that we acquired in the EUSA Acquisition and the Azur Merger. Personnel expenses and other research and development expenses in 2012 were consistent with prior year levels.

Research and development expenses decreased by $11.5 million in 2011 compared to 2010 primarily due to lower clinical studies and outside services costs, and to a lesser extent, a decrease in personnel and other expenses. The decrease in 2011 was primarily due to our decision to discontinue the development of JPZ-6, our then product

candidate for the treatment of fibromyalgia, as well as our discontinuation of certain research activities related to two line extension projects for existing products.

A discussion of the risks and uncertainties with respect to our research and development activities, including completing the development of our product candidates, and the consequences to our business, financial position and growth prospects can be found in “Risk Factors” in Part I, Item 1A of this report.

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Intangible Asset Amortization

We acquired finite-lived intangible assets in connection with the Azur Merger and the EUSA Acquisition that are expected to be amortized over their useful economic lives of two to 15 years. We recorded amortization related to these intangibles of $59.7 million in 2012, which accounted for all of the increase in the amortization expense. During 2011 and 2010, our intangible assets consisted primarily of developed technology related to Xyrem and Luvox CR.

Interest Expense, Net

Interest expense increased in 2012 as compared to 2011 primarily due to a larger debt balance. In June 2012, we entered into a credit agreement that provides for a term loan in an aggregate principal amount of $475.0 million, which bears interest at a variable interest rate that was 5.25% as of December 31, 2012. In July 2011, we fully repaid a term loan outstanding at that time. Interest expense decreased in 2011 compared to 2010 due to lower average borrowings and lower interest rates.

Foreign Currency Loss

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

Loss on Extinguishment of Debt

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

Income Tax Benefit

During 2012, we recognized an income tax benefit of $83.8 million. This tax benefit included a deferred tax benefit of $113.9 million, offset by an income tax provision of $30.1 million, relating to the United States, Ireland and other foreign jurisdictions. 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.

During 2011 and 2010, we had operations only in the United States and made no provision for income taxes due to our utilization of U.S. federal net operating loss carryforwards to offset both regular taxable income and alternative minimum taxable income and to our utilization of deferred state tax benefits. The 2012 effective income tax rate on continuing activities before utilization of NOL 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.

Income from Discontinued Operations, Net of Taxes

In 2012, we sold the women’s health business to 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.

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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	$(5,787)
Income tax expense (1)	(2,020)
Loss from discontinued operations, net of taxes	(7,807)
Gain on sale of discontinued operations (2)	35,244
Income from discontinued operations, net of taxes	$27,437

(1) The income tax expense relates to profits generated by the women's health business in 2012 which are attributable to the United States.
(2) The gain on sale of discontinued operations was not impacted by income taxes as the value attributable to the women's health business was held in a non-taxable jurisdiction.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we use certain non-GAAP adjusted financial measures as shown in the table and footnotes below. We believe that these non-GAAP financial measures are 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 during 2012. They are not meant to be considered in isolation or as a substitute for comparable GAAP measures, and should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP. Our management regularly uses these supplemental non-GAAP financial measures internally to understand, manage and evaluate our business and make operating decisions. Compensation of our executives is based in part on the performance of our business based on these non-GAAP measures. In addition, we believe that the use of these non-GAAP measures enhances the ability of investors to compare our results from period to period. The adjusted financial measures, as used by us in this report, may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by our competitors and other companies. Adjusted net income measures exclude from continuing operations intangible asset amortization, share-based compensation expense, acquisition accounting inventory fair value step-up adjustments, transaction and integration costs, restructuring charges, change in fair value of contingent consideration, loss on extinguishment of debt, other non-cash expense/income, tax related to acquisition restructuring and the release of the valuation allowance against substantially all of our U.S. deferred tax assets, and adjust the income tax provision to the estimated amount of taxes payable in cash.

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

	Year Ended December 31,		
	2012	2011	2010
GAAP income from continuing operations	$261,149	$124,984	$32,778
Intangible asset amortization	65,351	7,448	7,825
Share-based compensation expense	23,006	20,704	