JAZZ PHARMACEUTICALS INC
Form 10-K
March 04, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2009

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, INC.

(Exact name of registrant as specified in its charter)

Delaware	05-0563787
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3180 Porter Drive

Palo Alto, CA 94304

(650) 496-3777

(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
Common Stock, par value $.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 ¨ No x

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 x

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

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

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

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

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2009, based upon the last sale price reported for such date on the NASDAQ Global Market, was $43,684,868. The calculation of the aggregate market value of voting and non-voting stock excludes 17,268,570 shares of the registrant s common stock held by current executive officers, directors, and stockholders that the registrant has concluded are affiliates of the registrant. 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 26, 2010, a total of 31,269,350 shares of the registrant s Common Stock, $.0001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement for the 2010 Annual Meeting of Stockholders 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, INC.

2009 ANNUAL REPORT ON FORM 10-K

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In this report, Jazz Pharmaceuticals, we, us, and our refer to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries. We own or have rights to various copyrights, trademarks, and trade names used in our business, including the following: Jazz Pharmaceuticals®; Xyrem® (sodium oxybate) oral solution; Luvox CR® (fluvoxamine maleate) Extended-Release Capsules; and Luvox® (fluvoxamine). This report also includes trademarks, service marks, and trade names of other companies.

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This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, potential and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading Risk Factors. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I

Item 1. Business

Overview

We are a specialty pharmaceutical company that, since our inception, has focused on the development and commercialization of pharmaceutical products to meet important unmet medical needs in neurology and psychiatry. With our JZP-6 product candidate for the treatment of fibromyalgia, for which we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in December 2009, and which NDA was filed by the FDA in February 2010, we expanded our development activities to include rheumatology and pain management. We currently market two products: Xyrem (sodium oxybate) for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy; and Luvox CR (fluvoxamine maleate) for the treatment of both obsessive compulsive disorder and social anxiety disorder. We are building a portfolio of products through a combination of internal development, acquisition and in-licensing activities, and we utilize our specialty sales force to promote our products in our target markets. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes our two marketed products, which generated net product sales of $115.1 million in 2009, our late-stage JZP-6 product candidate, and several product candidates in various stages of clinical development.

Our marketed products and late-stage product candidate are:

Xyrem® (sodium oxybate) oral solution. Xyrem is the only product approved by the FDA for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain s inability to regulate sleep-wake cycles. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. We promote Xyrem in the United States for its FDA-approved indications to sleep specialists, neurologists, pulmonologists and psychiatrists through our specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring the rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 14 countries in Europe. In 2009, our Xyrem net sales were $96.8 million.

Luvox CR® (fluvoxamine maleate) Extended-Release Capsules. Once-daily Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder and social anxiety disorder in February 2008. We began promoting Luvox CR through our specialty sales force in April 2008. Luvox CR is a once-daily extended-release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, or SSRI. According to the National Institute of Mental Health, obsessive compulsive disorder and social anxiety disorder affect approximately 2.2 million and 15 million adults in the United States, respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the United States. In 2009, our Luvox CR net sales were $18.3 million.

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JZP-6 (sodium oxybate). We are developing sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. According to the American College of Rheumatology, approximately two to four percent of the U.S. population suffers from fibromyalgia. Our development program includes two completed Phase III pivotal clinical trials and a long-term safety trial that is expected to be completed in mid-2010. In November 2008 and June 2009, we announced positive top-line results from our first and second Phase III pivotal clinical trials, respectively. The two randomized, double-blind, placebo-controlled studies demonstrated that sodium oxybate significantly decreased pain and fatigue, and improved daily function and patient global impression of change, in patients with fibromyalgia. We submitted an NDA for JZP-6 in December 2009 and the NDA was filed by the FDA in February 2010. If our NDA is approved by the FDA, we expect to market JZP-6 in the United States to physicians who treat fibromyalgia patients, through an expanded specialty sales force and/or in partnership with third parties. We have licensed to UCB the commercialization rights to JZP-6 in 54 countries outside of the United States in exchange for development funding, commercial milestones and royalties.

Our other product candidates in clinical development are oral tablet forms of sodium oxybate; JZP-8 (intranasal clonazepam), being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens; JZP-4 (elpetrigine), being developed for the treatment of epilepsy and bipolar disorder; and JZP-7 (ropinirole gel), being developed for the treatment of restless legs syndrome. We are actively seeking development partners for JZP-4, JZP-7 and JZP-8 and we do not anticipate significant progress on these programs in the near term until we obtain a partner or otherwise obtain additional funding.

Marketed Products and Late-Stage Product Candidate

Xyrem (sodium oxybate) oral solution

Xyrem is a sodium oxybate oral solution approved in the United States for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. Sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a formulation of the sodium salt of g-hydroxybutyrate, an endogenous neurotransmitter and metabolite of g-aminobutyric acid. Initial FDA approval for Xyrem as a treatment for cataplexy in patients with narcolepsy was obtained in July 2002, and in November 2005, the FDA approved a supplemental NDA, or sNDA, for the treatment of excessive daytime sleepiness in patients with narcolepsy. Xyrem is currently the only FDA-approved treatment for both excessive daytime sleepiness and cataplexy in patients with narcolepsy. In 2009, our net product sales of Xyrem were $96.8 million.

Market Opportunity

Narcolepsy is a chronic neurologic disorder caused by the brain s inability to regulate sleep-wake cycles normally. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. The primary symptoms of narcolepsy include excessive daytime sleepiness, cataplexy, sleep paralysis, sleep-onset and waking hallucinations and fragmented nighttime sleep. These symptoms can lead to a variety of complications, such as limitations on education and employment opportunities, driving or machine accidents, difficulties at work resulting in disability, forced retirement or job dismissal and depression.

Cataplexy. Cataplexy, the sudden loss of muscle tone, is the most distinctive symptom of narcolepsy. According to a 1996 article published in *Neurologic Clinics,* cataplexy is present in between 60% and 100% of patients with narcolepsy. Cataplexy can range from slight weakness or a drooping of the face to the complete loss of muscle tone and it is often triggered by strong emotional reactions such as laughter, anger or surprise.

Excessive Daytime Sleepiness. Excessive daytime sleepiness is the most common symptom of narcolepsy and is present in all narcolepsy patients. Excessive daytime sleepiness results in a chronic, pervasive sleepiness that triggers sudden irresistible and overwhelming urges to sleep (inadvertent naps and sleep attacks).

Attributes of Xyrem

Xyrem is the only product approved by the FDA to treat both excessive daytime sleepiness and cataplexy in patients with narcolepsy. Xyrem is administered at night in two equal doses and quickly metabolized so that during the daytime, very little of the active drug is present in the patient. Xyrem has a well established safety profile. 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.

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Commercialization

We promote Xyrem in the United States through our approximately 120 person specialty sales force. Pursuant to an agreement originally executed in 2003 and subsequently amended, we have licensed to UCB the exclusive right to register and market Xyrem for the treatment of narcolepsy in 54 countries outside of the United States in exchange for milestone and royalty payments to us. UCB currently markets the product in 14 countries in Europe. We are entitled to additional commercial milestone payments from UCB of up to $6.0 million specifically associated with UCB s sales of Xyrem for the treatment of narcolepsy and royalties on all commercial sales of Xyrem by UCB. In October 2005, the European Medicines Agency, or EMA, approved Xyrem for the treatment of cataplexy in adult patients with narcolepsy, and in March 2007, the EMA approved the product for the treatment of narcolepsy with cataplexy in adult patients. In December 2006, we licensed to Valeant the Canadian marketing rights to Xyrem for the treatment of narcolepsy, subject to our right to later reacquire these rights. Valeant began marketing the product in Canada in 2007.

The term of our agreement with UCB, as it applies to Xyrem for the treatment of narcolepsy, extends to the later of the expiration of our associated patent rights in the territories covered by the agreement or ten years from the date of EMA approval to commercially promote and distribute Xyrem for the treatment of narcolepsy, subject to automatic extension unless and until UCB terminates the agreement. UCB may terminate our agreement for any reason upon 12 months notice. We are responsible for supplying Xyrem to UCB in exchange for supply price payments. If we are materially unable to comply with our obligations to supply Xyrem to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months notice or assume manufacturing responsibility for Xyrem in their territory.

The FDA has granted Xyrem orphan drug status in the United States for excessive daytime sleepiness in patients with narcolepsy, which provides marketing exclusivity in the United States until November 2012 for this indication. The FDA had previously granted orphan drug exclusivity in the United States for cataplexy in patients with narcolepsy, but this exclusivity expired in July 2009. In addition to orphan drug exclusivity, Xyrem is covered by two formulation patents and a distribution patent that are listed in the FDA s approved drug products with therapeutic equivalence evaluation document, or Orange Book. The formulation patents will expire in 2020 and the distribution patent will expire in 2024. An additional process patent that covers the product is not listed in the Orange Book and expires in 2019. The Orange Book, among other things, lists drug products approved by the FDA and identifies applicable patent and non-patent marketing exclusivities. The listing of our formulation patents and distribution patent in the Orange Book requires potential competitors to certify as to non-infringement or invalidity of the patent prior to FDA approval of their product candidates unless they are willing to postpone market entry until patent expiry.

Our marketing, sale and distribution of Xyrem are subject to a Risk Evaluation and Mitigation Strategy program, or REMS, required in conjunction with Xyrem s approval by the FDA. Under the Xyrem REMS, Xyrem is distributed through a single central pharmacy. The central pharmacy we use is Express Scripts Specialty Distribution Services, or Express Scripts, with which we have an exclusive relationship. The central pharmacy maintains physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient receives materials concerning the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and obtain additional information by contacting the patient s insurance company. The central pharmacy also speaks with the patient before it ships any Xyrem to the patient. The central pharmacy ships the product directly to the patient by a courier service, and the patient or his/her designee signs for the package. The initial shipment may only be for a one-month supply and physicians may only prescribe up to six months of supply of Xyrem at one time. We believe that the strict manufacturing and distribution controls on sodium oxybate and Xyrem, and the strict risk management procedures required to market and sell the product, may make it less commercially attractive than it would otherwise be for other companies to seek to introduce generic formulations of Xyrem in the United States.

Pursuant to our exclusive agreement with Express Scripts and Curascript, Inc., or Curascript, an affiliate of Express Scripts, Express Scripts provides distribution and Express Scripts and Curascript provide other customer support services to us related to the sale and marketing of Xyrem in the United States. We are billed monthly for the services performed by Express Scripts and Curascript. Our agreement with Express Scripts and Curascript expires on December 31, 2010, subject to automatic one-year extensions thereafter until either party provides notice to the other of its intent to terminate the agreement at least 120 days prior to the end of the term. We may terminate the agreement with Express Scripts and Curascript upon five days notice if Express Scripts or Curascript is not in compliance with applicable regulatory requirements.

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We have contracted separately with third parties to supply the sodium oxybate used to produce Xyrem and to manufacture the product. We rely on a single source for our supply of sodium oxybate and a single manufacturer of the product. Lonza, Inc., or Lonza, our supplier of sodium oxybate has publicly announced its intention to close the plant where it manufactures sodium oxybate for us. We believe that there are other manufacturers that could manufacture and supply us with necessary quantities of sodium oxybate, and we are currently in discussion with a number of potential suppliers; however, any new suppliers will need to be approved by the FDA. In addition, quotas from the United States Drug Enforcement Administration, or DEA, are required in order to manufacture and package sodium oxybate. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for the request, obtaining a DEA quota is a difficult and time consuming process. In order to have Lonza manufacture additional supplies, or to have a new supplier qualified, we will need additional DEA quota. We will need to negotiate with the DEA any time we need additional quota, and these negotiations may be protracted and may not provide us with as much quota as we believe is needed on a timely basis, or at all.

Competition

As an alternative to Xyrem, cataplexy is often treated with tricyclic antidepressants and selective serotonin or norepinephrine reuptake inhibitors, although Xyrem is the only drug that has been approved by the FDA for the treatment of cataplexy. Tricyclic antidepressants are a class of antidepressant drugs first used in the 1950s. The use of these drugs can often result in somnolence, which exacerbates excessive daytime sleepiness already experienced by all patients with narcolepsy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil® (modafinil) and Nuvigil® (armodafinil) which are each marketed by Cephalon, Inc. Xyrem, Provigil and Nuvigil are approved for the treatment of excessive daytime sleepiness in patients with narcolepsy, but Xyrem is also approved for the treatment of cataplexy. Provigil and Nuvigil are also approved for the treatment of excessive daytime sleepiness in patients with obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder.

Xyrem is a liquid solution that is taken twice nightly. Provigil and Nuvigil are pills that are usually taken once in the morning for excessive daytime sleepiness by patients with narcolepsy. Provigil and Nuvigil are distributed by numerous pharmacies. Xyrem s REMS requires that it be distributed in the United States through a single central pharmacy, and it takes longer for a patient to receive medicine under the Xyrem distribution system than it takes to fill a typical prescription at a pharmacy. Xyrem is administered at night and can be used in conjunction with stimulants and wakefulness promoting drugs, which are administered during the day. During the pivotal Phase III trials of Xyrem for use in patients with narcolepsy, approximately 80% of patients maintained concomitant stimulant use.

Luvox CR (fluvoxamine maleate) Extended-Release Capsules

Luvox CR is a once-a-day product approved by the FDA for the treatment of obsessive compulsive disorder and social anxiety disorder. Luvox CR received FDA approval on February 28, 2008, and we began promoting Luvox CR in April 2008. Our specialty sales force promotes Luvox CR to psychiatrists, and certain general practitioners, for its approved indications. In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR in the United States. Solvay retained the rights to market and distribute Luvox CR outside of the United States. Luvox CR is a once-daily extended-release formulation of fluvoxamine developed by Solvay in collaboration with Elan. Luvox CR incorporates Elan s SODAS drug delivery technology which is designed to minimize peak-to-trough plasma fluctuations over a 24-hour period and enable once-a-day dosing. FDA approval of Luvox CR includes our post marketing commitment to conduct a safety and efficacy study in adolescent patients with social anxiety disorder, and to conduct a long-term safety and efficacy study in patients with social anxiety disorder.

Market Opportunity

Obsessive Compulsive Disorder. 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 use rituals to help control anxiety related to their obsessive thoughts, and these rituals become disruptive to their daily life.

Social Anxiety Disorder. Social anxiety disorder is characterized by the fear and avoidance of everyday social or performance situations where patients feel that others may scrutinize them and they may embarrass themselves. According to the National Institute of Mental Health, social anxiety disorder affects approximately 15 million adults in the United States. Despite the prevalence of the disorder, social anxiety disorder remains underdiagnosed and undertreated by clinicians.

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Attributes of Luvox CR

We believe that Luvox CR offers an opportunity to improve upon the immediate-release formulation of fluvoxamine, the active pharmaceutical ingredient in Luvox CR. Fluvoxamine, in its immediate-release form, is a broadly prescribed therapy for the treatment of obsessive compulsive disorder.

In a Phase III clinical trial in obsessive compulsive disorder, patients taking Luvox CR demonstrated a statistically significant improvement compared to patients receiving placebo as assessed by the Yale-Brown Obsessive Compulsive Scale at week 12. In two Phase III clinical trials in social anxiety disorder, patients receiving Luvox CR demonstrated statistically significant improvement compared to patients receiving placebo as assessed by the Liebowitz Social Anxiety Scale total score at week 12.

We believe the once-a-day dosing regimen afforded by the extended-release formulation of Luvox CR improves patient compliance and acceptability. Furthermore, we believe that Luvox CR offers a strong combination of proven efficacy in treating obsessive compulsive disorder and social anxiety disorder and favorable tolerability with a weight neutral profile and a low incidence of sexual adverse events seen in the 12-week clinical trials.

Commercialization

We began promoting Luvox CR in April 2008. A substantial majority of prescriptions for the treatment of obsessive compulsive disorder and social anxiety disorder are written by psychiatrists. We continue to believe that this concentration provides an attractive, focused market opportunity for us.

Through our license agreement with Solvay, we have the exclusive rights to market and distribute Luvox CR in the United States, and Solvay retained the rights to market and distribute Luvox CR outside of the United States. Solvay assigned to us its rights and obligations under its license and supply agreement with Elan, and we have sublicensed back to Solvay the rights under that agreement outside of the United States. Under a supply agreement with Solvay, we are responsible for purchasing, and Solvay is responsible for providing us with, the active pharmaceutical ingredient necessary to manufacture Luvox CR. We are responsible for providing the active pharmaceutical ingredient free of charge to Elan under the license and supply agreement with Elan. Elan has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. We are responsible for satisfying Solvay s commercial requirements of Luvox CR outside of the United States in exchange for supply price payments to us. Currently, Solvay does not market Luvox CR outside of the United States. We paid Solvay $2.0 million upon execution of the agreement. As a result of approval by the FDA and the first commercial sale of Luvox CR, both of which occurred during the first quarter of 2008, we were obligated to make payments under this agreement in 2008 totaling $41.0 million. We amended the agreement several times in 2008 and paid Solvay $27.0 million in 2008 under the original and amended terms of the agreement. In February 2009, we amended the agreement again, changing the timing of our remaining payment obligations of $19.0 million. Under that most recent amendment, we paid Solvay $6.0 million in 2009, and we owe Solvay an additional $4.0 million in 2010, $4.5 million in 2011, and $5.0 million in 2012. We also agreed to pay Solvay $5.0 million in 2015 if our net sales of Luvox CR reach a cumulative amount of $100 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the United States as of December 31, 2014. In addition, pursuant to this most recent amendment, Solvay may terminate the license agreement if any of these payments is not made within fifteen days after it is due.

Our license and supply agreements with Solvay will remain in force until terminated by either Solvay or us as a result of an uncured breach by the other party.

The license and supply agreement with Elan that was assigned to us by Solvay will expire upon the later of (i) 10 years after commercial launch of Luvox CR or (ii) the last to expire patent licensed under the agreement with Elan. In addition, either we or Elan may terminate the license agreement in the event of an uncured material breach or in the event of a change of ownership of the other party in excess of 40% or an acquisition of 20% or more of the equity of the other party by a third party offering competing products.

Luvox CR s FDA approval included a commitment for two Phase IV clinical trials, one in adolescent patients with social anxiety disorder and one a long-term duration of effect study in patients with social anxiety disorder. We are in the process of planning these studies and we are in discussion with the FDA concerning the studies. The cost of these Phase IV clinical trials is significant.

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Luvox CR has three years of marketing exclusivity that began February 28, 2008, the date Luvox CR was approved by the FDA. In addition, Luvox CR is covered by a patent owned by Elan with claims covering the orally administered formulation of extended-release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours. This patent is listed in the Orange Book, and will expire on May 10, 2020. In August 2009, we received a Paragraph IV Patent Certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an abbreviated new drug application, or ANDA, with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen Pharmaceuticals, Inc., or Anchen, advising that Anchen has filed an ANDA with the FDA for a generic version of Luvox CR. We and Elan have filed lawsuits in response to the Paragraph IV certifications. For a more detailed description of our dispute with Anchen and Actavis, please see Item 3. Legal Proceedings. We cannot assure you that these lawsuits will prevent the introduction of generic products for any particular length of time, or at all.

Competition

Selective serotonin reuptake inhibitors, or SSRIs, are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. In addition, serotonin-norepinephrine reuptake inhibitors, or SNRIs, are sometimes used to treat anxiety disorders, including obsessive compulsive disorder and social anxiety disorder.

The presence in a particular patient of more than one psychiatric condition is an important consideration by physicians in the selection of drugs to treat obsessive compulsive disorder and/or social anxiety disorder. Certain drugs are approved for one or more well recognized psychiatric disorders such as major depressive disorder, which may give them broader recognition and use by physicians and patients than Luvox CR, which is indicated only for obsessive compulsive disorder and social anxiety disorder.

The market for drugs to treat obsessive compulsive disorder and social anxiety disorder is very fragmented. We believe that, in addition to Luvox CR, a large number of branded, and related generic, drugs are used for the treatment of these disorders.

Seven branded products, including Luvox CR, and generic equivalents of many of them, have been approved by the FDA for the treatment of obsessive compulsive disorder, and we believe that other branded and generic products are regularly used for the treatment of obsessive compulsive disorder. We believe that none of these products has a significant percentage of the market.

Five branded products, including Luvox CR, and generic equivalents of many of them, have been approved by the FDA for the treatment of social anxiety disorder, and we believe that other branded and generic products are regularly used for the treatment of social anxiety disorder. We believe that none of these products has a significant percentage of the market.

The currently approved SSRI products, including Luvox CR, all have significant adverse side effects and a boxed warning concerning suicidal thinking and behavior in children and adolescents.

JZP-6 (sodium oxybate)

We are developing sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. In November 2008 and June 2009, we announced positive top-line results from our first and second Phase III pivotal clinical trials, respectively, of JZP-6 for the treatment of fibromyalgia. Both randomized, double-blind, placebo-controlled studies achieved their primary endpoints, demonstrating that sodium oxybate significantly decreased pain and fatigue, and improved daily function and patient global impression of change, in patients with fibromyalgia. We submitted an NDA for this product candidate in December 2009 and it was filed by the FDA in February 2010.

Market Opportunity

Fibromyalgia is a chronic condition characterized by widespread pain. According to the American College of Rheumatology, approximately two to four percent of the U.S. population suffers from fibromyalgia. Fibromyalgia is believed to be a central nervous system condition, resulting from neurological changes in how the brain perceives and responds to pain. In addition to pain, the main symptoms are fatigue, disturbed sleep and morning stiffness. The exact causes of fibromyalgia are unknown. It may be triggered by physical trauma, emotional stress, chronic pain or infection. Genetics, neurochemicals that affect pain modulation, neurohormones and sleep physiology abnormalities are thought to play a role. Research also has suggested a relationship between sleep and pain. Fibromyalgia patients experience a high prevalence of sleep problems, including a reduction in non-restorative or deep sleep.

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Attributes of JZP-6

We are seeking FDA approval of JZP-6 for the treatment of fibromyalgia. While the primary symptom of fibromyalgia is widespread pain, fatigue, disturbed sleep and morning stiffness are also recognized as common symptoms. We believe that JZP-6 will, if approved for commercial sale, provide important benefits to patients by offering improvements in three important fibromyalgia symptoms: pain, fatigue and sleep disturbances.

Product Development

The first 14-week Phase III pivotal clinical trial conducted in the United States included 548 adult patients with fibromyalgia randomized to one of three treatment arms: sodium oxybate 4.5 grams per night, sodium oxybate 6 grams per night or placebo. The second 14-week Phase III trial, conducted in the United States and seven European countries, included 573 adult patients with fibromyalgia randomized to one of the same three treatment arms used in the first Phase III pivotal clinical trial. For both trials, the primary outcome measure, viewed by both the FDA and the EMA as a clinically meaningful endpoint, was the proportion of patients who achieved at least 30% reduction in pain from baseline to endpoint based on the Pain Visual Analog Scale. The EMA has indicated that the Fibromyalgia Impact Questionnaire data is equally relevant.

A significant number of patients in our first Phase III pivotal clinical trial treated with sodium oxybate achieved 30% or greater improvement in their pain compared to patients treated with placebo. Of those patients receiving sodium oxybate treatment, 46.2% of patients treated with 4.5 grams of sodium oxybate nightly and 39.3% of patients treated with 6 grams of sodium oxybate nightly reported at least this level of pain relief as measured by the Pain Visual Analog Scale, compared with 27.3% of patients treated with a placebo. Likewise, in our second Phase III pivotal clinical trial, significantly more patients treated with sodium oxybate achieved 30% or greater improvement in their pain compared to patients treated with a placebo. Of those patients receiving sodium oxybate treatment, 35% of patients treated with 4.5 grams and 35% of patients treated with 6 grams reported this level of pain relief on the Pain Visual Analog Scale, compared with 20% of patients treated with a placebo. In our Phase III pivotal clinical trials, using the efficacy endpoint of at least a 30% or greater reduction in pain from baseline to endpoint, sodium oxybate demonstrated highly statistically significant overall treatment effects compared with placebo.

The results for the first Phase III pivotal clinical trial for patients physical functioning and ability to perform daily tasks, as measured by the Fibromyalgia Impact Questionnaire, were statistically significantly different from placebo for the 4.5 grams of sodium oxybate nightly dose and approached but did not achieve statistical significance for the 6 grams of sodium oxybate per night. In our second Phase III pivotal clinical trial, patients physical functioning and ability to perform daily tasks, as measured by the Fibromyalgia Impact Questionnaire, were statistically significantly different from placebo for the 4.5 gram dose and for the 6 gram dose. Reduction in pain and improvement in physical functioning and the ability to perform daily tasks were also endpoints in our successful Phase II trial of sodium oxybate in the treatment of fibromyalgia.

In both Phase III pivotal clinical trials, patients receiving sodium oxybate at both dosage levels also reported significant improvement in fatigue, another common symptom of fibromyalgia.

Adverse events for our trial patients were similar to those seen in previous experience with Xyrem in narcolepsy patients. The most common adverse events, with incidence greater than or equal to 5% and at least twice the rate of placebo, were headache, nausea, dizziness, vomiting, diarrhea, anxiety and sinusitis in the first trial and nausea, dizziness, vomiting, insomnia, anxiety, somnolence, fatigue, muscle spasms, and peripheral edema in the second trial. Sodium oxybate was generally well tolerated, with the majority of adverse events reported being mild to moderate in nature.

Commercialization Strategy

If JZP-6 is approved by the FDA, we believe that a significant number of prescriptions for the product to treat fibromyalgia will be written by pain specialists, rheumatologists and primary care physicians who are treating patients with fibromyalgia. Because the number of pain specialists, rheumatologists and primary care physicians who are treating patients with fibromyalgia in the United States is relatively small, we expect to be able to expand our specialty sales force and/or to enter into a partnership with a third party to promote JZP-6 in the United States. We may also identify one or more partners or a contract sales organization to promote JZP-6 to other physicians.

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In 2006, we amended our agreement with UCB to grant UCB the right to market JZP-6 for the treatment of fibromyalgia in 54 countries outside the United States, and in July 2008 we amended our agreement to revise the timing and size of certain milestone payments and certain notice periods for UCB s ability to terminate the agreement in whole or in part. Under the terms of the amended agreement, we are entitled to a payment of up to $25 million upon EMA approval of JZP-6, royalties on UCB s sales and additional commercial milestone payments of up to $100 million. The term of our agreement with UCB, as it applies to JZP-6, extends to the later of the expiration of our associated patent rights in the territories covered by the agreement or ten years from the date of EMA approval to commercially promote and distribute the product for the treatment of fibromyalgia, subject to automatic extension unless UCB provides 12 months notice. UCB may terminate our agreement for any reason upon 12 months notice and may terminate its rights to JZP-6 for the treatment of fibromyalgia on six months notice at any time prior to the receipt of marketing approval of JZP-6 for fibromyalgia in the European Union. We are responsible for supplying JZP-6 to UCB in exchange for supply price payments. If we are unable to comply with our obligations to supply JZP-6 to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months notice.

We have contracted with our active pharmaceutical ingredient supplier of sodium oxybate for the manufacture of Xyrem, and with our manufacturer of Xyrem, for the production of JZP-6 to conduct our clinical trials. We rely on a single source for our supply of sodium oxybate and a single manufacturer of the product. Lonza, our supplier, has publicly announced its intention to close the plant where it manufactures sodium oxybate for us. We believe that there are other manufacturers that could manufacture and supply us with necessary quantities of sodium oxybate, and we are currently in discussion with a number of potential suppliers; however, any new suppliers will need to be approved by the FDA. In addition, quotas from the DEA are required in order to manufacture and package sodium oxybate. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for the request, obtaining a DEA quota is a difficult and time consuming process. In order to have our current supplier make launch quantities of sodium oxybate for us before closing its plant, and in order to qualify a new supplier for JZP-6, we will need additional quota from the DEA. We will need to negotiate with the DEA any time we need additional quota, and these negotiations may be protracted and may not provide us with as much quota as we believe is needed on a timely basis, or at all.

We expect that one of our formulation patents and our distribution patent associated with Xyrem will also cover JZP-6. In addition, we hold a U.S. patent, which expires in 2017, and patents and patent applications in 29 other countries which expire in 2018, that cover the use of sodium oxybate for the treatment of fibromyalgia. If JZP-6 is approved by the FDA, we expect that it will receive three years of marketing exclusivity under the requirements of the Drug Price Competition and Patent Restoration Act of 1984, or Hatch-Waxman Act.

We expect that the manufacture and distribution of JZP-6 will be subject to restrictions and risk management policies similar to the restrictions and risk management processes in place for Xyrem.

Competition

Three products are currently approved by the FDA for the treatment of fibromyalgia: Lyrica® (pregabalin), marketed by Pfizer, Cymbalta® (duloxetine), marketed by Eli Lilly, and Savella® (milnacipran), marketed by Forest Laboratories. In clinical practice, a variety of drugs are often prescribed to address individual symptoms of fibromyalgia, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants. Based on available market data, we estimate that more than 13.2 million total prescriptions were written to treat fibromyalgia symptoms in 2009. Of these, approximately 26% were for antidepressants, 16% for drugs treating neuropathic pain, 14% for analgesics/antiarthritics, 13% for muscle relaxants, 9% for anti-epileptics and 22% for other therapeutics. Physicians generally prescribe one or more drug therapies based on the dominant symptom or symptoms of fibromyalgia in a particular patient. This polypharmacy approach has significant limitations, as none of the current therapies used to treat fibromyalgia is approved to comprehensively address the condition and many of its related symptoms.

We believe that the strict manufacturing and distribution controls on sodium oxybate, and that we expect on JZP-6, and the strict risk management procedures required to market and sell the product, may make it less commercially attractive than it would otherwise be for other companies to seek to introduce generic formulations of JZP-6 in the United States. However, the supply and accessibility issues could make JZP-6 less attractive to physicians and patients than other products that are currently, or that in the future may be, approved for the treatment of fibromyalgia, which could limit potential sales of JZP-6.

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Clinical Development Pipeline

JZP-8 (intranasal clonazepam)

We are developing JZP-8, an intranasal formulation of clonazepam, for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens. Recurrent acute repetitive seizures are bouts of multiple seizures occurring over a short period of time. According to an article published in the New England Journal of Medicine, approximately 30% of epilepsy patients are unresponsive, or refractory, to treatment despite being on an effective dose of an antiepilepsy regimen, and a subset of these refractory patients experience recurrent acute repetitive seizures. We have received orphan drug designation from the FDA for this product candidate for the treatment of recurrent acute repetitive seizures. In January 2009, we completed a Phase II clinical trial of JZP-8 to evaluate the effectiveness and safety of several dosage strengths for the treatment of recurrent acute repetitive seizures in patients with epilepsy who have seizures while on stable anti-epileptic regimens. We plan to conduct additional formulation testing this year and are currently evaluating our data to determine what additional studies are needed to continue this program.

JZP-4 (sodium channel antagonist)

JZP-4 is a controlled release formulation of an anticonvulsant that is believed to work through a similar mechanism of action as Lamictal® (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy, and according to the National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder. We are currently conducting product formulation activities in preparation for the possible initiation of a Phase II clinical program for JZP-4 if we are able to partner or out-license this program.

JZP-7 (ropinirole gel)

We are developing JZP-7, a transdermal gel formulation of ropinirole, a dopamine agonist, for the treatment of restless legs syndrome. Ropinirole is currently available for the treatment of restless leg syndrome in an oral dosage form. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome. We are currently evaluating the data from certain studies conducted in preparation for the possible initiation of a Phase III clinical program for JZP-7 and are seeking to partner or out-license this program.

Other Development Programs

We are developing oral tablet forms for sodium oxybate, which is currently administered as a twice nightly liquid. Our objective is to improve patient convenience and compliance. We expect to apply for patents covering these new product candidates, and marketing exclusivity may be available if we are successful in developing, and obtaining FDA approval of, these product candidates.

Sales and Marketing

As of February 26, 2010, we had a specialty sales force consisting of approximately 120 full-time sales professionals, which include our Specialty Sales Consultants, Regional Sales Managers, and Area Business Directors, who currently promote Xyrem and Luvox CR. Our Specialty Sales Consultants have an average of ten years of specialty pharmaceutical selling experience. Our regional sales management team has an average of ten years of specialty sales management experience and 18 years of industry experience. Our sales force calls primarily on sleep specialists, psychiatrists, neurologists and certain primary care physicians. If JZP-6 is approved by the FDA, we expect to be able to expand our specialty sales force and/or to enter into partnerships with third parties to promote JZP-6 to additional specialists treating fibromyalgia in the United States.

We have established marketing, commercial operations and account management, trade and distribution departments to support our sales efforts. 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.

Customers and Financial Information about Geographic Areas

In the United States, Xyrem is sold to one specialty pharmacy which ships Xyrem directly to patients. Luvox CR is sold primarily to distributors who distribute the product to pharmacies. During the year ended December 31, 2009, the specialty pharmacy for Xyrem was Express Scripts, and the principal distributors for Luvox CR in the United States were Cardinal Health, McKesson and AmerisourceBergen. Outside the United States, UCB Pharma is our principal wholesale distributor for Xyrem. Luvox CR is not sold outside the United States.

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Information on total revenues attributed to domestic and foreign sources is included in Note 16 to our consolidated financial statements.

Manufacturing

We do not have, and do not intend to establish in the near term, our own manufacturing capability for our products or product candidates, or their active pharmaceutical ingredients, or the capability to package our products. We have entered into manufacturing and supply agreements with third parties for our marketed and approved products. For each of our marketed and approved products, we utilize a single supplier for the active pharmaceutical ingredient and a separate drug product manufacturer. We have agreements with these suppliers and manufacturers for Luvox CR and Xyrem.

Pursuant to an agreement with Lonza, Inc., or Lonza, which was originally executed in November 1996 and subsequently amended, we purchase our worldwide supply of sodium oxybate from Lonza. Our purchase price for this supply is volume-based. Our agreement with Lonza continues until December 31, 2011 and will automatically extend for three-year terms thereafter until either party gives notice of its intent to terminate the agreement at least 18 months prior to the end of any such term. We may terminate the agreement upon 30 days notice if Lonza is unable to meet our minimum requirements or timeframes for supply. Lonza recently publicly announced that it is closing its U.S. facility where it manufactures sodium oxybate for us. Although Lonza is contractually obligated to meet our supply needs through December 2011 and has indicated a willingness to work with us to avoid an interruption in supply, we will likely need to secure one or more new manufacturers for the supply of sodium oxybate. Any new manufacturer of sodium oxybate would need to be registered with the DEA and obtain a DEA quota, and any new manufacturers of sodium oxybate will need to be approved by the FDA. We are using our production planning program to coordinate with Lonza to manage our inventory levels so as to minimize the risk that we run out of inventory of sodium oxybate during any transition period. However, we may need to build significant additional supplies of sodium oxybate before Lonza closes its plant, and we cannot assure you that we will be able to obtain sufficient and timely DEA quota to manufacture additional inventory or that Lonza will have the capacity to timely meet our requirements. We cannot assure you that we and any new suppliers or manufacturers will be able to complete all of the necessary validation and other activities prior to the time at which Lonza ceases manufacturing sodium oxybate for us or we run out of inventory. We are responsible for supplying Xyrem to UCB. If we are materially unable to comply with our obligations to supply Xyrem to UCB, UCB has the right under certain circumstances to terminate our agreement upon nine months notice or assume manufacturing responsibility for Xyrem in their territory. Any failure to obtain sufficient commercial and clinical quantities of sodium oxybate could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We have an agreement with Patheon Pharmaceuticals, or Patheon, which became effective in January 2008, under which we have agreed to purchase, and Patheon has agreed to supply, our worldwide supply of Xyrem. Under the agreement with Patheon, our price for the manufacture, supply and packaging of Xyrem is volume-based. The initial term of the agreement with Patheon will extend until December 2012 and may be extended, at our option, for additional two-year terms.

Quotas from the DEA are required in order to manufacture and package sodium oxybate. Lonza and Patheon each require quota from the DEA to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quota on an annual basis and requires a detailed submission and justification for the request, obtaining a sufficient DEA quota can be a difficult and time consuming process. The DEA has issued to Lonza and Patheon quotas for 2010 that are substantially the same as those issued for 2009 but that are less than the quotas that we believe we will need to provide commercial supplies of Xyrem, support our development needs and prepare for the potential commercial launch of JZP-6. In addition to needing additional quota for 2010, in light of Lonza s announcement of the closing of its plant, we will need to request quota to cover 2011 supplies. We are, in cooperation with our procurement and manufacturing partners, continuing to seek increased quotas to satisfy our needs. However, we may not be successful in obtaining increased quotas from the DEA, and without sufficient DEA quotas, there could be shortages of Xyrem, sodium oxybate or, if approved, JZP-6 for the marketplace or for use in our clinical studies, or both.

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Pursuant to a supply agreement with Solvay, we are responsible for purchasing, and Solvay is responsible for providing us with, fluvoxamine maleate, the active pharmaceutical ingredient necessary to manufacture Luvox CR. Solvay assigned to us its rights and obligations under its license and supply agreement with Elan. Pursuant to the license and supply agreement with Elan, we are responsible for providing the active pharmaceutical ingredient free of charge to Elan, and Elan has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. We are responsible for satisfying Solvay s commercial requirements of Luvox CR outside of the United States (of which there currently are none) in exchange for supply price payments to us. Lonza, through Solvay, is our sole supplier of fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR. Lonza recently publicly announced that it is closing its U.S. facility where it manufactures fluvoxamine maleate. Lonza may need to move its manufacture of fluvoxamine maleate to a new site, and all of its sites, other than the one it announced it is closing, are currently outside the United States, or Solvay may need to secure one or more new manufacturers for the supply of fluvoxamine maleate. Any new manufacturers of fluvoxamine maleate or new sites will need to be approved by the FDA. We cannot assure you that Solvay and Lonza and/or any new suppliers or manufacturers chosen by Solvay will be able to complete all of the necessary validation and other activities prior to the time at which Lonza ceases manufacturing fluvoxamine maleate for Solvay at the current U.S. site. Any failure of Solvay to obtain and supply to us sufficient commercial and clinical quantities of fluvoxamine maleate could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In an effort to minimize the risks associated with shortages of our products and product candidates for commercial and clinical trial needs, we have adopted a production planning program to assess and manage manufacturing logistics among the vendors supplying the required finished product components of active pharmaceutical ingredient, drug product and packaging.

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

Government Regulation

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

Drug Approval Process

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

The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory tests and animal tests;
- submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication;

the submission to the FDA of an NDA;

satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made, analyzed and stored to assess compliance with cGMP;

potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and

FDA review and approval of the NDA.

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Preclinical studies may include laboratory evaluations of the product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as outlined in the IND and places the proposed study on clinical hold prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Typically, each protocol is submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA s good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

Clinical trials typically are conducted in three sequential phases prior to approval, but the phases may overlap. A fourth, or post-approval, phase may include additional clinical studies. These phases generally include the following:

Phase I. Phase I clinical trials involve the initial introduction of the drug into human subjects, frequently healthy volunteers. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the adverse effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase I, the drug is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamic properties.

Phase II. Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the drug for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Although there are no statutory or regulatory definitions for Phase IIa and Phase IIb, Phase IIa is commonly used to describe a Phase II clinical trial evaluating efficacy, adverse effects, and safety risks and Phase IIb is commonly used to describe a subsequent Phase II clinical trial that also evaluates dosage tolerance and optimal dosage. Some of our product candidates, particularly those using the same active pharmaceutical ingredient as products already on the market, may be able to skip or have abbreviated Phase II studies.

Phase III. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) studies, the clinical trial program will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites. Phase III studies usually include several hundred to several thousand patients. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA, but for some product candidates, particularly those using the same active pharmaceutical ingredient as products already on the market, only one Phase III trial may be required.

Phase IV. Phase IV clinical trials are studies required of or agreed to by a sponsor that are conducted after the FDA has approved a product for marketing. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase III/IV post approval clinical trials. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

The applicant must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, in the form of an NDA, including payment of a user fee. The

FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than, or before, accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

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After FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission, and six months to review a Class 2 resubmission. The FDA may also refer an application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

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

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

Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to:

- report certain adverse reactions to the FDA;
- submit annual and periodic reports summarizing product information and safety data;
- comply with certain requirements concerning advertising and promotional labeling for their products; and
- continue to have quality control and manufacturing procedures conform to cGMP after approval.

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

Section 505(b)(1) New Drug Applications

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.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval of, for example, new indications or improved formulations of previously-approved products, a company may submit a Section 505(b)(2) NDA, instead of a stand-alone or full NDA filing under Section 505(b)(1). Section 505(b)(2) of the FDCA was enacted as part of the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For

example, the Hatch-Waxman Act permits the applicant to rely upon the FDA s findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug product for all or some of the label indications for which the referenced product has been approved, or for a new indication sought by the Section 505(b)(2) applicant.

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To the extent that the Section 505(b)(2) applicant is relying on the FDA s findings for an already-approved product, the applicant is required to certify that there are no Orange Book-listed patents for that product or that for each Orange Book-listed patent that:

the listed patent has expired;

the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

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

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

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

In the NDA submissions for our product candidates, we intend to follow the development pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates.

The Hatch-Waxman Act

Under the Hatch-Waxman Act, newly-approved drugs and indications may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active moiety. The Hatch-Waxman Act prohibits having an effective approval date for an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under the Hatch-Waxman Act will not prevent the submission or approval of another full NDA; however, the applicant would 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. On February 28, 2008, we received three years of marketing exclusivity for Luvox CR in connection with its approval by the FDA.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Act amended the FDCA to require each NDA sponsor to submit with its application information on any patent that claims the active pharmaceutical ingredient, drug product (formulation and composition), and method-of-use for which the applicant submitted the NDA and with respect to which a claim of patent infringement could reasonably be asserted

if a person not licensed by the owner engaged in the manufacture, use or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our products and product candidates, and to vigorously defend any Orange Book-listed patents for our approved products.

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

Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the Food and Drug Administration Amendments Act, or the FDAAA, was enacted into law, amending both the FDCA and the Public Health Service Act. The FDAAA makes a number of substantive and incremental changes to the review and approval processes in ways that could make it more difficult or costly to obtain approval for new pharmaceutical products, or to produce, market and distribute existing pharmaceutical products. Most significantly, the law changes the FDA s handling of postmarket drug product safety issues by giving FDA authority to require post approval studies or clinical trials, to request that safety information be provided in labeling, or to require an NDA applicant to submit and execute a Risk Evaluation and Mitigation Strategy, or REMS. Xyrem is subject to REMS requirements, and we expect that JZP-6, if approved, will be subject to a REMS requirement. We are working with the FDA to develop an amended REMS for Xyrem under the FDAAA, and we will work with the FDA if the agency determines that REMS are necessary for Luvox CR or for our product candidates.

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Orphan Drug Designation and Exclusivity

Some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.

The FDA designated and approved Xyrem as an orphan drug for each of excessive daytime sleepiness and cataplexy in patients with narcolepsy. The period of orphan drug exclusivity for cataplexy expired in July 2009 and the period of orphan drug exclusivity for excessive daytime sleepiness in patients with narcolepsy will expire in November 2012. In December 2007, we received orphan drug designation from the FDA for JZP-8.

Pediatric Exclusivity

The FDCA provides an additional six months of non-patent marketing exclusivity and patent protection for any such protections listed in the Orange Book for new or marketed drugs for specific pediatric studies conducted at the written request of the FDA. The Pediatric Research Equity Act of 2003, or PREA, as reauthorized and amended by the FDAAA, authorizes the FDA to require pediatric studies for drugs to ensure the drugs safety and efficacy in children. The PREA requires that certain new NDAs or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from the PREA. Unless otherwise required by regulation, the PREA does not apply to any drug for an indication with orphan designation. We plan to work with the FDA to determine the need for pediatric studies for our product candidates, and we may consider attempting to obtain pediatric exclusivity for some of our product candidates.

Fast Track Designation

The FDA s fast track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, applicants may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a fast track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA will determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor s request.

If the FDA grants fast track designation, it may initiate review of sections of an NDA before the application is complete. This so-called rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant has paid applicable user fees. The FDA s PDUFA review clock for both a standard and priority NDA for a fast track product does not begin until the complete application is submitted. Additionally, fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by emerging data, or if the designated drug development program is no longer being pursued.

In some cases, a fast track designated drug candidate may also qualify for priority NDA review. When appropriate, we intend to seek fast track designation or priority review for our product candidates. We cannot predict whether any of our product candidates will obtain fast track or priority review designation, or the ultimate impact, if any, of these expedited review mechanisms on the timing or likelihood of the FDA approval of any of our product candidates.

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Other Regulatory Requirements

In addition to regulation by the FDA and certain state regulatory agencies, the DEA imposes various registration, recordkeeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products under the Controlled Substances Act. A principal factor in determining the particular requirements, if any, applicable to a product is the actual or potential abuse profile. The DEA regulates drug substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Sodium oxybate in its base form is regulated by the DEA as a Schedule I controlled substance, but when contained in Xyrem it is regulated as a Schedule III controlled substance. Xyrem is a Schedule III controlled substance. JZP-6, along with certain of our early-stage product candidates, contains sodium oxybate. These product candidates, if approved for marketing by FDA, will also likely be Schedule III controlled substances. JZP-8 and certain of our early-stage product candidates will likely be regulated as controlled substances if approved for marketing by the FDA. Controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, and the DEA regulates the amount of certain of the scheduled substance that would be available for clinical trials and commercial distribution. Sodium oxybate, as a Schedule I substance, is subject to additional controls, including quotas that limit the amount of product that can be manufactured. As a Schedule III drug, Xyrem is subject to limitations on prescription refills. The third parties who perform our clinical and commercial manufacturing, distribution, dispensing and clinical studies for Xyrem and JZP-6 are required to maintain necessary registrations from the DEA. The DEA periodically inspects facilities for compliance with its rules and regulations. Failure to comply with current and future regulations of the DEA 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 harm our business and financial condition.

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

Pharmaceutical Pricing and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. We anticipate that 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 requirements to pay prescription drug rebates to government health care programs, and increases in currently required rebates paid to Medicaid;

controls on healthcare providers;

challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;

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changes of drug importation laws;

expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and

public funding for cost effectiveness research, which may be used by government and private third party payors to make coverage and payment decisions.

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

We may also face competition for our products from lower priced products from foreign countries that have placed price controls on pharmaceutical products. Proposed federal legislative changes may expand consumers ability to import lower priced versions of our and competing products from Canada. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts. The importation of foreign products that compete with our own products could negatively impact our business and prospects.

Patents and Proprietary Rights

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products, inventions and improvements that we consider important to the development of our business. We own nine issued U.S. patents and have rights to four other U.S. issued patents. In addition to the issued U.S. patents, we own or have rights to 16 pending U.S. patent applications and more than 100 issued and pending foreign patents and patent applications. Our owned and licensed patents and patent applications cover formulations of our products and product candidates, uses of our products and product candidates to treat particular conditions, drug delivery technologies and delivery profiles relating to our products and product candidates and methods for producing our products and product candidates. However, patent protection is not available for the active pharmaceutical ingredients in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. The patents and patent applications that relate to our products and product candidates include the following:

Xyrem. Xyrem is covered by two U.S. formulation patents that are listed in the Orange Book, both having an expiration date of July 4, 2020. In February 2010, an additional patent issued in the United States covering the method for distributing Xyrem using a centralized distribution system issued; it is listed in the Orange Book. The patent will expire on March 7, 2024. Xyrem is also covered by a U.S. patent not listed in the Orange Book that covers a process for preparing the formulation that expires on December 22, 2019. A Xyrem formulation patent has issued in 17 other countries and will expire on December 22, 2019. It is currently pending in three additional countries.

Luvox CR. Luvox CR is covered by U.S. Patent No. 7,465,462 owned by Elan with claims covering the orally administered formulation of extended-release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours. This patent is listed in the Orange Book, and will expire on May 10, 2020. We obtained a license to this patent as a result of Solvay s assignment of its license and supply agreement with Elan to us in connection with our exclusive license of the rights to market and distribute Luvox CR in the United States. A continuation application is pending in the United States.

JZP-6. We expect that our distribution patent and one of our current formulation patents associated with Xyrem will be applicable to JZP-6. We also own patents and patent applications with claims covering the use of sodium oxybate for the treatment of fibromyalgia that will expire in the United States on August 29, 2017 and in 29 other countries on August 27, 2018.

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Other product candidates. We have filed U.S. and foreign patent applications with claims covering JZP-8. These applications would, if issued, expire in 2027. The claims do not cover the JZP-8 composition of matter. JZP-4 is covered by a U.S. composition of matter patent that we acquired from GlaxoSmithKline that will expire on February 26, 2018. The JZP-4 composition of matter is covered by patents in 50 other countries that expire in 2018. In addition, we hold a U.S. patent that covers the use of JZP-4 for the treatment of bipolar disorder, pain or functional bowel disorder that will expire on February 26, 2018, and a U.S. patent that covers the preparation of the active pharmaceutical ingredient in JZP-4 that will expire on May 2, 2021. We have filed a U.S. patent application with claims covering a sustained release composition for delivering JZP-4 that, if issued, would expire on February 14, 2026. We have filed U.S. and foreign patent applications with claims covering JZP-7. These applications would, if issued, expire in 2027. The claims do not cover the JZP-7 composition of matter.

We cannot be certain that any of our patent applications, or those of our licensors, will result in 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 further patents we may own or license, may not prevent other companies from developing similar or therapeutically equivalent products. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. We cannot assure you that our patents will not be challenged by third parties, that we will have the funds to defend such challenges 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.

In August 2009, we received a Paragraph IV Patent Certification notice from Actavis advising that Actavis has filed an ANDA, with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen advising that Anchen has filed an ANDA with the FDA for a generic version of Luvox CR. Actavis Paragraph IV Certification alleges that Elan s U.S. Patent No. 7,465,462 is invalid on the basis that the inventions claimed therein were obvious. Anchen s Paragraph IV Certification alleges that Elan s U.S. Patent No. 7,465,462 will not be infringed by Anchen s manufacture, use or sale of the generic product for which the ANDA was submitted and that the patent is invalid on the basis that the inventions claimed therein were obvious. We and Elan have filed lawsuits in response to the Paragraph IV certifications. We cannot assure you that these lawsuits will prevent the introduction of generic products for any particular length of time or at all. For a more detailed description of our dispute with Anchen and Actavis, please see Item 3. Legal Proceedings.

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

We have also applied for a number of trademarks and service marks to further protect the proprietary position of our products. We own 63 registered trademarks and service marks in the United States and 22 registered trademarks and service marks in other jurisdictions. We also have eight pending trademark and service mark applications in the United States and six pending trademark and service mark applications in other jurisdictions. 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.

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Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, such as Pfizer, Eli Lilly and GlaxoSmithKline, as well as specialty pharmaceutical companies that market psychiatry and neurology products. Most of these companies have financial resources and marketing capabilities substantially greater than ours. Our ability to remain competitive in the marketplace is also impacted by our ability to compete successfully with other specialty pharmaceutical companies for product and product candidate acquisition and in-licensing opportunities. Some of these competitors include Cephalon, Shire Pharmaceuticals, Endo Pharmaceuticals and Forest Laboratories. These established companies may have a competitive advantage over us due to their size and financial resources.

Our products and product candidates may also compete with new products currently under development by others, alternate therapies during the period of patent protection and generic equivalents once patent protection is no longer available. 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 most significant marketed product and late-stage product candidates face competition from the following products:

Xyrem. We believe that the primary competition for Xyrem is Provigil and Nuvigil, wakefulness promoting agents and the only other FDA-approved products for the treatment of excessive daytime sleepiness in patients with narcolepsy.

Luvox CR. The market for drugs to treat obsessive compulsive disorder and social anxiety disorder is very fragmented. We believe that, in addition to Luvox CR, a large number of branded, and related generic, drugs are used for the treatment of these disorders.

JZP-6. We believe the primary competition for JZP-6 (if it is approved by the FDA for the treatment of fibromyalgia) will be Lyrica, marketed by Pfizer, Cymbalta, marketed by Eli Lilly and Savella, marketed by Forest Laboratories.

For a more detailed description of current products that compete with Xyrem, please see Marketed Products and Late-Stage Product Candidate Xyrem (sodium oxybate) oral solution Competition. For a more detailed description regarding the competitive position of Luvox CR, please see Marketed Products and Late-Stage Product Candidate Luvox CR (fluvoxamine maleate) Extended-Release Capsules Competition. For a more detailed description of current products that may be competitive with JZP-6, please see Marketed Products and Late-Stage Product Candidate JZP-6 (sodium oxybate) Competition.

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

the availability of substantial capital resources to fund development and commercialization activities;

our ability to complete clinical development and obtain regulatory approvals for our product candidates;

the timing and scope of regulatory approvals;

efficacy, safety and reliability of our product candidates;

product acceptance by physicians, other health care providers and patients;

protection of our proprietary rights and the level of generic competition;

obtaining reimbursement for product use in approved indications;

our ability to supply commercial quantities of a product to the market;

our ability to recruit and retain skilled employees; and

our ability to expand and grow our specialty sales force.

Employees

As of February 26, 2010, we had approximately 228 full-time employees. Of the full-time employees, approximately 140 were engaged in sales and marketing, 46 were engaged in manufacturing, product development and clinical activities, and 42 were engaged in general and administrative activities.

None of our employees is represented by a labor union, and we consider our employee relations to be good. We currently utilize TriNet Employer Group, Inc., or Trinet, an employer services company, to provide human resource services. TriNet is the employer of record for payroll, benefits, employee relations and other employment-related administration.

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Executive Officers of the Registrant

The following table sets forth certain information concerning our executive officers as of February 26, 2010:

Name	Age	Position
Bruce C. Cozadd	46	Chairman and Chief Executive Officer
Robert M. Myers	46	President
Kathryn E. Falberg	49	Senior Vice President and Chief Financial Officer
Carol A. Gamble	57	Senior Vice President, General Counsel and Corporate Secretary
Janne L.T. Wissel	54	Senior Vice President and Chief Regulatory Officer
Joan E. Colligan	58	Executive Director and Principal Accounting Officer

Bruce C. Cozadd is a co-founder and has served as our Chairman and Chief Executive Officer since April 2009. From 2003 until 2009, he served as our Executive Chairman. From 1991 until 2001, he held various positions with ALZA Corporation, a pharmaceutical company now owned by Johnson & Johnson, most recently as its Executive Vice President and Chief Operating Officer, with responsibility for research and development, manufacturing and sales and marketing. Previously at ALZA Corporation he held the roles of Chief Financial Officer and Vice President, Corporate Planning and Analysis. He serves on the boards of Cerus Corporation, a biopharmaceutical company, Threshold Pharmaceuticals, a biotechnology company, and The Nueva School and Stanford Hospital and Clinics, both non-profit organizations. He received a B.S. from Yale University and an M.B.A. from the Stanford Graduate School of Business.

Robert M. Myers is a co-founder and was appointed as our President in March 2007 and has served as a member of our Board of Directors since April 2009. From 2003 until 2007, he served as our Executive Vice President and Chief Business Officer. From 2002 until 2003, he served as Executive Vice President, Pharmaceuticals at Exelixis, a biotechnology company. He previously held various positions with ALZA. He received a B.S. and M.S. from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

Kathryn E. Falberg joined us as our Senior Vice President and Chief Financial Officer in December 2009. Prior to joining Jazz Pharmaceuticals, Ms. Falberg was Chief Financial Officer and Chief Operating Officer at ARCA biopharma, Inc., a biopharmaceutical company. From 2001 until joining ARCA biopharma in February 2009, Ms. Falberg worked as an active investor and consultant to small companies and served as a corporate director and audit committee chair for several companies. From 1995 through 2001, Ms. Falberg was with Amgen, Inc., where she served as Senior Vice President Finance, Strategy and Chief Financial Officer, and before that as Vice President, Controller and Chief Accounting Officer, and Vice President, Treasurer. Ms. Falberg received an M.B.A. and B.A. in Economics from the University of California, Los Angeles and is a CPA. Ms. Falberg currently serves on the Boards of Directors of Halozyme Therapeutics, a biopharmaceutical company and QLT, Inc., a pharmaceutical company.

Carol A. Gamble was appointed as Senior Vice President in 2004 and has served as our General Counsel and Corporate Secretary since 2003. From 2002 to 2003, she served as a consultant to various companies in the pharmaceutical industry. From 2000 to 2002, she served as General Counsel and Corporate Secretary of Aerogen, a biopharmaceutical company later acquired by Nektar Therapeutics. From 1988 to 2000, she held various positions with ALZA Corporation, most recently as its Senior Vice President and Chief Corporate Counsel. She received a B.S. from Syracuse University and a J.D. from the University of California, Berkeley, Boalt Hall.

Janne L. T. Wissel has served as Senior Vice President and Chief Regulatory Officer since October 2007. Prior to that she served as our Senior Vice President of Development from 2004 to 2007, and previously she served as our Vice President of Development. From 1981 to 2003, she held various positions at ALZA Corporation, most recently as its Senior Vice President, Operations, with responsibility for ALZA Corporation s global regulatory, quality, general operations and manufacturing activities. She has led the development, registration and launch of more than 20 pharmaceutical products in the neurology, pediatric psychiatry, endocrinology, urology and oncology areas. She received a B.S. from the University of California, Davis and an M.B.A. from the University of Phoenix.

Joan E. Colligan has served as our Controller since July 2004, and in March 2009 she was designated by our Board as our principal accounting officer and she served as acting principal financial officer from March to December 2009. From 2000 to 2004, she served as Controller for research and development at ALZA Corporation. She received a B.S.C. and an M.B.A. from Santa Clara University.

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About Jazz Pharmaceuticals

We were incorporated in California in March 2003 and reincorporated in Delaware in January 2004. Our principal offices are located at 3180 Porter Drive, Palo Alto, California, 94304, and our telephone number is 650-496-3777. Our website address is *www.jazzpharmaceuticals.com*. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K. Service marks, trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

Available Information

We file electronically with the U.S. Securities and Exchange Commission our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at *www.jazzpharmaceuticals.com*, 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.

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Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment.

Risks Relating to Our Business

We depend on sales of Xyrem and Luvox CR to generate the cash necessary to operate our business and to meet all of our ongoing financial obligations, and, if we are not able to maintain or increase sales of our products, it would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We depend on sales of Xyrem and Luvox CR to generate the cash necessary to operate our business and to meet all of our ongoing financial obligations, and our future plans assume that sales of our products will increase. Sales and prescriptions of Xyrem increased in 2008 and 2009; however, cataplexy and excessive daytime sleepiness associated with narcolepsy are orphan conditions, which means that a relatively limited number of people suffer from those conditions. We cannot assure you that the number of patients using Xyrem will continue to increase, or that, if there is growth in the number of patients, the rate of growth will not be lower than in prior years. We significantly increased the price of Xyrem during 2009, including an approximately 20% increase in October 2009. We cannot assure you that these or future price increases will not negatively affect Xyrem sales volumes in the future. In July 2009, our orphan drug exclusivity for Xyrem for cataplexy in patients with narcolepsy expired and we cannot assure you that a generic equivalent will not be introduced for that indication. If sales of Luvox CR do not increase as expected, they may not cover the payments due to Solvay under our license agreement for Luvox CR plus the cost to manufacture, market and sell the product and to fulfill our Phase IV clinical trial commitment to the U.S. Food and Drug Administration, or FDA. If prescriptions and revenue from sales of Xyrem and Luvox CR do not increase as expected, we may be required to reduce our operating expenses, decrease our 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.

Our only product candidate currently in late-stage development is JZP-6 for the treatment of fibromyalgia, for which we submitted a New Drug Application, or NDA, to the FDA in December 2009. Although we believe our completed Phase III pivotal clinical trials have shown JZP-6 to be safe and effective for the treatment of fibromyalgia, the FDA may not approve JZP-6 for marketing or may approve it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are currently seeking approval of JZP-6 for the treatment of fibromyalgia. Our development program for JZP-6 includes two completed Phase III pivotal clinical trials and a long-term safety trial that is expected to be completed in mid-2010. Although we received statistically significant positive results from both of our Phase III pivotal clinical trials and believe the results show JZP-6 to be safe and effective for the treatment of fibromyalgia, we do not know if the FDA will agree with our interpretation of the results of these trials or whether the FDA and other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia. Although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy, this does not assure approval by the FDA, or any other regulatory authorities, of this active pharmaceutical ingredient for the treatment of fibromyalgia. Lyrica (pregabalin), marketed by Pfizer, Cymbalta (duloxetine), marketed by Eli Lilly, and Savella (milnacipran), marketed by Forest Laboratories, were approved by the FDA in June 2007, June 2008, and January 2009, respectively, for the treatment of fibromyalgia. With treatments for fibromyalgia already approved, the FDA may be less willing to approve JZP-6 for the treatment of fibromyalgia. None of these products has been approved by the EMA for the treatment of fibromyalgia. A failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia patients could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Even if the FDA approves JZP-6 for the treatment of fibromyalgia, the FDA will likely require us to have a Risk Evaluation and Mitigation Strategy program, or REMS, which may be similar to the one we use for Xyrem. Under the current Xyrem REMS, Xyrem is distributed through a single central pharmacy. The central pharmacy maintains physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient receives materials concerning the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy verifies the prescription and obtains additional information by contacting the patient. The central pharmacy also speaks with the patient before it ships any Xyrem to the patient. The central pharmacy ships the product directly to the patient by a courier service, and the patient or his/her designee signs for the package. The initial shipment may only be for a one-month supply, and physicians may only prescribe up to six months of supply of Xyrem at one time.

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The Xyrem REMS is labor intensive, complex and expensive to operate. Since Xyrem is currently prescribed for a relatively small number of patients, the Xyrem REMS does not prevent us from effectively supplying Xyrem to narcolepsy patients. However, significantly more patients are diagnosed with fibromyalgia, and if the same or a similar REMS is required for JZP-6, scale-up of the REMS could make it difficult for us to timely supply all of the patients who may be prescribed JZP-6 for the treatment of fibromyalgia. This could make JZP-6 less attractive to physicians and patients than other products that are currently, or that in the future may be, approved for the treatment of fibromyalgia, which could limit potential sales of JZP-6.

We depend upon UCB Pharma Limited, or UCB, to market and promote Xyrem outside the United States, and we are dependent upon our collaboration with UCB for the development and potential commercialization of JZP-6 for the treatment of fibromyalgia in major markets outside of the United States.

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the United States. If UCB does not obtain regulatory approvals for and launch Xyrem in its licensed countries in the time frames we expect, or at all, our revenues would be adversely affected. In addition, under the terms of our collaboration with UCB, we granted UCB the exclusive right to commercialize JZP-6 for the treatment of fibromyalgia in the same territories in which UCB has the right to market and promote Xyrem for patients with narcolepsy. There are currently no approved fibromyalgia treatments in the European Union. In October 2008, April 2009 and July 2009 panels of European regulators recommended against approving Cymbalta, Lyrica and Savella, respectively, as treatments for fibromyalgia. We cannot be sure that the European Medicines Agency, or EMA, will approve any treatment, or JZP-6 in particular, for fibromyalgia.

UCB has the right to terminate our collaboration on 12-months notice (or less in certain circumstances), and UCB may terminate its rights to JZP-6 for the fibromyalgia indication on six-months notice at any time prior to the receipt of marketing approval of JZP-6 for fibromyalgia in the European Union. If UCB terminates our collaboration or terminates its rights to JZP-6 for the fibromyalgia indication, we would need to find another party or parties to commercialize Xyrem and JZP-6 in UCB s territories. We may be unable to do this on acceptable terms, or at all, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We depend on one central pharmacy distributor for Xyrem sales in the United States, and the loss of that distributor or its failure to distribute Xyrem effectively would adversely affect sales of Xyrem.

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the United States must be shipped directly to patients through a single central pharmacy. The process under which patients receive Xyrem under the Xyrem REMS is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, or Express Scripts, 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. Changing central pharmacy distributors could take a significant amount of time. In addition, sodium oxybate, the active pharmaceutical ingredient in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. Any new central pharmacy would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute Xyrem under the REMS approved by the FDA. If we change central pharmacies, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new central pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the United States, and/or result in additional costs and expenses for us, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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Our supplier of the active pharmaceutical ingredient and our product manufacturer for Xyrem must obtain DEA quotas in order to supply us with Xyrem, JZP-6 and sodium oxybate, and these quotas may not be sufficient to satisfy our clinical and commercial needs.

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 and JZP-6, sodium oxybate, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient and our product manufacturers must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our supplier s and contract manufacturer s DEA quotas, our supplier and contract manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. The DEA has issued a quota for 2010 that is substantially the same as that issued for 2009 but that is less than the quota that we believe we will need to provide commercial supplies of Xyrem, support our development needs and prepare for the potential commercial launch of JZP-6. We are in discussions with the DEA concerning the 2010 quota; however, since the 2010 quota was issued in January 2010, we will have to request an increase in the aggregate 2010 quota, and our suppliers will need to request additional quota, which could delay the potential commercial launch of JZP-6. In addition, Lonza, Inc., or Lonza, is our sole supplier of sodium oxybate and recently publicly announced that it is closing its U.S. facility where it manufactures sodium oxybate. We may need to build significant additional supplies of sodium oxybate before Lonza closes its plant, and we cannot assure you that we will be able to obtain sufficient and timely DEA quota to manufacture additional inventory. If we arrange for a new supplier, that supplier will also need quota from the DEA, and we cannot assure you that we will be able to timely obtain sufficient quota for a new supplier. In the future and in cooperation with our manufacturing partners, we will continue to seek increased quotas to satisfy our clinical and commercial needs. We will need to negotiate with the DEA any time we need additional quota, and these negotiations may be protracted and may not provide us with as much quota as we believe is needed on a timely basis, or at all, and without sufficient and timely DEA quotas, there could be shortages of Xyrem, as sodium oxybate or, if approved, JZP-6 for the marketplace or for use in our clinical studies, or both.

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

We do not have, and do not intend to establish in the near term, our own manufacturing or packaging capability for our products or product candidates, or their active pharmaceutical ingredients. Accordingly, we have entered into manufacturing and supply agreements with single source suppliers and manufacturers for our commercialized products and product candidates. The deterioration in worldwide economic conditions and the disruption to the credit and financial markets in the United States and worldwide may materially and adversely impact the financial position of our single source suppliers and manufacturers. If our suppliers and contract manufacturers are unable to obtain the necessary capital to operate their respective businesses or for other reasons, our suppliers and contract manufacturers may not be able to manufacture our products or product candidates without interruption, or may not comply with their obligations to us under our supply and manufacturing arrangements. We may not have adequate remedies for any breach, and their failure to supply us could result in a shortage of our products or product candidates.

The availability of our products for commercial sale depends upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a prior approval supplement and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer. For Xyrem, JZP-6 or sodium oxybate, the new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. If there are delays in qualifying the new manufacturer or the new manufacturer is unable to obtain a sufficient quota from the DEA, there could be a shortage of Xyrem, sodium oxybate or, if approved, JZP-6 for the marketplace or for use in our clinical studies, or both.

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Lonza is our sole supplier of sodium oxybate, the active pharmaceutical ingredient in Xyrem and, through Solvay Pharmaceuticals, Inc., or Solvay, our sole supplier of fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR. Lonza recently publicly announced that it is closing its U.S. facility where it manufactures sodium oxybate and fluvoxamine maleate for us. Although Lonza is contractually obligated to meet our supply needs through December 2011 and has indicated a willingness to work with us to avoid an interruption in supply, we will likely need to secure one or more new manufacturers for the supply of sodium oxybate and Solvay may need to secure one or more new manufacturers for the supply of fluvoxamine maleate. We may need to build significant additional supplies of sodium oxybate before Lonza closes its plant, and, even if we are able to obtain sufficient and timely DEA quota to manufacture additional inventory, we cannot assure you that Lonza will have the capacity to timely meet our requirements. Any new manufacturer of sodium oxybate would need to be registered with the DEA and obtain a DEA quota, and any new manufacturers of sodium oxybate and fluvoxamine maleate will need to be approved by the FDA. We cannot assure you that we and any new suppliers or manufacturers will be able to complete all of the necessary validation and other activities prior to the time at which Lonza ceases manufacturing sodium oxybate and fluvoxamine maleate for us or we run out of inventory. Any failure to obtain sufficient commercial and clinical quantities of sodium oxybate and fluvoxamine maleate could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Elan Pharma International Limited, or Elan, has the right and obligation to manufacture the worldwide commercial requirements of Luvox CR. In June 2001, Solvay s NDA for Luvox CR was withdrawn due to manufacturing difficulties. We cannot assure you that Elan will be able to continue to supply in a timely manner or at all our ongoing commercial needs of Luvox CR. Any failure of Elan to supply necessary quantities of Luvox CR could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Due to FDA-mandated dating requirements, the limited market size for our approved products and DEA quotas relating to sodium oxybate, Xyrem and JZP-6, we are subject to complex manufacturing logistics and minimum order quantities that could result in excess inventory as determined under our accounting policy, unsalable inventory as a result of product expiring prior to use, and competition with others for manufacturing services when needed or expected. We have adopted a production planning program to assess and manage manufacturing logistics among the vendors supplying our requirements of active pharmaceutical ingredient, drug product and packaging; however, unexpected market requirements or problems with vendors facilities, among other things, could result in shortages of one or more of our products for the marketplace or product candidates for use in our clinical studies, or both.

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. In addition, under our agreement with UCB, we are responsible for the supply of Xyrem and, if approved, JZP-6 to UCB. Our failure to meet our contractual obligations to supply UCB with adequate quantities of Xyrem and JZP-6 would result in lost revenues to us and, if material, could result in termination of our agreements by UCB.

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

Even if our product candidates are approved for sale by the appropriate regulatory authorities, physicians may not prescribe our products, in which case we would not generate the revenues we anticipate. Market acceptance of any of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved, including any potential additional restrictions placed upon the product in connection with its approval;
- 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.

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

Significant additional research and development, financial resources and additional personnel will be required to obtain necessary regulatory approvals for our product candidates and to develop them into commercially viable products. As a condition to regulatory approval, each product candidate must undergo extensive clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The clinical trials for a product candidate can cost between $40 million and $100 million, and potentially even more. If a product candidate fails at any stage of development, we will not be able to commercialize it and we will not receive any return on our investment from that product candidate.

Clinical testing can take many years to complete, and failure can occur any time during the clinical trial process. In addition, the results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed successfully through initial clinical testing. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials. The completion of clinical trials for our product candidates may be delayed or halted for many reasons, including:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;

regulators or institutional review boards may not authorize us to commence or continue a clinical trial;

our inability, or the inability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials;

delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;

risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;

difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data;

poor effectiveness of product candidates during clinical trials;

safety issues, including adverse events associated with product candidates;

the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;

governmental or regulatory delays or changes in regulatory requirements, policies and guidelines;

varying interpretation of data by the FDA or foreign regulatory agencies; and

insufficient funds to complete the trials.

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In addition, our product candidates are subject to competition for clinical study sites and patients from other therapies under development that may delay the enrollment in or initiation of our clinical trials. Many of these companies have far greater financial and human resources than we do.

The FDA or foreign regulatory authorities may require us to conduct unanticipated additional clinical trials, which could result in additional expense and delays in bringing our product candidates to market. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

We design the clinical trials for our product candidates, but rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these 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.

Although we rely on third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, 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. Our reliance on third parties does not relieve us of these responsibilities and requirements. The FDA enforces good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our contract research organizations or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA s cGMP regulations. Our failure, or the failure of our contract manufacturers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

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

We could be materially adversely affected if we or our products are subject to negative publicity. For example, sodium oxybate, the active pharmaceutical ingredient in Xyrem and JZP-6, is a derivative of gamma hydroxybutyrate, or GHB, which has been a drug of abuse and may not be sold legally in the United States. If physicians and patients perceive Xyrem and JZP-6 to be the same as or similar to GHB, or if adverse effects become associated with our products, sales of our products could be adversely affected.

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 and JZP-6, is a derivative of GHB, Xyrem sometimes also receives (and it can be expected that JZP-6, if approved, could sometimes receive) negative mention in publicity relating to GHB. For the same reason, patients, physicians and regulators may view Xyrem and JZP-6 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 (and may oppose the prescription and use of JZP-6) because of its connection to GHB. Xyrem s label includes information about adverse events from GHB, and we anticipate that if JZP-6 is approved, its label will include similar information. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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The investigation by the U.S. Attorney s Office for the Eastern District of New York concerning the sales and marketing of Xyrem creates additional compliance-related operating costs and could result in additional fines, penalties or other adverse consequences.

In April 2006, we and our subsidiary, Orphan Medical, received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. We and Orphan Medical have settled this matter with the United States, acting through the Department of Justice, the U.S. Attorney s Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately $20 million in civil and criminal payments is required to be paid in connection with this matter, of which $1 million was paid in July 2007, $2 million was paid in January 2008, $2.5 million was paid in October 2009, and $3 million was paid in January 2010; the remaining amount will be due over the next two years.

While we were not prosecuted, as part of the settlement, we entered into a corporate integrity agreement with the Office of Inspector General, U.S. Department of Health and Human Services. That agreement requires us to maintain a comprehensive compliance program, and we will have additional ongoing compliance-related operating costs related to this compliance program and the corporate integrity agreement. In the event of an uncured material breach or deliberate violation, as the case may be, of the corporate integrity agreement or the other definitive settlement agreements we entered into, we could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

In addition, there is no assurance that we will not be subject to future investigations. Many pharmaceutical companies have announced government investigations of their sales and marketing practices for many of their products. Even with compliance training and a company culture of compliance, our current or future practices may nonetheless become the subject of an investigation. A number of laws, often referred to as whistleblower statutes, provide for financial rewards to employees and others for bringing to the attention of the government sales and marketing practices that the government views as illegal or fraudulent. The costs of investigating any claims, responding to subpoenas of investigators, and any resulting fines, can be significant and could divert the attention of our management from operating our business.

Xyrem cannot be advertised in the same manner as competing products, which could limit sales.

The FDA has required that Xyrem s label include a boxed warning regarding the risk of abuse. A boxed warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A boxed warning also means, among other things, that the product cannot be advertised through reminder ads, ads which mention the pharmaceutical brand name but not the indication or medical condition it treats. Provigil (modafinil) and Nuvigil (armodafinil), the only other products approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, do not have a boxed warning and can be advertised with reminder ads. 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. Unlike Xyrem, Provigil and Nuvigil were not approved under the FDA s Subpart H regulations and are not subject to the pre-review requirements. Accordingly, promotional materials for Provigil and Nuvigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

Because JZP-6 contains the same active pharmaceutical ingredient as Xyrem, we anticipate that the label for JZP-6, if approved by the FDA, will also include a boxed warning. One of the products already approved by the FDA for the treatment of fibromyalgia is not, and future competing products may not be, subject to this restriction, and the boxed warning may negatively affect potential JZP-6 sales if competing products can be advertised directly to consumers.

We face substantial competition from companies with greater resources than we have.

With respect to all of our existing and future products, we may compete with companies selling or working to develop products that may be more effective, safer or less costly than our products. The markets for which we are developing products are competitive and include generic and branded products, some of which are marketed by major pharmaceutical companies that have significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing and marketing and selling approved products than we do. While Xyrem is the only product approved by the FDA for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy, cataplexy is often treated with tricyclic antidepressants and selective serotonin reuptake inhibitors, or SSRIs, although none of these compounds has been approved by the FDA for the treatment of cataplexy. Other treatments for excessive daytime sleepiness in patients with narcolepsy consist primarily of stimulants and wakefulness promoting agents, including Provigil and Nuvigil, the only other FDA-approved products for the treatment of excessive daytime sleepiness in patients with narcolepsy.

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Luvox CR, an SSRI, is approved in the United States for the treatment of obsessive compulsive disorder and social anxiety disorder. SSRIs are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Six other branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, and most of these products have generic equivalents. Generic products are generally sold at significantly lower prices than non-generic branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Four other products are currently approved by the FDA for the treatment of social anxiety disorder, and each of these products has generic equivalents.

We are seeking FDA approval of JZP-6 for the treatment of fibromyalgia. The FDA has approved Lyrica, marketed by Pfizer, Cymbalta, marketed by Eli Lilly, and Savella, marketed by Forest Laboratories, for the treatment of fibromyalgia. In clinical practice, a variety of other drugs are often prescribed to address individual symptoms of fibromyalgia, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants, even though those products are not specifically approved by the FDA for the treatment of fibromyalgia. These treatments, as well as other product candidates that may be approved for the treatment of fibromyalgia may be better accepted by physicians and patients. Thus, even if we are able to obtain and maintain FDA approval of JZP-6 for the treatment of fibromyalgia, JZP-6 may not result in significant commercial revenues for us.

JZP-6 contains the same active pharmaceutical ingredient as Xyrem. While we have not established the price we will charge for JZP-6 if it is approved by the FDA and launched, Xyrem is substantially more expensive than the products currently approved by the FDA for the treatment of fibromyalgia. If the price we charge for JZP-6 is substantially higher than the price of other products that are now or that may in the future be approved for the treatment of fibromyalgia, we cannot assure you that JZP-6 will be included on formularies, or at what level it might be included on formularies, or that there will not be managed care, government or insurance restrictions on its use. Any such restrictions could negatively affect the commercial potential of JZP-6.

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

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

If generic products that compete with any of our products are approved, sales of our products may be adversely affected.

Our products are or may become subject to competition from generic equivalents if there is no proprietary protection for some of our products or because our protection has expired or is not sufficiently broad. The FDA had previously granted Xyrem orphan drug exclusivity in the United States for the treatment of cataplexy in patients with narcolepsy, but this exclusivity expired in July 2009, and other companies could possibly introduce generic equivalents of Xyrem for the cataplexy indication if they do not infringe our existing patents covering Xyrem. Although the FDA has granted orphan drug exclusivity for Xyrem until November 2012 for the treatment of excessive daytime sleepiness in patients with narcolepsy, prescriptions for Xyrem for the excessive daytime sleepiness in patients with narcolepsy indication, or if approved by the FDA, JZP-6, could possibly be filled with generic equivalents that are granted approval for the treatment of cataplexy in patients with narcolepsy, even if the patient is diagnosed with excessive daytime sleepiness or fibromyalgia.

Although Xyrem, Luvox CR and JZP-6 are covered by patents that we own or license, it is possible that other companies could manufacture generic equivalents of Xyrem, JZP-6 and Luvox CR in ways that are not covered by the claims of our patents. In addition, patent protection is not available for the active pharmaceutical ingredient in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6.

In August 2009, we received a Paragraph IV Patent Certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an abbreviated new drug application, or ANDA, with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen Pharmaceuticals, Inc., or Anchen, advising that Anchen has filed an ANDA with the FDA for a generic version of Luvox CR. We and Elan have filed lawsuits in response to the Paragraph IV certifications. We cannot assure you that these lawsuits will prevent the introduction of generic products for any particular length of time, or at all.

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

We may not be able to successfully acquire, in-license or develop additional products or product candidates to grow our business.

In order to grow our business, we will need to acquire, in-license or develop additional products and product candidates that we believe have significant commercial potential. Any growth through acquisitions or in-licensing will depend upon the continued availability of suitable acquisition or in-license products and product candidates at favorable prices and upon advantageous terms and conditions, and any growth through development will depend upon our obtaining product candidates, our ability to develop those product candidates and the availability of funding to complete the development, obtain regulatory approval of and commercialize these product candidates. Even if such opportunities are present, we may not be able to successfully identify products or product candidates suitable for potential acquisition, in-licensing or development, or we may not have the financial resources necessary to pursue opportunities. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for the right to acquire and in-license such products or product candidates.

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

We have a relatively small number of sales representatives compared with the number of sales representatives of most other pharmaceutical companies with marketed products. Each of our sales representatives is responsible for a territory of significant size. Our potential future commercial products, including JZP-6, may require expansion of our sales force and sales support organization, and we will need to commit significant additional funds, management and other resources to the growth of our sales organization before the commercial launch of those product candidates. We may not be able to achieve the necessary growth in a 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.

Turnover in our sales force could also negatively affect sales of our products. If we elect to rely on third parties to sell our products in the United States, we may receive less revenue or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately size our sales force or collaborate with third parties to sell our products, our ability to generate revenues would be adversely affected.

If we fail to retain key personnel, or to retain our executive management team, we may be unable to successfully develop or commercialize our products.

Our success depends in part on our continued ability to 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 key personnel. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry key person insurance. Any member of our executive management team and any other key employees may terminate his or her employment at any time without notice and without cause or good reason. For example, in early 2009, our then chief executive officer left the company.

Competition for qualified personnel in the life sciences industry has historically been intense. If we need to hire additional personnel to expand our development, clinical and commercial activities, or to support those activities, we may not be able to attract and retain quality personnel on acceptable terms. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage our personnel resources effectively, and our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

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Our offices are located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could damage our facilities, which could adversely affect our operations.

Our offices are located in the San Francisco Bay Area, near known earthquake fault zones and are therefore vulnerable to damage from earthquake. In October 1989, a major earthquake in our area caused significant property damage and a number of fatalities. We are also vulnerable to damage from other disasters such as power loss, fire, floods and similar events. If a significant disaster occurs, our ability to continue our operations could be seriously impaired and we may not have adequate insurance to cover any resulting losses. Any significant unrecoverable losses could seriously impair our operations and financial conditions.

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

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. In the case of Luvox CR, for example, Actavis Paragraph IV Certification alleges that Elan s U.S. Patent No. 7,465,462, listed in the Orange Book, is invalid on the basis that the inventions claimed therein were obvious; Anchen s Paragraph IV Certification alleges that Elan s U.S. Patent No. 7,465,462, listed in the Orange Book, will not be infringed by Anchen s manufacture, use or sale of the generic product for which the ANDA was submitted and that the patent is invalid on the basis that the inventions claimed therein were obvious. The expiration date for the patent at issue is May 10, 2020. The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or partners might not have been the first to make the inventions covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;
- we or our licensors or partners might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative products without infringing our intellectual property rights;
- our pending patent applications may not result in issued patents;

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

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

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

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

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

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

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

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents or in or our licensed patents or those of our partners, 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 would consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party s activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity. In October 2009, we and Elan filed lawsuits in response to the Paragraph IV certifications that we received from Actavis and Anchen. We cannot assure you that these lawsuits will be successful in stopping the infringement of our related patents, that the 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 and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Patent infringement 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 third party patent rights. In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

- pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;
- cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;

expend significant resources to redesign our products so they do not infringe others patent rights, which may not be possible;

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discontinue manufacturing or other processes incorporating infringing technology; or

obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all.

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. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the United States.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for inventions covered by our licensors or our issued patents or pending applications, or that we or our licensors were the first inventors. Our competitors may have filed, and may in the future file, patent applications covering subject matter similar to ours. Any such patent application may have priority over our or our licensors patents or applications and could further require us to obtain rights to issued patents covering such subject matter. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

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

Risks Related to Our Industry

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

The research, testing, manufacturing, selling and marketing of pharmaceutical products are subject to extensive regulation by FDA and other regulatory authorities in the United States and other countries, and regulations differ from country to country. Approval in the United States, or in any jurisdiction, does not ensure approval in other jurisdictions. The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain approval for our product candidates. We are not permitted to market our product candidates in the United States until we receive approval from the FDA, generally of an NDA. An NDA must contain, among other things, data to demonstrate that the drug is safe and effective for its intended uses and that it will be manufactured to appropriate quality standards. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process, and the FDA has substantial discretion in the approval process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, untitled letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs. 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.

In 2008, the FDA announced that, in light of staffing issues, it has given its managers discretion to miss Prescription Drug User Fee Act, or PDUFA, deadlines for completing reviews of NDAs. Although the FDA has since publicly expressed a recommitment to meeting PDUFA deadlines, it remains unclear whether and to what extent the FDA will adhere to PDUFA deadlines in the future. If the FDA were to miss a PDUFA deadline for JZP-6 or one of our other product candidates, delaying the approval and launch, the delay could have a material adverse effect on our business.

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

We are subject to significant ongoing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products are, and any of our product candidates that may be approved by the FDA will be, subject to extensive and ongoing regulatory requirements. If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the commercial potential of the product. If we become aware of previously unknown problems with any of our products in the United States or overseas or at our contract manufacturers facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers facilities, or withdraw the product from the market. In addition, we may 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, including class action suits. The FDA and other governmental authorities also actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

We are also subject to regulation by regional, national, state and local agencies, including the DEA, the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which we commercialize our products. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including preclinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information, promotion, marketing, and pricing to government purchasers and government health care programs. Our manufacturing partners are subject to many of the same requirements, which include obtaining sufficient quota from the DEA each year to manufacture sodium oxybate, Xyrem and JZP-6. These statutes and regulations include anti-kickback statutes and false claims statutes.

The federal health care 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 health care 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 identified common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. 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.

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Many pharmaceutical and other health care companies have been prosecuted under these laws for a variety of alleged marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company s products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government health care programs. Other companies have been prosecuted for causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other health care companies have also been prosecuted on other legal theories of Medicare and Medicaid fraud. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company s products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing meals to prescribers or other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

We participate in the federal Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, as well as several state supplemental rebate programs. Under the Medicaid rebate program, we pay a rebate to each state Medicaid program for our products that are reimbursed by those programs. The minimum amount of the rebate for each unit of product is set by law at 15.1% of the average manufacturing price of that product, or if it is greater, the difference between the average manufacturing price and the best price we make available to any non-federal customer. The rebate also includes an additional amount if price increases exceed the rate of inflation.

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 Centers for Medicare & Medicaid Services at the U.S. Department of Health and Human Services of our current average manufacturing price 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 average manufacturing price or best price for that quarter. 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. In addition to retroactive rebates (and interest, if any), if we are found to have knowingly submitted false average manufacturer price or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. 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.

Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Service s pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The Public Health Service pricing program extends discounts comparable to the Medicaid rebates to 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 poor patients and children.

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

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

In recent years, there have been a number of legislative and regulatory changes in and proposals to change the healthcare system in ways that could impact our ability to sell our products profitably. These changes and proposals include measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control and regulations changing the rebates we are required to provide. For example, a final rule published by the Department of Defense, or DoD, in March 2009 under the National Defense Authorization Act of 2008, established a program under which DoD requires rebates from pharmaceutical manufacturers on all prescriptions of covered prescription drugs filled under the TRICARE retail pharmacy program from January 28, 2008 forward, unless DoD agrees to a waiver or compromise of amounts due. Additionally, under the final rule, to remain eligible for inclusion on the DoD Uniform Formulary, a pharmaceutical manufacturer must enter into a pricing agreement under which it agrees to pay rebates to DoD on TRICARE retail pharmacy utilization on a prospective basis, and, in compliance with this rule, we entered into a pricing agreement with DoD in July 2009. These legislative and regulatory changes, including our entering into the pricing agreement with DoD, could impact our ability to maximize revenues in the Federal marketplace. Some of the proposals that have been made for additional legislative and regulatory changes include expanding the 340B drug pricing program to allow additional types of health care providers to purchase drugs at significant discounts and to require those discounts on inpatient drugs as well, increasing the minimum Medicaid drug rebate percentage, expanding Medicaid rebate liability to drugs purchased under Medicaid managed care contracts, increasing the Medicaid rebate on new formulations of existing drugs, and requiring Medicaid rebates to be paid on drugs provided to certain enrollees in the Medicare Part D prescription drug benefit.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed. Congress is currently considering enacting healthcare reform, which, if enacted, could have a material adverse effect on the prices of our products and the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

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Prescription drug importation from Canada and other countries could increase pricing pressure on our products and could decrease our revenues and profit margins.

Under current U.S. law, there is a general prohibition on imports of unapproved drug products. The FDA has published internal guidance that sets forth the agency s enforcement priorities for imported drugs. Under this policy, the FDA allows its personnel to use their discretion in permitting entry into the United States of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the United States from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 permits pharmacists and wholesalers to import prescription drugs into the United States from Canada under specified circumstances. These additional import provisions will not take effect until the Secretary of Health and Human Services makes a required certification regarding the safety and cost savings of imported drugs and the FDA has promulgated regulations setting forth parameters for importation. These conditions have not been met to date and the law has therefore not taken effect. However, legislative proposals have been introduced to remove these conditions and implement changes to the current import laws, or to create other changes that would allow foreign versions of our products priced at lower levels than in the United States to be imported or reimported to the United States from Canada, Europe and other countries. In addition, there have been indications that the current presidential administration is considering changing certain rules to make it easier to import drugs from other countries, and we cannot predict what, if any changes will happen. If these provisions or changes in the rules take effect, the volume of prescription drug imports from Canada and elsewhere could increase significantly and our products could face competition from lower priced imports.

Even if these provisions do not take effect and alter current law, the volume of prescription drug imports from Canada and elsewhere could increase due to a variety of factors, including the further spread of internet pharmacies and actions by a number of state and local governments to facilitate Canadian and other imports. These imports may harm our business.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products entail significant risk of product liability claims or recalls. Side effects of, or manufacturing defects in, the products sold by us could result in exacerbation of a patient s condition, serious injury or impairments or even death. This could result in product liability claims and/or recalls of one or more of our products. For example, studies and publications suggest that SSRIs, including the active pharmaceutical ingredient in Luvox CR and its immediate release formulation Luvox, may increase the risk of suicidal behavior in adults and adolescents. In addition, the current SSRI products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Side effects associated with SSRIs include sexual dysfunction, adverse drug interaction and risk of hypertension. Claims may be brought by individuals seeking relief for themselves or by groups seeking to represent a class. While we have not had to defend against any product liability claims to date, as sales of our products increase, we believe it is likely product liability claims will be made against us. 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.

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Risks Relating to Our Financial Condition

We have a substantial amount of secured debt, which matures in less than two years and may adversely affect our ability to operate our business.

As of December 31, 2009, our total consolidated indebtedness was $128.9 million, $119.5 million of which constituted secured indebtedness under our senior secured notes due in June 2011, or the Senior Notes, and $9.4 million of which constituted secured indebtedness under our line of credit with Silicon Valley Bank, or SVB. Pursuant to our secured line of credit with SVB, we currently may borrow up to the lesser of 75% of eligible accounts receivable or $15 million. Our substantial debt, combined with our other financial obligations and contractual commitments, could have important consequences. For example, it could:

- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, capital expenditures and acquisitions;
- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a competitive disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, in the event of a default under the agreement governing the Senior Notes, or the Senior Note Agreement, the holders of our Senior Notes could accelerate, or demand immediate repayment of, all or a portion of our indebtedness under the Senior Notes. Any such acceleration would have a material adverse effect on our business, financial condition and results of operations.

We did not timely make the quarterly interest payments on the Senior Notes due on December 31, 2008, March 31, 2009 and June 30, 2009. In addition, we failed to comply with a covenant to establish and maintain a minimum cash balance in an account pledged to the collateral agent for the Senior Notes, which became applicable in May 2009 because our annualized aggregate net product sales did not exceed $100 million for the three months ended March 31, 2009. The failure to make the quarterly interest payments when due and the failure to establish the required restricted cash balance account in May 2009 constituted events of default under the Senior Note Agreement, which then permitted the holders of more than 50% in principal amount of the Senior Notes to accelerate payment of the Senior Notes.

In July 2009, we paid the overdue interest and, because our annualized aggregate net product sales exceeded $100 million for the three months ended June 30, 2009, we were no longer required to maintain the minimum cash balance. In November 2009, we amended the Senior Note Agreement to provide, among other things, for amortization of a portion of the principal amount of the Senior Notes. In connection with that amendment, the holders of the Senior Notes have waived the prior events of default described above. However, our failure to comply with the terms of the Senior Note Agreement on an ongoing basis could result in the holders of our Senior Notes attempting to accelerate our indebtedness under the Senior Notes. We do not currently expect to be able to repay the Senior Notes in full at maturity without new financing or additional cash resources.

If we do not have sufficient funds to pay all remaining principal on our Senior Notes when it is due in June 2011, service our indebtedness under the Senior Notes, or to restrict cash if required under the Senior Note Agreement, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or obtain additional equity capital, including on terms that may be onerous or highly dilutive, none of which we can assure you that we would be able to do in a timely manner or at all. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. In addition, our ability to refinance any amounts that may become accelerated under the Senior Notes or to secure future waivers from the holders of the Senior Notes with respect to compliance with the Senior Note Agreement

covenants may be adversely affected by our prior defaults under the Senior Notes. The holders of the Senior Notes currently have a first priority security interest in all of our assets other than inventory and accounts receivable, on which SVB has a lien and first priority security interest.

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We have a history of net losses, and, if we are to grow our business in the future, we will need to commit substantial resources, which could result in future losses.

We have incurred significant net losses since our inception in 2003, and we may incur net losses in the future. To grow our business in the future, we will need to commit substantial resources to costly and time-consuming product development and clinical trials of our product candidates and significant funds to our commercial operations. Our future capital requirements will depend on many factors, including:

- the amount of sales and other revenues from our commercial products, including selling prices for products that we may begin selling and price increases for our current products;
- market acceptance of and the number of prescriptions written for our products;
- selling and marketing costs associated with Xyrem and Luvox CR in the United States;
- the timing of potential receipt of FDA approval of JZP-6 and its potential commercialization;
- revenues from current and potential future development and/or commercial collaboration partners, in particular our current partnership with UCB;
- the scope, rate of progress, results and costs of our preclinical studies, clinical trials, including our Phase IV clinical trial commitment to the FDA for Luvox CR, and other research and development activities;
- the number and characteristics of product candidates that we pursue;
- the cost and timing of establishing clinical and commercial supplies of our product candidates and products, including the cost and timing of procuring new arrangements for the supply of sodium oxybate and fluvoxamine maleate;
- the cost and timing of obtaining regulatory approval;
- payments of milestones to third parties;
- increased expenses associated with our current employees and new employees hired to support our continued growth;
- the cost of investigations, litigation and/or settlements related to regulatory activities;
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and

the extent to which we acquire, in-license or invest in new businesses, products or product candidates.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Our operations have generated negative cash flows, and, if our cash flow estimates are incorrect, we may be required to secure additional funding, significantly scale back our operations, significantly reduce our headcount, and/or discontinue many of our activities which could negatively affect our business and prospects.

Over the next twelve months, we plan to fund our operations and meet all of our obligations as they become due through our existing cash balances, cash generated from operations and borrowings under our revolving bank line of credit. The adequacy of our cash resources to meet our plan during the next twelve months depends on many assumptions, including primarily our assumptions with respect to continued growth in our product sales and continued access to our revolving bank line of credit, which currently expires in May 2010. Our assumptions may prove to be wrong, and we could exhaust our available cash resources. Beyond the next twelve months, we do not expect our cash resources to be sufficient to cover all of our operating requirements as well as launch expenses for our JZP-6 product candidate if approved by the FDA, the cost of our Luvox CR Phase IV clinical trial commitments, any significant additional costs related to the development of our product candidates and repayment of our Senior Notes at maturity. In order to fund these additional activities and requirements, we will need to do one or more of: raise additional funds, partner or license one or more of our product candidates or draw down funds under our committed equity financing facility. If we are unable to raise sufficient additional funds when or if needed, we would be required to further reduce operating expenses. Furthermore, any additional funds we may raise could be on terms that are not favorable to us and may be dilutive to existing stockholders.

We cannot predict with certainty the level of our product sales. If product sales do not meet our expectations and/or we do not raise additional funds, we will need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we may take may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and prospects.

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The terms of our Senior Notes could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.

The terms of our Senior Notes currently contain, and any future indebtedness may contain, a number of restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests. The terms of the Senior Notes include covenants restricting, among other things, our ability to:

- incur additional debt;
- dispose of certain assets;
- repurchase our capital stock or make distributions to our stockholders;
- impair our lenders security interests in our assets; and
- voluntarily prepay our debt prior to the repayment of the Senior Notes.

In addition, the terms of the Senior Notes require us to maintain restricted cash balances under certain circumstances.

Our ability to use our net operating losses to offset potential future taxable income and related income taxes that would otherwise be due could be limited or lost entirely, which could materially and adversely affect our business, financial condition, and results of operations if we generate taxable income, if we do not generate taxable income in a timely manner or if an ownership change pursuant to Section 382 of the Internal Revenue Code is triggered.

We have significant net operating loss carryforwards, or NOLs. Our ability to use our 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, if ever, we will be able to generate future taxable income. In addition, even if we generate taxable income, realization of our NOLs to offset potential future taxable income and related income taxes that would otherwise be due could be restricted by annual limitations on use of NOLs triggered by an ownership change under Section 382 of the Internal Revenue Code and similar state provisions. An ownership change may occur if, during a three-year period, the percentage ownership of our company by our 5% shareholders increases by 50% or more. If we generate taxable income, the loss of some or all of our NOLs could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Effective July 7, 2009, we entered into an NOL preservation lock-up agreement with most of our significant stockholders that restricts transferability of shares of our common stock by the stockholders who entered into the agreement until June 2011, unless terminated earlier under certain circumstances, in order to minimize the risk that we will undergo an ownership change within the meaning of Section 382(g) of the Internal Revenue Code prior to that time. Section 382 of the Internal Revenue Code is an extremely complex provision with respect to which there are many uncertainties. Although the NOL preservation lock-up agreement and 5% shareholder limitation are intended to minimize the risk of such an ownership change, we cannot assure you that such an ownership change will not occur. In addition, we have not requested a ruling from the Internal Revenue Service, or IRS, regarding whether we have effectively preserved our NOLs, and, therefore, we have not established whether the IRS agrees with us that our NOLs have been effectively preserved for purposes of Section 382 of the Internal Revenue Code.

Risks Relating to Our Common Stock

The market price of our common stock may be volatile, and the value of your investment could decline significantly.

Investors who purchase our common stock may not be able to sell their shares at or above the purchase price. Our common stock has historically had a very low average trading volume, and our stockholders may not be able to sell any or all of their holdings quickly or at all. The price of our stock has also fluctuated significantly since the beginning of 2009 and we cannot predict if it will continue to do so. In addition, the stock

market in general, and the market for life sciences companies in particular, have 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 common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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The following factors, in addition to other risks described herein, may have a significant effect on our common stock market price:

- the success of Xyrem and Luvox CR in the United States;
- conditions or trends in the pharmaceutical industry, the credit and financial markets or the United States and worldwide economy in general;
- the failure or delay by the DEA in providing sufficient quotas for sodium oxybate, Xyrem or JZP-6;
- the success of our development efforts and clinical trials;
- announcement of FDA approval or non-approval of our product candidates, including JZP-6, or specific label indications for their use, or delays in the FDA review process;
- the review, evaluation and recommendations of any FDA advisory committee regarding the potential approval of JZP-6;
- our ability to successfully market JZP-6 in the United States if approved by the FDA for the treatment of fibromyalgia, or any delays in the potential commercial launch of JZP-6;
- our ability to obtain adequate clinical and commercial supplies of our product candidates and products from our single source suppliers and manufacturers, and to make timely new arrangements for the supply of sodium oxybate and fluvoxamine maleate;
- the ability of Elan to provide us with sufficient commercial supply of Luvox CR;
- our financial situation, including our ability or inability to raise additional capital when needed and the terms on which we raise it;
- actual or expected fluctuations in our operating results, including as a result of fluctuating demand for our commercial products as a result of purchases by wholesalers in connection with product launches, stockpiling or inventory drawdowns by our customers, or otherwise;
- hedging or arbitrage trading activity that may develop involving our common stock;
- changes in the market prices for our products;
- the success of our efforts to acquire or in-license additional products or product candidates;

introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;

the filing of, and thereafter the possible FDA approval of, ANDAs for generic forms of Xyrem, Luvox CR and, if approved by the FDA, JZP-6;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

announcements of product innovations by us, our partners or our competitors;

changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements;

actions taken by regulatory agencies with respect to our products, clinical trials, manufacturing process or sales and marketing terms;

developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;

disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

actual or expected changes in our growth rates or our competitors growth rates;

changes in the market valuation of similar companies;

trading volume of our common stock; and

sales of our common stock by us or our stockholders.

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Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock, and could impair our ability to raise capital through the sale of additional equity securities. As of February 26, 2010, we had 31,269,350 shares of common stock outstanding, all of which shares were 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 and the restrictions under our NOL preservation lock-up agreement.

As of February 26, 2010, the holders of up to approximately 18,312,159 shares of common stock, based on shares outstanding as of that date, including 785,728 shares underlying outstanding warrants, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, under an amended and restated investor rights agreement that we entered into with these holders. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights under the amended and restated investor rights agreement with respect to registration of the shares of common stock acquired on exercise. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights, these sales may impair our ability to raise capital. We also entered into a registration rights agreement pursuant to which we filed a registration statement covering the resale of the 562,192 shares underlying the warrants that we issued in connection with the issuance of the Senior Notes. In addition, we have filed registration statements on Form S-8 under the Securities Act to register the shares of our common stock reserved for issuance under our stock option 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.

We entered into a committed equity financing facility, or CEFF, on May 7, 2008 with Kingsbridge Capital Limited, or Kingsbridge, that was amended in November 2009. The perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. The registration rights agreement entered into in connection with the CEFF, as amended, requires that we use commercially reasonable efforts to ensure that the registration statement we filed in connection with the CEFF, and any additional registration statements that we file with the SEC to cover the resale of the shares issuable under the CEFF, remain effective for up to one year following the termination of the CEFF. We have not drawn down funds and have not issued shares of our common stock under the CEFF with Kingsbridge. Our ability to draw down funds and sell shares under the CEFF requires that the registration statement we filed in connection with the CEFF continue to be effective. In addition, the registration statement that we filed in connection with the CEFF registers approximately 76% of the 4,922,064 total shares of our common stock issuable under the CEFF, or 3,726,727 shares, and our ability to access the CEFF to sell the 1,195,337 remaining shares issuable under the CEFF is subject to our ability to prepare and file one or more additional registration statements registering the resale of these shares, which we may not file until the later of 60 days after Kingsbridge and its affiliates have resold substantially all of the common stock registered for resale under the registration statement that we have filed in connection with the CEFF, or six months after the effective date of such registration statement. These subsequent registration statements may be subject to review and comment by the Staff of the SEC, and will require the consent of our independent registered public accounting firm. Therefore, the timing of effectiveness of these subsequent registration statements cannot be assured. The effectiveness of these subsequent registration statements is a condition precedent to our ability to sell the shares of common stock subject to these subsequent registration statements to Kingsbridge under the CEFF. In addition, we will not be able to sell shares under the CEFF unless certain other conditions are met, including a minimum average price of our common stock of at least $2.50 per share. Because our ability to draw down amounts under the CEFF is subject to a number of conditions, there is no guarantee that we will be able to draw down any portion or all of the $75 million available to us under the CEFF. In addition, although the CEFF provides for our ability to draw down amounts of up to $75 million, the maximum number of shares of common stock that we can issue to Kingsbridge under the CEFF is limited to 4,922,064 shares. As a result, since we will issue shares of our common stock at a discount of up to 9.5% from the then average price of our common stock if we draw down amounts under the CEFF, even if we are able to issue the maximum number of shares provided for under the CEFF to Kingsbridge, the aggregate proceeds to us could be substantially less than $75 million. Once Kingsbridge acquires shares in connection with a drawdown there are no restrictions on its ability to sell those shares or engage in other transactions that could put downward pressure on the price of our common stock.

Pursuant to the terms of an investor rights agreement dated July 7, 2009 we entered into in connection with a private placement completed on July 7, 2009, we filed a registration statement under the Securities Act registering the resale of the 1,895,734 shares of common stock we issued to the investors pursuant to a securities purchase agreement we entered into with the investors on July 6, 2009, as well as the 947,867 shares of common stock underlying the warrants we issued to the investors pursuant to the securities purchase agreement. 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 are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock 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.

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The CEFF may result in dilution to our stockholders.

Pursuant to the CEFF, Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of $75 million of our common stock or 4,922,064 shares of our common stock over a three-year period beginning in December 2009. If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment as described below, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to 9.5% from the average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price. In addition, we are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statements that we have filed or may in the future file with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant we issued to Kingsbridge. If we deliver a blackout notice during a certain number of trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge, or issue Kingsbridge additional shares of our common stock in lieu of this payment.

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

As of February 26, 2010, our executive officers and directors, together with the stockholders with which our executive officers and directors are affiliated or associated, beneficially owned approximately 65.5% of our capital stock, of which approximately 4.9% was beneficially owned by our executive officers. Accordingly, our executive officers and directors, together with their respective affiliates or associates, are able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our common stock, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

We incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules of the Securities and Exchange Commission and The NASDAQ Stock Market LLC have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel must continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may incur substantial costs to maintain the same or similar coverage

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. For example, we were required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our Annual Report on Form 10-K for the year ended December 31, 2008, and to allow our independent registered public accounting firm to issue a report on the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K for the fiscal year ending December 31, 2010. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

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Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new, operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, or for a change in the composition of our board of directors or management to occur, even if doing so would benefit our stockholders. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- dividing our board of directors into three classes;
- limiting the removal of directors by the stockholders;
- eliminating cumulative voting rights and therefore allowing the holders of a majority of the shares of our common stock to elect all of the directors standing for election, if they should so choose;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless, among other exceptions, such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, because some corporate takeovers occur through an acquirer s purchase, in the public market or otherwise, of sufficient stock to give it control of a company, the NOL preservation lock-up agreement, which restricts the transferability of our securities, could have the effect of delaying or discouraging such a takeover of us.

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

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently plan to invest all available funds and future earnings in the development and growth of our business and in the payment of our obligations. In addition, the agreements governing our debt restrict our ability to pay dividends on our common stock. As a result, capital appreciation, if any, of our common stock will be your

sole source of potential gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters are located in Palo Alto, California, where we occupy approximately 44,000 square feet of office space. The annual lease payments for our corporate headquarters building through December 2010 are approximately $824,000. In June 2009, we amended our lease to extend the term for an additional three years beginning August 31, 2009. We have the right to extend the term for up to an additional four years.

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Item 3. Legal Proceedings

In August 2009, we received a Paragraph IV Patent Certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an abbreviated new drug application, or ANDA, with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen Pharmaceuticals, Inc., or Anchen, advising that Anchen has filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. We have not been informed as to the timing or status of the FDA s review of either party s filing, or whether either filer has complied with FDA requirements for proving bioequivalence. Actavis Paragraph IV Certification alleges that Elan s U.S. Patent No. 7,465,462, or the 462 patent, is invalid on the basis that the inventions claimed therein were obvious. Anchen s Paragraph IV Certification alleges that the 462 patent will not be infringed by Anchen s manufacture, use or sale of the generic product for which the ANDA was submitted and that the 462 patent is invalid on the basis that the inventions claimed therein were obvious. On October 6, 2009, we and Elan, as plaintiffs, filed a lawsuit against Actavis, Anchen, and Anchen Incorporated, the parent of Anchen, in the United States District Court for the District of Delaware claiming infringement of the 462 patent by the defendants in response to the Paragraph IV Certifications filed by Actavis and Anchen. We are seeking a permanent injunction that prevents Actavis and Anchen from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. On October 27, 2009, Anchen and Anchen Incorporated filed a motion to dismiss for lack of jurisdiction. On November 16, 2009, we and Elan filed our response. On January 14, 2010, we and Elan filed a motion to enjoin the later-filed duplicative proceeding in the United States District Court for the Central District of California referenced below. On February 1, 2010, Anchen and Anchen Incorporated responded. The court has not ruled on either motion and no hearing dates are scheduled. We cannot predict or determine the outcome of this matter.

On October 14, 2009, we and Elan, as plaintiffs, also filed a lawsuit in the United States District Court for the Central District of California against Anchen and Anchen Incorporated claiming infringement of the 462 patent based upon Anchen s Paragraph IV Certification. The plaintiffs are seeking a permanent injunction that prevents Anchen from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. Since Anchen is incorporated in California, the additional protective lawsuit was filed in California in an effort to both ensure jurisdiction over Anchen in the event that the United States District Court for the District of Delaware finds that it does not have jurisdiction over Anchen in Delaware, and to prevent the FDA from approving the ANDA filed by Anchen until the earliest of 30 months following the filing of the lawsuit, expiration of the 462 patent, settlement of the lawsuit or a decision in the infringement case that is favorable to Anchen in California. On December 14, 2009, the court in the United States District Court for the Central District of California held a scheduling conference to discuss the status of the case and the Delaware case. Following the conference and submission of scheduling proposals by both parties, the court scheduled a patent claim construction or *Markman* hearing for June 1, 2010. Following a ruling in that hearing, the court indicated that it will set the remaining schedule following consultation with both parties. We cannot predict or determine the outcome of this matter.

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

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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

The following table sets forth the high and low intraday sales prices of our common stock, par value $.0001, on The NASDAQ Global Market under the symbol JAZZ from January 1, 2008 through December 31, 2009 for the periods indicated.

	High	Low
Calendar Quarter - 2008		
First Quarter	$ 15.58	$ 8.82
Second Quarter	$ 9.87	$ 5.13
Third Quarter	$ 8.85	$ 3.26
Fourth Quarter	$ 5.52	$ 0.91
Calendar Quarter - 2009		
First Quarter	$ 2.10	$ 0.58
Second Quarter	$ 5.27	$ 0.52
Third Quarter	$ 11.88	$ 3.59
Fourth Quarter	$ 9.28	$ 6.01

On February 26, 2010, the last reported sales price per share of our common stock was $9.78 per share.

Holders of Common Stock

As of February 26, 2010, there were 38 holders of record of our common stock.

Dividends

Under the terms of the senior secured note and warrant purchase agreement we and JPI Commercial, LLC, or JPIC, our wholly-owned subsidiary, entered into in March 2008 with certain purchasers, we are not permitted to pay any dividends, either in cash or property, on any shares of our capital stock. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. We have never declared or paid any cash dividends and we do not presently plan to pay cash dividends in the foreseeable future.

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Performance Measurement Comparison (1)

The following graph shows the total stockholder return on the last day of each month of an investment of $100 in cash on June 1, 2007 for (i) our common stock; (ii) the NASDAQ Composite Index; and (iii) the NASDAQ Pharmaceutical Index as of December 31, 2009. We are included in the NASDAQ Pharmaceutical Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends; however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 31 MONTH CUMULATIVE TOTAL RETURN

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

the NASDAQ Pharmaceutical Index

(1) This section is not soliciting material , is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Jazz Pharmaceuticals, Inc., 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.

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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, 2009, 2008 and 2007 and the consolidated balance sheet data as of December 31, 2009 and 2008 from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The selected consolidated statements of operations data for the years ended December 31, 2006 and 2005, and the selected consolidated balance sheet data as of December 31, 2007, 2006, and 2005 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2009(1)	2008(1)	2007(1)	2006(1)	2005(2)
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net	$ 115,108	$ 64,637	$ 53,536	$ 43,299	$ 18,796
Royalties	2,203	1,739	1,156	594	146
Contract revenues	11,138	1,138	10,611	963	2,500
Total revenues	128,449	67,514	65,303	44,856	21,442
Operating expenses:					
Cost of product sales (excluding amortization of acquired developed technology and intangible asset impairment)	9,638	13,924	8,903	6,968	4,292
Research and development	36,561	69,963	69,792	54,956	45,783
Selling, general and administrative	58,652	111,401	78,540	51,384	23,551
Intangible asset amortization	7,668	12,828	9,217	9,600	4,960
Intangible asset impairment		29,763	20,160		
Provision for government settlement			17,469		
Purchased in-process research and development					21,300
Total operating expenses	112,519	237,879	204,081	122,908	99,886
Income (loss) from operations	15,930	(170,365)	(138,778)	(78,052)	(78,444)
Interest income	34	1,834	5,942	2,307	1,318
Interest expense (including $1,183, $1,179, $4,104, $4,047 and $2,089 for the years ended December 31, 2009, 2008, 2007, 2006 and 2005, respectively, pertaining to a related party)	(22,796)	(19,742)	(13,647)	(14,129)	(7,129)
Other (expense) income	(4)	16	1,797	(1,109)	(901)
Gain on extinguishment of development financing obligation				31,592	
Gain on sale of product rights		3,918	5,860		
Net loss	(6,836)	(184,339)	(138,826)	(59,391)	(85,156)
Beneficial conversion feature				(21,920)	
Loss attributable to common stockholders	$ (6,836)	$ (184,339)	$ (138,826)	$ (81,311)	$ (85,156)
Loss per share attributable to common stockholders, basic and diluted	$ (0.23)	$ (7.19)	$ (10.04)	$ (6,254.69)	$ (14,192.67)

Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	30,018	25,646	13,829	13	6

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(1) Total operating expenses in 2009, 2008, 2007 and 2006 included employee stock-based compensation costs of $5.7 million, $8.1 million, $6.1 million and $3.5 million, respectively, due to our adoption of Accounting Standards Codification 718 (formerly Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment), on a modified prospective basis on January 1, 2006. No employee stock-based compensation was recognized in reported amounts in any period prior to January 1, 2006. See Note 12 of the notes to our financial statements for details on the composition of total employee stock-based compensation.

(2) We acquired Orphan Medical, Inc. on June 24, 2005, and the results of Orphan Medical are included in the consolidated financial statements from that date. In connection with the acquisition, we recorded a charge of $21.3 million for acquired in-process research and development.

	As of December 31,				
	2009 (1)	2008 (2)	2007	2006	2005
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 15,595	$ 25,907	$ 102,945	$ 78,948	$ 20,614
Working capital (deficit)	(22,287)	(129,492)	79,235	61,043	8,048
Total assets	107,396	117,498	207,554	214,571	164,781
Liability under government settlement, non-current	10,658	13,063	14,881		
Senior secured notes (including $6,552, $6,747, $23,474, $23,213 and $23,009 as of December 31, 2009, 2008, 2007, 2006 and 2005, respectively, held by a related party)	91,107	118,534	75,116	74,283	73,629
Convertible preferred stock				263,852	163,862
Common stock subject to repurchase		12,492	13,241	8,183	5,924
Accumulated deficit	(507,644)	(500,808)	(316,469)	(177,643)	(118,252)
Total stockholders (deficit) equity	(72,830)	(92,878)	54,992	(176,296)	(118,248)

(1) Working capital included the current portion of our senior secured notes.

(2) Working capital included the entire amount of our senior secured notes.

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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 pharmaceutical company that, since our inception, has focused on the development and commercialization of pharmaceutical products to meet important unmet medical needs in neurology and psychiatry. With our JZP-6 product candidate for the treatment of fibromyalgia, for which we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in December 2009, and which NDA was filed by the FDA in February 2010, we expanded our development activities to include rheumatology and pain management. We currently market two products: Xyrem (sodium oxybate) for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy; and Luvox CR (fluvoxamine maleate) for the treatment of both obsessive compulsive disorder and social anxiety disorder. We are building a portfolio of products through a combination of internal development, acquisition and in-licensing activities, and we utilize our specialty sales force to promote our products in our target markets. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes our two marketed products, which generated net product sales of $115.1 million in 2009, our late-stage JZP-6 product candidate, and several product candidates in various stages of clinical development.

Our marketed products and late-stage product candidate are:

Xyrem® (sodium oxybate) oral solution. Xyrem is the only product approved by the FDA for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. We promote Xyrem in the United States for its FDA-approved indications to sleep specialists, neurologists, pulmonologists and psychiatrists through our specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring the rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 14 countries in Europe. In 2009, our Xyrem net sales were $96.8 million.

Luvox CR® (fluvoxamine maleate) Extended-Release Capsules. Once-daily Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder and social anxiety disorder in February 2008. We began promoting Luvox CR through our specialty sales force in April 2008. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the United States. In 2009, our Luvox CR net sales were $18.3 million.

JZP-6 (sodium oxybate). We are developing sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. Our development program includes two completed Phase III pivotal clinical trials and a long-term safety trial that is expected to be completed in mid-2010. In November 2008 and June 2009, we announced positive top-line results from our first and second Phase III pivotal clinical trials, respectively. The two randomized, double-blind, placebo-controlled studies demonstrated that sodium oxybate significantly decreased pain and fatigue, and improved daily function and patient global impression of change, in patients with fibromyalgia. We submitted an NDA for JZP-6 in December 2009 and the NDA was filed by the FDA in February 2010. If our NDA is approved by the FDA, we expect to market JZP-6 in the United States to physicians who treat fibromyalgia patients, through an expanded specialty sales force and/or in partnership with third parties. We have licensed to UCB the commercialization rights to JZP-6 in 54 countries outside of the United States in exchange for development funding, commercial milestones and royalties.

Our other product candidates in clinical development are oral tablet forms of sodium oxybate; JZP-8 (intranasal clonazepam), being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable anti-epileptic regimens; JZP-4 (elpetrigine), being developed for the treatment of epilepsy and bipolar disorder; and JZP-7 (ropinirole gel), being developed for the treatment of restless legs syndrome. We are actively seeking development partners for JZP-4, JZP-7 and JZP-8 and we do not anticipate significant progress on these programs in the near term until we obtain a partner or otherwise obtain additional funding.

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Although we have incurred significant net losses since our inception, our net loss for our fiscal year ended December 31, 2009 was $6.8 million, which was significantly lower than the losses of $184.3 million and $138.8 million in our fiscal years ended December 31, 2008 and 2007, respectively. This improvement in our net loss in 2009 as compared to 2008 and 2007 was due to a significant increase in revenue from product sales and a significant decrease in operating expenses. In the fourth quarter of 2009, we reported both net income and cash generated from operations.

We depend primarily on revenues generated from Xyrem and Luvox CR product sales to fund our operations and meet our near-term obligations. Xyrem and Luvox CR accounted for 84% and 16%, respectively, of our 2009 revenues from net product sales. We had a significant increase in revenue from product sales in 2009 due primarily to Xyrem price increases; however, we expect a more modest percentage increase in our 2010 Xyrem volume and our revenue from product sales.

In July 2009, Xyrem s orphan drug exclusivity for the treatment of cataplexy in patients with narcolepsy expired, and Xyrem s orphan exclusivity for the excessive daytime sleepiness indication in patients with narcolepsy will expire in November 2012. We are currently involved in ANDA litigation concerning Luvox CR. If generic products were to be introduced for either or both of our products, our revenue from product sales would decline. In addition, any delays in the potential FDA marketing approval of our JZP-6 product candidate would result in a delay of future revenues, if any, from the approved product.

Over the next twelve months, we plan to fund our operations and meet all of our obligations as they become due through our existing cash balances, cash generated from operations and borrowings under our revolving bank line of credit. The adequacy of our cash resources to meet our plan during the next twelve months depends on many assumptions, including primarily our assumptions with respect to continued growth in our product sales and continued access to our revolving bank line of credit, which currently expires in May 2010. Our assumptions may prove to be wrong, and we could exhaust our available cash resources. Beyond the next twelve months, we do not expect our cash resources to be sufficient to cover all of our operating requirements as well as launch expenses for our JZP-6 product candidate if approved by the FDA, the cost of our Luvox CR Phase IV clinical trial commitments, any significant additional costs related to the development of our product candidates and repayment of our Senior Notes at maturity. In order to fund these additional activities and requirements, we will need to do one or more of: raise additional funds, partner or license one or more of our product candidates or draw down funds under our committed equity financing facility.

Critical Accounting Policies and Significant Estimates

Revenue Recognition

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. In evaluating arrangements with multiple elements we consider whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on their respective fair values when there is reliable evidence of fair value for all elements of the arrangement. If there is no evidence of fair value for all the elements of the arrangement, consideration is allocated based on the residual value method for the delivered elements. Under the residual method, the amount of revenues allocated to the delivered elements equals the total arrangement consideration less the aggregate fair value of any undelivered elements. The applicable revenue recognition criteria are applied to each of the separate units. Payments received in advance of work performed or milestones achieved are recorded as deferred revenues and recognized when the service is provided or the milestone is achieved, as applicable.

Product Sales, Net

We sell Xyrem in the United States to a single source specialty pharmaceutical distributor, Express Scripts Specialty Distribution Services, Inc., or Express Scripts. In 2009 sales of Xyrem to Express Scripts accounted for 83% of our net product sales. We recognize revenues from sales of Xyrem within the United States upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment directly to a patient.

We accept returns from Express Scripts of any product returned by patients to Express Scripts with defects that were not reasonably discoverable upon receipt of the consigned product by Express Scripts. Based on our experience over the past five years since we acquired the rights to Xyrem, product returns to Express Scripts are extremely rare once product is shipped to patients. We provide Express Scripts with a credit for product returned by patients. During 2009 we issued credits for returned product totaling less than $10,000.

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We sell limited quantities of Xyrem to UCB for sale in territories outside of North America, and to Valeant, for sale in Canada, under license and distribution agreements. The agreements provide our international licensees with a fixed period of time after delivery to inspect and reject shipments for failure to meet specifications. We do not recognize revenue on the sales to our international licensees until the right of return has lapsed, which occurs when we are notified of their acceptance, or when the time for them to inspect or reject a shipment has lapsed, if earlier. We recognized revenue of $1.0 million, $769,000 and $306,000 from international sales of Xyrem during 2009, 2008 and 2007, respectively.

Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder and social anxiety disorder in February 2008. We shipped initial stocking orders of Luvox CR to our wholesaler customers in March 2008 and began promoting Luvox CR through our specialty sales force in April 2008. We grant rights to our wholesaler customers to return product six months prior to and up to twelve months after product expiration. Given our limited history of selling Luvox CR and the lengthy return period, we have not been able to reliably estimate expected returns of Luvox CR at the time of shipment, and therefore we recognize revenue when units are dispensed through prescriptions, at which point, the product is not subject to return. We do not accept product returns of Luvox CR that have been dispensed to patients. In order to estimate units dispensed, we purchase dispensing data from an independent prescription tracking service. We believe this data to be reasonably accurate and reliable and not subject to material adjustments. In 2009 and in 2008, we recorded revenue of $18.3 million and $5.7 million, respectively, related to Luvox CR, net of estimated wholesaler fees, discounts, chargebacks and rebates. As of December 31, 2009, we had recorded a deferred revenue liability related to shipments of Luvox CR of $1.5 million, which represented amounts paid by wholesaler customers in excess of revenue recognized, net of estimated wholesaler fees, discounts, chargebacks and certain rebates.

Prior to the sale of our rights to Antizol® (fomepizole) and Antizol-Vet® in August 2008, Antizol and Antizol-Vet were shipped to our wholesaler customers in the United States with free on board destination shipping terms, and we recognized revenues when delivery occurred.

Revenues from sales of products within the United States are recorded net of estimated allowances for amounts paid to Express Scripts, wholesaler fees, prompt payment discounts, Medicaid rebates, TRICARE rebates and certain other items. Calculating certain of these items involves estimates and judgments based on sales or invoice data and historical experience. Adjustments to estimates for allowances have not been material.

	Year Ended December 31,		
	2009	2008	2007
	(In thousands)		
Amounts paid to Express Scripts	$ 2,625	$ 2,320	$ 1,496
Wholesaler fees	400	198	147
Prompt pay discounts	2,478	1,360	1,111
Medicaid rebates	2,203	486	263
TRICARE rebates	1,425		
Other	898	449	299
	$ 10,029	$ 4,813	$ 3,316

Amounts paid to Express Scripts. Express Scripts, our sole Xyrem distributor in the United States, provides services such as collecting patient registry information, providing reimbursement support, providing nursing assistance, distributing educational materials and administering a patient co-payment rebate program. All fees we pay to Express Scripts other than reimbursement for the cost of freight are recorded as a reduction of Xyrem product sales and are based on actual invoices rather than estimates. The services Express Scripts performs increase as shipments increase and therefore these fees would generally increase in proportion to increases in sales of Xyrem in the United States.

Wholesaler fees. Our service agreements with certain U.S. wholesaler customers, to whom we sell Luvox CR, require us to pay them fees for services they performed for us. These fees are generally calculated as a percentage of product sales, and consequently they vary as sales of Luvox CR vary.

Prompt payment discounts. We offer Express Scripts and our U.S. wholesaler customers a 2% prompt payment discount as an incentive to remit payment within 30 days after the date of our invoice. In addition, we extended our prompt payment discount term to 90 days and offered an additional 5% discount on initial orders of Luvox CR placed in March 2008. Because Express Scripts and our U.S. wholesaler customers typically earn the prompt payment discount, we accrue 100% of the prompt payment discounts when we recognize revenue on product sales. Adjustments to accrued prompt payment discounts have not been material and we do not anticipate that changes to estimates will have a material impact on product sales.

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Medicaid rebates. Our products are subject to state government-managed Medicaid programs under which we provide rebates to participating state governments. We record rebates to be provided through the Medicaid drug rebate program as a reduction of product sales when the product is sold. We pay rebates to states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is derived from our average manufacturer price. We determine our estimate of the Medicaid rebate accrual primarily based on historical experience regarding Medicaid rebates, as well as current and historical prescription activity and our current sales prices. We adjust our estimate to reflect actual experience, expected changes in future prescription volumes and any changes in business circumstances or trends. Rebate amounts are generally invoiced quarterly in arrears and paid 30 days after they are invoiced. Based on our history of estimating Medicaid rebates, we do not anticipate that changes to our estimated accrual for Medicaid rebates will have a material impact on product sales.

TRICARE rebates. In 2009, we recorded, as a reduction of revenues, an accrual of $1.4 million as a result of a final rule issued by the Department of Defense in March 2009 for potential rebates due for drugs sold by retail pharmacies to TRICARE beneficiaries on or after January 28, 2008. We requested a waiver from the Department of Defense for approximately $999,000 of the $1.4 million accrual and have not yet received a response to our waiver request. Of the total amount requested in our waiver, $596,000 relates to product sales in 2008. Other than the amount in conjunction with the waiver requested, we do not anticipate that changes to our estimated accrual for TRICARE rebates will have a material impact on product sales.

Other. Other includes patient rebates, managed care rebates, government chargebacks, and state supplemental rebates and we do not anticipate that changes to our estimated allowance for these items will have a material impact on product sales.

Royalties, Net

We receive royalties primarily from UCB based on its net sales of Xyrem and we will receive royalties on UCB s net sales of JZP-6 if it is approved for the treatment of fibromyalgia in countries for which JZP-6 is licensed to UCB. In 2009, we earned royalties at a rate of 15% of net sales of Xyrem by UCB. The royalties are reasonably estimable, and we recognize revenues based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material.

Contract Revenues

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

UCB Agreement

In June 2006, we entered into an agreement with UCB that amended and restated a prior agreement between Orphan Medical and UCB. Under the terms of the agreement, and a subsequent amendment in July 2008, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia in 54 countries outside of the United States. UCB has made nonrefundable milestone payments to us related to Xyrem for the treatment of narcolepsy totaling $2.5 million, of which $500,000 was paid in June 2006 and $2.0 million was paid in March 2007. These payments were recognized as revenue when the respective milestone was achieved. UCB has also made payments to us related to JZP-6 for the treatment of fibromyalgia totaling $32.5 million, which included an upfront payment of $5.0 million upon execution of the amended agreement in June 2006, an additional upfront payment of $10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia, a $7.5 million non-refundable milestone payment due and recognized as revenue in September 2007, and a $10.0 million nonrefundable milestone payment received in July 2008, which we recognized as revenue in April 2009 upon the completion of the last patient in our second Phase III pivotal clinical trial of JZP-6 for the treatment of fibromyalgia.

We recognized contract revenues of $1.1 million during each of the years ended December 31, 2009, 2008, and 2007 related to the two upfront payments totaling $15.0 million related to JZP-6. As of December 31, 2009, $11.3 million was recorded as deferred revenues and is being recognized ratably through 2019, the end of the expected performance period under the agreement. There has been no change in the expected performance period under our agreement with UCB since its establishment in 2006 at the time of the initial upfront payment.

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The amended agreement requires UCB to make additional milestone payments of up to $131.0 million, contingent on certain future events, of which up to $6.0 million relates specifically to Xyrem for the treatment of narcolepsy, up to $25.0 million is due upon approval of JZP-6 by the European Medicines Agency for the treatment of fibromyalgia, and up to $100.0 million is due upon achievement of commercial milestones related to sales of JZP-6 for the treatment of fibromyalgia and sales of Xyrem for the treatment of narcolepsy.

Inventory Valuation

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. During 2009, we recorded charges to cost of product sales related to Luvox CR totaling $82,000 for inventory we judged to be in excess of expected requirements. During 2008, we recorded charges to cost of product sales related to Luvox CR totaling $4.2 million, which was composed of a write down for inventory we judged to be in excess of expected requirements in the amount of $3.5 million and a $671,000 liability to a contract manufacturer for cancelled production orders. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for the product. If our estimate of future demand is too high we may have to write down the carrying value of inventory and record additional charges to cost of product sales.

Goodwill and Intangible Assets

Goodwill

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then in the second step, the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable.

Intangible Assets

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

As of December 31, 2009 the intangible asset related to Xyrem developed technology had a remaining estimated useful life of five years. In developing this estimate of the useful life of the product we incorporated the following:

Orphan drug exclusivity for the FDA-approved indication of excessive daytime sleepiness indication in patients with narcolepsy expires in November 2012.

Xyrem is covered by two U.S. formulation patents, both having expiration dates in 2020, and a U.S. distribution patent, having an expiration date in 2024 that are each listed in the Orange Book. Xyrem is also covered by a U.S. process patent that is not listed in the Orange Book and expires in 2019.

Sodium oxybate and Xyrem are subject to strict manufacturing and distribution controls, primarily implemented through a DEA controlled quota system and the requirements included in the NDA.

The risk management program required to market and sell Xyrem may make it less commercially attractive than other products to potential generic competitors.

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In February 2009, we amended our product license agreement with Solvay for the rights to market Luvox CR and Luvox in the United States such that the existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR and future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million. As a result, we recorded an increase of $5.0 million in the value of the intangible asset for Luvox CR developed technology in 2009.

We tested the intangible asset related to Luvox CR developed technology for impairment in September 2009, in response to a notice we received in August 2009 of the filing of an ANDA with the FDA by a third party seeking approval to market a generic version of Luvox CR. Based on the estimated undiscounted cash flows related to the asset, we determined at that time that the asset was not impaired but that its remaining estimated useful life should be shortened to 2.7 years from 4.0 years. In projecting future cash flows, the estimate that requires the most judgment relates to projected product net sales, which were estimated by extrapolating the growth trends of the product and adjusting for known or expected events based on experience and analysis of comparable products.

As of December 31, 2009, the gross carrying amount of goodwill was $38.2 million and the gross carrying amounts and net book values of intangible assets were as follows:

	December 31, 2009			
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Weighted Average Remaining Useful Life
		(In thousands)		(In years)
Developed technology - Xyrem	$ 39,700	$ 18,842	$ 20,858	5.0
Developed technology - Luvox CR	9,700	2,443	7,257	2.4
Agreements not to compete	3,900	3,523	377	0.5
Trademarks	2,600	1,234	1,366	5.0
	$ 55,900	$ 26,042	$ 29,858	

Stock-Based Compensation

We have elected to use the Black-Scholes option pricing model to calculate the fair value of stock options and grants under our 2007 Employee Stock Purchase Plan, or ESPP, and are using the straight-line method to allocate compensation cost to reporting periods. The fair value of stock options was estimated using the following assumptions:

	Year Ended December 31,		
	2009	2008	2007
Weighted-average volatility	91%	60%	56%
Weighted-average expected term (years)	6.1	6.1	6.1
Range of risk-free rates	1.8-3.1%	2.7-3.4%	3.4-4.9%
Expected dividend yield	0.0%	0.0%	0.0%

We completed our initial public offering in June 2007 and, as such, our common stock has a limited trading history. A public market for options on our common stock did not exist before June 2009, and the market that does exist is not very liquid, particularly for options with more than one year to expiration. Due to the limited trading history of our common stock, through 2008 we used the historic volatility of a peer group to estimate the future volatility for our stock option grants and we used the historic and implied volatility of a peer group in addition to the historic volatility of our own common stock to estimate volatility for grants under our ESPP. In 2009, we relied on our peer group and on the historic volatility of our own common stock to estimate future volatility for stock option grants. To estimate the fair value of the most recent grants under our ESPP we relied exclusively on the implied volatility of our own common stock.

We have limited historical information with which to develop reasonable expectations about the expected term of our stock options. As a result, for stock option grants made during the years ended December 31, 2009, 2008 and 2007, the expected term was estimated by assuming stock options would be exercised at the mid-point between the vest date and the contractual term.

The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of our stock option grants. The expected dividend yield assumption was based on our history and expectation of no dividend payouts.

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Accrued Liabilities

As part of the process of preparing financial statements, we are required to estimate accrued liabilities. This process involves identifying goods received and services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated accrued liabilities include the cost of marketing and promotional materials, contract service fees, such as amounts paid to clinical monitors, data management organizations, clinical research organizations and fees paid to contract manufacturers in conjunction with the production of clinical materials, and professional service fees, such as fees to lawyers and accountants. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. To the extent that we do not identify certain costs that have begun to be incurred or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often subject to our judgment. We make these judgments in accordance with the facts and circumstances known to us through our internal processes. Our internal processes require substantially all of our spending for services to be under contracts with our service providers and to be documented and tracked under internally-generated purchase orders based on designated spending authorizations. As of each balance sheet date, employees who are responsible for managing the contracts, and who are in contact with the outside service providers as to progress or stage of completion of the services and the agreed upon fee to be paid for such services, review current contracts and the related open purchase orders. We adjust for spending not already reflected in our accounting records in accordance with generally accepted accounting principles. To date, there have been no material differences between the amounts of expenses accrued at our balance sheet dates and the amount at which such expenses were subsequently invoiced. Although we do not expect our current estimates to be materially different when invoiced, our understanding of the status and timing of services provided relative to the actual timing and levels of service provided may vary and may result in adjustments in future periods.

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Results of Operations

Comparison of Years Ended December 31, 2009 and 2008

	2009	2008	Increase/ (Decrease)	Increase/ (Decrease)
		(In thousands)		
Product sales, net	$ 115,108	$ 64,637	$ 50,471	78%
Xyrem	96,763	53,803	42,960	80%
Luvox CR	18,345	5,728	12,617	220%
Antizol		5,106	(5,106)	N/A(1)
Royalties	2,203	1,739	464	27%
Contract revenues	11,138	1,138	10,000	N/A(1)
Cost of product sales (excluding amortization of acquired developed technology and intangible asset impairment)	9,638	13,924	(4,286)	(31%)
Research and development	36,561	69,963	(33,402)	(48%)
Selling, general and administrative	58,652	111,401	(52,749)	(47%)
Intangible asset amortization	7,668	12,828	(5,160)	(40%)
Intangible asset impairment		29,763	(29,763)	N/A(1)
Interest income	34	1,834	(1,800)	(98%)
Interest expense	22,796	19,742	3,054	15%
Other (expense) income	(4)	16	(20)	N/A(1)
Gain on sale of product rights		3,918	(3,918)	N/A(1)

(1) Comparison to prior period is not meaningful.

Product Sales, Net

The increase in Xyrem product sales in 2009 compared to 2008, was due to a 10% increase in volume, which related primarily to increases in the number of patients on Xyrem and a slightly higher average dose for patients, with the remainder of the increase in Xyrem product sales due to price increases. Most of the increase in Luvox CR product sales, net was due to increases in volume following its launch in 2008 with the remainder due to price increases. We expect total product sales in 2010 to be higher than in 2009 due primarily to the impact of price increases on Xyrem taken during 2009.

Royalties, Net

The increase in royalties in 2009 compared to 2008 was entirely due to the increase in royalties we received under our agreement with UCB related to UCB s sales of Xyrem in territories outside of North America. We expect modest growth in royalty income in 2010.

Contract Revenues

UCB made a nonrefundable milestone payment of $10.0 million in July 2008, which we recorded as contract revenue in 2009 upon the completion of the last patient in our second Phase III pivotal clinical trial of sodium oxybate for the treatment of fibromyalgia. The milestone payment was recorded as deferred revenue in 2008. We expect contract revenue in 2010 to consist of amortization of the upfront payments previously paid by UCB currently recorded as deferred revenue.

Cost of Product Sales

Cost of product sales decreased in 2009 compared to 2008 as a result of higher Luvox CR manufacturing scale up costs in 2008 and a charge of $3.5 million in 2008 for Luvox CR inventory judged to be in excess of our needs.

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Research and Development Expenses

Research and development expenses were 48% lower in 2009 compared to 2008 as we focused our development efforts on our JZP-6 product candidate, completing our second Phase III pivotal clinical trial and submitting an NDA to the FDA in December 2009, while we did not conduct substantial development work on our other projects. As a result, our direct development costs decreased $24.9 million. Our direct development costs consist primarily of out-sourced study costs, including investigator payments and consulting fees, and do not include salaries and benefits or general administrative costs related to maintaining a research and development organization. Salaries, benefits and general administrative costs incurred in the research and development organization decreased $8.5 million in 2009 compared to 2008, primarily due to our lower staffing levels in 2009.

We expect our research and development spending in 2010 to be lower than 2009 and to be focused primarily on prosecuting our NDA for JZP-6, completing ongoing safety studies for JZP-6, and developing oral tablet forms of sodium oxybate, the active pharmaceutical ingredient in both Xyrem and JZP-6. We do not currently anticipate significant additional development spending on our other programs in the near term unless or until we partner a program or otherwise obtain additional funding.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were 47% lower in 2009 compared to 2008. In November 2008, we reduced the size of our sales force, which resulted in a $29.8 million reduction in 2009 sales and sales support costs compared to 2008. In addition, direct marketing expenses for Luvox CR were $16.4 million lower in 2009 compared with 2008, the year we launched Luvox CR. Launch planning and preparation activities related to our JZP-6 product candidate are expected to result in an increase in our selling, general and administrative expenses in 2010.

Intangible Asset Amortization

Our intangible assets consist primarily of developed technology related to Xyrem and Luvox CR which are amortized on a straight-line basis over their estimated useful lives. Amortization costs in 2009 were lower as compared to 2008 primarily due to a $29.8 million write down of the Luvox CR intangible asset in 2008.

Intangible Asset Impairment

The intangible asset impairment charge in 2008 resulted from an impairment of the intangible asset associated with Luvox CR.

Interest Income

Interest income was lower in 2009 as compared to 2008 due to lower average cash balances and to lower average interest rates.

Interest Expense

Interest expense relates primarily to interest on our Senior Notes and, to a small extent, interest on our liability under a government settlement. The increase in interest expense in 2009 as compared to 2008 was primarily due to interest expense recorded on the additional $40.0 million principal amount of the Senior Notes we issued in March 2008 and the two percentage point increase in the annual interest rate on the principal amount of the Senior Notes from January 1, 2009 through to July 7, 2009 as a result of our defaults under the agreement with the holders of our Senior Notes during that period. Interest on the Senior Notes is comprised of quarterly cash payments for interest, amortization of a debt discount related to warrants that were issued in conjunction with the Senior Notes and amortization of debt issuance costs. In 2010, we expect interest expense to decrease slightly as we make required quarterly principal payments on the Senior Notes.

Gain on Sale of Product Rights

In August 2008, we sold our rights to and interests in Antizol and Antizol-Vet, along with the associated product registrations, commercial inventory and trademarks, for $5.8 million and recorded a gain of $3.9 million.

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Comparison of Years Ended December 31, 2008 and 2007

	2008	2007	Increase/ (Decrease)	Increase/ (Decrease)
		(In thousands)		
Product sales, net	$ 64,637	$ 53,536	$ 11,101	21%
Xyrem	53,803	39,018	14,785	38%
Luvox CR	5,728		5,728	N/A(1)
Antizol	5,106	14,153	(9,047)	(64)%
Cystadane		365	(365)	N/A(1)
Royalties	1,739	1,156	583	50%
Contract revenues	1,138	10,611	(9,473)	(89%)
Cost of product sales (excluding amortization of acquired developed technology and intangible asset impairment)	13,924	8,903	5,021	56%
Research and development	69,963	69,792	171	0%
Selling, general and administrative	111,401	78,540	32,861	42%
Intangible asset amortization	12,828	9,217	3,611	39%
Intangible asset impairment	29,763	20,160	9,603	48%
Provision for government settlement		17,469	(17,469)	N/A(1)
Interest income	1,834	5,942	(4,108)	(69%)
Interest expense	19,742	13,647	6,095	45%
Other income	16	1,797	(1,781)	(99%)
Gain on sale of product rights	3,918	5,860	(1,942)	(33%)

(1) Comparison to prior period is not meaningful.

Product Sales, Net

The increase in product sales in 2008 compared to 2007 was primarily due to increases of $14.8 million in Xyrem sales and the launch of Luvox CR, offset by a $9.0 million decrease million in Antizol sales as a result of the sale of our product rights in August 2008. The increase in Xyrem product sales was due to an 18% increase in volume with the remainder of the increase due to price increases. Prior to the sale of our rights to Antizol in August 2008, revenues from the product had declined substantially compared with the same period in 2007 due to competition from generic products introduced after the expiration of Antizol s last orphan drug exclusivity.

Royalties, Net

The increase in royalties in 2008 compared to 2007 was largely due to an increase in sales of Xyrem by UCB.

Contract Revenues

The decrease in contract revenues in 2008 compared to 2007 was primarily due to milestone payments totaling $9.5 million which we received in 2007 under our agreement with UCB. Although UCB made a nonrefundable milestone payment of $10.0 million in July 2008, we recorded it as deferred revenue pending the completion of the last patient in our second Phase III pivotal clinical trial of sodium oxybate for the treatment of fibromyalgia, which occurred in 2009 as planned.

Cost of Product Sales

The increase in cost of product sales in 2008 compared to 2007 was primarily related to $7.1 million of costs for Luvox CR, which was launched in 2008, offset by a decrease in cost of product sales related to Antizol of $2.0 million due to the sale of our Antizol product rights in August 2008. Xyrem cost of product sales in 2008 were substantially the same compared to 2007.

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Research and Development Expenses

Research and development expenses were slightly higher in 2008 compared to 2007. Direct spending on JZP-6 increased $9.3 million as we conducted two major pivotal Phase III studies of our JZP-6 product candidate and enrolled patients in a long-term safety study. Increased spending on JZP-6 was offset by a number of factors, including a $7.2 million reduction in direct spending on Luvox CR due to its commercial launch early in 2008, and, to a small extent, our decisions to limit spending on our other development programs. An additional $1.3 million reduction in research and development expenses resulted from a reduction in force in mid-2008 of our early-stage research and development staff.

Selling, General and Administrative Expenses

The increase in selling, general and administrative expenses in 2008 compared to 2007 was attributable to a number of factors, including an increase in headcount and related salaries and benefits, primarily due to the expansion of our specialty sales force; an increase in product marketing spending in preparation for the launch of Luvox CR; and an increase in spending on activities related to supporting the sales force. These factors were partially offset by a decrease in legal fees associated with our response to the U.S. Attorney s investigation of past activities of Orphan Medical related to the promotion of Xyrem after we reached an agreement to settle that matter in 2007.

Intangible Asset Amortization

Amortization costs in 2008 were higher compared to 2007 as a result of amortization of Luvox CR intangible assets beginning in March 2008.

Intangible Asset Impairment

The intangible asset impairment charges in 2008 and 2007 resulted from impairment charges recorded related to Luvox CR and Antizol, respectively.

Provision for Government Settlement

In April 2006, we and Orphan Medical received subpoenas from the U.S. Department of Justice in connection with the sale and marketing of Xyrem. In July 2007, we reached a comprehensive settlement with the U.S. government in connection with this matter and agreed to make payments totaling $20.0 million, including interest, over the next several years. We recorded a charge of $17.5 million in 2007, which represented the present value of these payments discounted at an interest rate of 4.6%.

Interest Income

The decrease in interest income in 2008 compared to 2007 was primarily due to lower average cash balances.

Interest Expense

Interest expense relates primarily to interest on our Senior Notes, and, to a small extent, interest on our liability under a government settlement. Interest on the Senior Notes is comprised of quarterly cash payments for interest, amortization of a debt discount related to warrants that were issued in conjunction with the notes and amortization of debt issuance costs. The increase in 2008 compared to 2007 is primarily due to the addition of $40.0 million aggregate principal amount of Senior Notes issued in March 2008.

Other Income

We recorded a benefit of $1.8 million in 2007 in other income to reflect changes in the fair value of a preferred stock warrant liability.

Gain on Sale of Product Rights

In August 2008, we sold our rights to and interests in Antizol and Antizol-Vet, along with the associated product registrations, commercial inventory and trademarks, for $5.8 million and recorded a gain of $3.9 million.

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In March 2007, we sold our rights to Cystadane, along with the associated product registrations, commercial inventory and trademarks, for $9.0 million and recorded a gain of $5.1 million in 2007. In December 2007, we sold our rights to receive royalties on another product for $1.2 million and recorded a gain of $715,000.

Liquidity and Capital Resources

As of December 31, 2009, we had $15.6 million of cash and cash equivalents, $9.4 million borrowed under our revolving bank line of credit and $119.5 million principal amount of Senior Notes outstanding. Although we have incurred significant losses since inception, our net loss for our fiscal year ended December 31, 2009 was $6.8 million, which was significantly lower than the losses of $184.3 million and $138.8 million in our fiscal years ended December 31, 2008 and 2007, respectively. The improvement in our net loss in 2009 as compared to 2008 and 2007 was due to a significant increase in product sales and a significant decrease in operating expenses. In the fourth quarter of 2009, we reported both net income and cash generated from operations. In 2009, our primary focus was to increase sales of Xyrem and Luvox CR while limiting our spending primarily to activities necessary to generate product sales, to complete two Phase III pivotal clinical trials of our JZP-6 product candidate and submit an NDA to the FDA, and to fund necessary general and administrative functions.

At the beginning of 2009, we were in default under our agreement with the holders of our Senior Notes, or Senior Note Agreement, as a result of our failure to timely make a $4.5 million interest payment to the holders of the Senior Notes due in December 2008. We also did not make timely payments for two subsequent $5.1 million quarterly interest payments due on March 31, 2009 and June 30, 2009 and, as a result of the default, we were unable to borrow under our revolving bank line of credit.

The following events during 2009 were significant factors in our ability to continue our operations:

In February 2009, we amended our product license agreement with Solvay as a result of which the then existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR, as well as future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million, of which $6.0 million was paid in 2009, $4.0 million is payable in 2010, $4.5 million is payable in 2011 and $5.0 million is payable in 2012. If we pay these amounts when due, the payment due in 2012 will decrease to $4.5 million. In addition, we agreed to pay Solvay $5.0 million in 2015 if net sales of Luvox CR have reached a cumulative amount of $100.0 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the United States as of December 31, 2014.

In July 2009, we received net proceeds of $6.8 million through a private placement of units, priced at $3.6925 per unit, consisting of an aggregate of 1,895,734 shares of common stock and warrants to purchase an aggregate of 947,867 shares of our common stock for $4.00 per share any time through July 2016, subject to certain restrictions.

In July 2009, with the $6.8 million in net proceeds from the private placement and cash on hand, we paid $14.6 million to the holders of the Senior Notes which represented all of the accrued and unpaid interest as of June 30, 2009. We made timely interest payments due to the holders of the Senior Notes at the non-default rate of 15% on September 30, 2009 and December 31, 2009.

In September 2009, we amended our existing revolving bank line of credit agreement and, subject to certain limitations, we are able borrow 75% of eligible accounts receivable, with a maximum borrowing of $15.0 million. Borrowings under the revolving bank line of credit are secured by a first priority security interest in our accounts receivable and inventory and bear interest at a variable rate which was 6.5% at December 31, 2009. In addition, a minimum monthly interest payment of $14,000 and a collateral monitoring fee up to 0.15% per month on the outstanding principal amount are payable. As of December 31, 2009, the balance outstanding was $9.4 million, which was the maximum amount available for borrowing at that time under the revolving bank line of credit.

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In November 2009, we amended our Senior Note Agreement and reduced the exercise price of the related warrants to purchase 1,347,920 shares of common stock issued to the holders of the Senior Notes to $9.34 per share. Under the terms of the amended agreement we are required to make principal payments of $3.0 million, $6.0 million, $9.0 million, $10.0 million and $12.0 million on March 31, 2010, June 30, 2010, September 30, 2010, December 31, 2010 and March 31, 2011, respectively, without a prepayment penalty. The remaining principal amount of $79.5 million is due on June 24, 2011. We are also required to pay a $500,000 fee to the holders of the Senior Notes on the maturity date of the Senior Notes, or upon earlier repayment in full of the Senior Notes. In the event of default, or if we prepay the Senior Notes before they are due, we are obligated to pay a prepayment penalty which would have been 8.8% as of February 28, 2010 and reduces to zero ratably through June 24, 2011. Upon a change in control, the holders of the Senior Notes could accelerate payment of the Senior Notes and if accelerated, a prepayment penalty would be incurred. The holders of the Senior Notes have a security interest in all of our assets other than accounts receivable and inventory and there are certain restrictions on working capital borrowings, dividends and certain other payments. If our total net sales in any quarter are less than $25.0 million, there are certain minimum restricted cash balance requirements.

In November 2009 we also amended our previously unused committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, to increase the number of shares we could sell during any draw down period, to reduce the discount we give to Kingsbridge when it purchases shares of our common stock, and to reduce the minimum stock price above which we are eligible to utilize the CEFF. In exchange for the changes in the CEFF we reduced the exercise price of a warrant to purchase 220,000 shares of our common stock previously issued to Kingsbridge from $11.20 to $9.20 per share. Under the amended CEFF we can require Kingsbridge to purchase shares of our common stock at varying discounts to its then market price, subject to a limit of the lesser of $75.0 million, or 4,922,064 shares of common stock, and certain other conditions and limitations, including a requirement to maintain an effective registration statement with the SEC. As of December 31, 2009, we had an effective registration statement for 3,726,727 shares related to the CEFF which limits the amount we able to draw down under the CEFF. There are no minimum commitments or minimum use penalties. The CEFF, which expires in December 2012, has not been used to date.

Over the next twelve months, we plan to fund our operations and meet all of our obligations as they become due through our existing cash balances, cash generated from operations and borrowings under our revolving bank line of credit. The adequacy of our cash resources to meet our plan during the next twelve months depends on many assumptions, including primarily our assumptions with respect to growth in our product sales and continued access to our revolving bank line of credit which currently expires in May 2010, and other factors as set forth in Part I Item 1A of this Annual Report on Form 10-K under the headings *We have a history net losses, and, if we are to grow our business in the future, we will need to commit substantial resources, which could result in future losses.* Our assumptions may prove to be wrong or other factors may adversely affect our business, and we could exhaust our available cash resources. Beyond the next twelve months, we do not expect our cash resources to be sufficient to cover all of our operating requirements as well as launch expenses for our JZP-6 product candidate if approved by the FDA, the cost of our Luvox CR Phase IV clinical trial commitments, any significant additional costs related to the development of our product candidates and repayment of our Senior Notes at maturity. In order to fund these additional activities and requirements, we will need to do one or more of: raise additional funds, partner or license one or more of our product candidates or draw down funds under our committed equity financing facility

Under the amended terms of our agreement with the holders of our senior secured notes, or Senior Notes, we are required to repay an aggregate of $40.0 million of principal in quarterly installments in 2010 and in the first quarter of 2011, and the remaining $79.5 million of principal on June 24, 2011. We may seek to refinance our existing debt before it is due to lower the interest rate, extend the maturity date, or for other reasons. We may also seek to raise additional funds for general corporate purposes, including licensing or acquiring potential new product candidates, spending on our existing product candidates or spending related to launching JZP-6, if approved by the FDA. Refinancing or raising additional capital may be accomplished through one or more public or private debt or equity financings, collaborations, partnering arrangements or development financings. We believe we will be able to renew or replace our revolving bank line of credit agreement which expires in May 2010. If we were to seek to incur new secured debt without repaying the Senior Notes in full, the consent of the holders of our Senior Notes would be required. Because the holders of the Senior Notes currently have a first priority security interest in all of our assets other than accounts receivable and inventory, they may be unwilling to consent to any transaction that limits their rights or impacts their security interest. If we raise funds through the issuance of debt securities, these securities would have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any equity financing would be dilutive to our stockholders. In addition, if we raise funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. If we raise funds through collaborations, partnering arrangements, or development financings, we may be required to relinquish, on terms that are not favorable to us, rights to some of our products or product candidates that we could have otherwise sought to develop or commercialize ourselves. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization of our products or product candidates. Our need to raise capital soon may require us to accept terms that may harm our business or be disadvantageous to our current stockholders.

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

	Year Ended December 31,		
	2009	2008	2007
		(In thousands)	
Net cash used in operating activities	$ (15,878)	$ (130,232)	$ (81,091)
Net cash (used in) provided by investing activities	(6,124)	(11,942)	5,337
Net cash provided by financing activities	12,694	64,132	99,751
Net (decrease) increase in cash and cash equivalents	$ (9,308)	$ (78,042)	$ 23,997

In each of 2009, 2008 and 2007, net cash used in operating activities primarily reflected our net loss, adjusted for non-cash items including depreciation, amortization, impairment losses, losses on disposal of property and equipment, non-cash interest expense, stock-based compensation, gains on sales of product rights, changes in working capital and the provision for the government liability. In 2009, operating cash outflows included the $4.5 million quarterly interest payment that was due in December 2008 to the holders of the Senior Notes. In 2009, 2008 and 2007, operating cash outflows included $2.5 million, $2.0 million and $1.0 million, respectively, paid to the government as part of our settlement.

Net cash used in investing activities in 2009 included $6.0 million paid to Solvay for the rights to market Luvox CR, and an increase in restricted cash, offset by the maturity of an investment in a marketable security. Net cash used in investing activities in 2008 included $27.0 million paid to Solvay for the right to market Luvox CR, the purchase of property and equipment of $1.7 million, partially offset by the release of $12.0 million of cash that was previously restricted under the original senior note agreement entered into in June 2005, and proceeds of $5.8 million from the sale of our product rights to Antizol and Antizol-Vet. Net cash provided by investing activities in 2007 primarily included proceeds of $9.0 million from the sale of our rights to Cystadane, partially offset by purchases of property and equipment of $3.1 million and a net increase in the purchase, sale and maturity of short-term investments of $1.7 million.

Net cash provided by financing activities in 2009 included net proceeds of $6.8 million from a private placement of common stock and warrants in July 2009 and $5.5 million in net borrowings under our revolving bank line of credit. Net cash provided by financing activities in 2008 related primarily to the sale of $40.0 million aggregate principal amount of Senior Notes for net proceeds of $38.5 million, and $24.5 million of net proceeds from a registered direct public offering of common stock and warrants. Net cash provided by financing activities in 2007 related largely to the issuance of common stock in our initial public offering for net proceeds of $97.5 million.

Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2009:

		Payments due by period			
Contractual Obligations(1)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 years
			(In thousands)		
Senior secured notes(2)	$ 143,008	$ 44,799	$ 98,209	$	$
Liability under government settlement(3)	14,500	3,000	11,500		
Amounts due to Solvay(4)	13,000	4,000	9,000		
Line of credit	9,399	9,399			
Operating lease obligations(5)	4,227	1,995	2,194	38	
Purchase obligations(6)	3,648	3,648			
Total	$ 187,782	$ 66,841	$ 120,903	$ 38	$

(1) We have not included milestone or royalty payment obligations in the table above that we are not able to determine when or if the related milestones will be achieved, or when or if the events triggering payment of the obligations will occur.

(2) In addition to the amounts shown in the table above, if we make principal payments on our Senior Notes before they are due we will owe a prepayment penalty. The penalty, a percentage of the principal amount repaid, was 8.8% as of February 28, 2010, and reduces ratably to zero through June 2011. No prepayment penalty is due on the $40.0 million of required quarterly repayments due from March 31, 2010 through March 31, 2011 unless they are paid before they become due.

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(3) Under the terms of the settlement of the government investigation, if we are acquired, or in the event of an uncured default resulting from the failure to make payments when due, $2.5 million plus interest payable under the civil settlement agreement could become due immediately, to the extent then unpaid. In addition, if in any calendar year our audited financial statements show net income, we would be required to pay 50% of the net income shown in those financial statements within 30 days of their issuance, up to the remainder of the then remaining unpaid amount under the civil settlement agreement. The maximum amount due under the civil settlement agreement that could be accelerated under this provision is $1.2 million otherwise payable in January 2012.

(4) In February 2009, we amended our product license agreement with Solvay as a result of which the then existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR, as well as the future royalty and other obligations, were replaced with an obligation to pay a total of $19.0 million, of which $6.0 million was paid in 2009, $4.0 million is payable in 2010, $4.5 million is payable in 2011 and $5.0 million is payable in 2012. If we pay these amounts when due, which is assumed in the table above, the payment due in 2012 will decrease to $4.5 million. In addition, we agreed to pay Solvay $5.0 million in 2015 if net sales of Luvox CR have reached a cumulative amount of $100 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the United States as of December 31, 2014.

(5) Includes the minimum rental payments for our corporate office building and automobile lease payments for our sales force. In addition to the minimal rental payments on our office building we are obligated to pay for operating expenses for the lease property, which are not included in the table above.

(6) Consists of commitments to third party manufacturers of Xyrem and Luvox CR. We do not have any obligations under contracts for liquidated damages as of December 31, 2009.

The table above reflects only payment obligations for development products that are fixed and determinable. We also have contractual payment obligations, the amount and timing of which are contingent upon future events. Amounts and estimated timing of significant payments related to licensing and other arrangements not included in the contractual obligations table above are as follows:

In October 2004, we entered into an agreement with GlaxoSmithKline to acquire worldwide rights to the active pharmaceutical ingredient in JZP-4. We are currently conducting product formulation activities in preparation for possible initiation of a Phase II clinical program for JZP-4. Initiation of a Phase II clinical program is subject to partnering or otherwise securing funding for this program. The agreement includes aggregate payments of up to $113.5 million upon the achievement of future development and commercial milestones and royalties at specified rates based on net product sales. These future payments include a $5.0 million milestone payment due upon the enrollment of the first patient in a JZP-4 Phase II clinical trial.

The FDA approval of Luvox CR included a commitment for two Phase IV clinical trials, one in adolescent patients with social anxiety disorder and one a long-term duration of effect study in patients with social anxiety disorder. We are in the process of planning these studies and are in discussion with the FDA concerning the studies. The cost of these Phase IV clinical trials which we must conduct and find ourselves, will be significant.

Related Parties

In the private placement we completed in July 2009, 1,858,486 shares of common stock and a warrant to purchase 929,243 shares of common stock were acquired by Longitude Venture Partners, L.P. and 37,248 shares of common stock and a warrant to purchase 18,624 shares of common stock were acquired by Longitude Capital Associates, L.P. In July 2009, Patrick G. Enright was elected to our board of directors as a condition to the closing of the private placement. Mr. Enright is a managing member of Longitude Capital Partners, LLC, the sole general partner of Longitude Venture Partners, L.P. and Longitude Capital Associates, L.P.

In August 2008, in connection with the sale of our rights to Antizol and Antizol-Vet, pursuant to the terms of the Senior Note Agreement, we paid $327,000 to an entity affiliated with Kohlberg, Kravis & Roberts & Co. L.P., or KKR, a significant stockholder, as partial prepayment of the outstanding principal of the Senior Notes held by it.

As of December 31, 2008, an entity affiliated with KKR held Senior Notes with an aggregate principal amount of $6.8 million and warrants to purchase 70,156 shares of common stock exercisable at $20.36 per share. The exercise price of these warrants was reduced to $9.34 per share when we amended our Senior Note Agreement in November 2009. As of December 31, 2009, an entity affiliated with KKR held Senior Notes with an aggregate principal amount of $6.8 million and warrants to purchase 70,156 shares of common stock exercisable at $9.34 per share.

Cash paid for interest with respect to notes held by entities affiliated with KKR during the years ended December 31, 2009, 2008 and 2007 was $1.3 million, $796,000 and $3.8 million, respectively.

In the registered direct public offering that was completed in July 2008, a total of 60% of the investment was made by certain of our existing stockholders with which certain members of our board of directors are affiliated and/or associated; the remaining units were purchased by third party institutional investors on the same terms and conditions. Entities affiliated with KKR purchased 1,328,527 shares of common stock in this offering and warrants to purchase 597,837 shares of common stock exercisable at $7.37 per share through July 2014.

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Recent Accounting Pronouncements

In October 2009, the FASB issued authoritative guidance which amends the revenue recognition guidance to require companies to allocate revenue in multiple-element arrangements based on an element s estimated selling price if vendor-specific or other third-party evidence is not available. The guidance is effective beginning January 1, 2011. Earlier adoption is permitted. We are currently evaluating the effect that the adoption of this guidance will have on our results of operations and financial position.

In January 2010, the FASB issued additional guidance for improving disclosures about fair value measurements. Under this guidance, two new disclosures are required: (1) transfers in and out of Level 1 and 2 measurements and the reasons for the transfers, and (2) a gross presentation of activity within the Level 3 roll forward. This guidance also includes clarifications to existing disclosure requirements on the level of disaggregation and disclosures regarding inputs and valuation techniques. This guidance applies to all entities required to make disclosures about recurring and nonrecurring fair value measurements. The guidance is effective for interim annual reporting periods beginning after December 15, 2009. We do not expect that our adoption of the guidance will have an impact on our results of operations or financial position.

Off-Balance Sheet Arrangements

Since our inception, except for standard operating leases, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is confined to our cash equivalents, marketable securities and restricted cash, all of which have maturities of less than one year and bear interest rates at fixed rates and are denominated in, and pay interest in, U.S. dollars. The fair value of items exposed to market risk was $5.1 million and $26.7 million as of December 31, 2009 and 2008, respectively. The goals of our investment policy are liquidity and capital preservation. We limit our credit and liquidity risks through our investment policy and through regular reviews of our portfolio against our policy. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including U.S. government agencies, corporate bonds, commercial paper and money market funds. Our cash equivalents, marketable securities and restricted cash as of December 31, 2009 and 2008 consisted primarily of obligations of U.S. government agencies, commercial paper and money market funds. The effect of a hypothetical change of five hundred basis points in the average yield earned on our cash equivalents and short-term investments would have been immaterial.

Our Senior Notes have fixed interest payments, and therefore, interest rate payments on our Senior Notes will not change if market interest rates change. We pay interest on borrowings under our revolving bank line of credit at rates that vary with a bank s prime rate. As of December 31, 2009, our borrowing rate on the revolving bank line of credit was 6.5%. Because our average borrowings under our revolving bank line of credit are not substantial, changes in the interest rate will not have a significant impact on interest expense.

We have no operations outside the United States, and almost all of our operating expenses and capital expenditures are denominated in U.S. dollars. Operating expenses denominated in foreign currencies typically expose us to fluctuations in the exchange rates between the U.S. dollar and the Canadian dollar, the Euro and Pounds Sterling. We receive royalties on certain net product sales that are denominated in other currencies, primarily in Euros, but these royalties comprise a small portion of our revenues. The effect of a hypothetical change of ten percent in the U.S. dollar exchange rate against all other currencies would have resulted in a change in our operating expenses of $81,000 for the year ended December 31, 2009.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements as listed below are attached to this Annual Report on Form 10-K as pages F-1 through F-28.

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

Not applicable.

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Item 9A(T). Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision, and with the participation of, management including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e)) of the Securities Exchange Act of 1934, as amended, or Exchange Act) as of the end of the period covered by this annual report on Form 10-K. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2009.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting

No changes in our internal control over financial reporting occurred during our fiscal quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control over Financial Reporting

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

1. Jazz Pharmaceuticals management is responsible for establishing and maintaining adequate internal control over financial reporting.

2. Jazz Pharmaceuticals management has used the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO framework, to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of Jazz Pharmaceuticals internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of Jazz Pharmaceuticals internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

3. Management has assessed the effectiveness of Jazz Pharmaceuticals internal control over financial reporting as of December 31, 2009 and has concluded that such internal control over financial reporting was effective. There were no material weaknesses in internal control over financial reporting identified by management.

4. This annual report does not include an attestation report of Jazz Pharmaceuticals registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by Jazz Pharmaceuticals registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit Jazz Pharmaceuticals to provide only management s report in this annual report.

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Item 9B. Other Information

2009 Annual Meeting of Stockholders

On December 15, 2009, our 2009 Annual Meeting of Stockholders was held at our corporate offices in Palo Alto, California. During this meeting, our stockholders voted on the following three proposals:

(a) Proposal to elect three Class II directors to serve until the 2012 Annual Meeting of Stockholders or until their successors have been duly elected and qualified or until their earlier death, resignation or removal:

Nominee	Votes For	Votes Authority Withheld
Samuel D. Colella	22,027,341	153,857
James C. Momtazee	20,049,946	2,131,252
Robert M. Myers	22,047,256	133,942

Our Class III directors, Bruce C. Cozadd, Michael W. Michelson, Kenneth W. O Keefe and Alan M. Sebulsky, will each continue to serve on our Board of Directors until our 2010 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal. Our Class I directors, Bryan C. Cressey, Patrick G. Enright, James B. Tananbaum, M.D., and Nathaniel M. Zilkha will each continue to serve on our Board of Directors until our 2011 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal.

(b) Proposal to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2009:

For	Against	Abstain
19,979,714	2,041,492	159,992

(c) Proposal to approve the amended and restated form of indemnification agreement for our directors and officers and to ratify the indemnification agreements previously entered into by us with our directors and officers in accordance with the amended and restated form:

For	Against	Abstain	Broker Non-Vote
21,637,352	228,536	315,310	0

2010 Annual Meeting of Stockholders

Although we have not yet determined the date of our 2010 annual meeting of stockholders, we expect that it will be held in May or June of 2010 an will inform our stockholders of such date as soon as practicable. To be considered for inclusion in the proxy materials for our 2010 annual meeting of stockholders, all applicable requirements of Rule 14a-8 promulgated under the Securities Exchange Act of 1934 must be satisfied and such proposals must be received by us not later than a reasonable time before we begin to print and send our proxy materials. Stockholders wishing to submit proposals or director nominations that are not to be included in the proxy statement for our 2010 annual meeting of stockholders must do so no later than the close of business on the later of the 90th day prior to our 2010 annual meeting of stockholders or the tenth day following the day on which the date of our 2010 annual meeting of stockholders is first publicly announced. Stockholders are also advised to review Jazz Pharmaceuticals bylaws, which contain additional advance notice requirements, including requirements with respect to advance notice stockholder proposals and director nominations.

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PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2010 annual meeting of stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to our executive officers may be found under the caption, Executive Officers of the Registrant in Item 1 of this Annual Report on Form 10-K. The information required by this item relating to our directors and nominees for director may be found under the section entitled Proposal 1 Election of Directors in the proxy statement for our 2010 annual meeting of stockholders. The information required by this item relating to our audit committee, audit committee financial expert and procedures by which stockholders may recommend nominees to our board of directors, may be found under the section entitled Corporate Governance and Board Matters appearing in the proxy statement for our 2010 annual meeting of stockholders. Such information is incorporated herein by reference. Information regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, may be found under the section entitled Section 16(a) Beneficial Ownership Reporting Compliance appearing in our proxy statement for our 2010 annual meeting of stockholders. Such information is incorporated herein by reference.

The Jazz Pharmaceuticals Code of Conduct applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Conduct is available on our website at *www.jazzpharmaceuticals.com* under the section entitled Company at Corporate Responsibility . Stockholders may request a free copy of the Code of Conduct by submitting a written request to Jazz Pharmaceuticals, Inc., Attention: Investor Relations, 3180 Porter Drive, Palo Alto, California 94304. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Item 11. Executive Compensation

The information required by this item is included in our proxy statement for our 2010 annual meeting of stockholders under the sections entitled Executive Compensation, Director Compensation, Corporate Governance and Board Matters Compensation Committee Interlocks and Insider Participation and Corporate Governance and Board Matters Compensation Committee Report and is incorporated herein by reference.

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

The information required by this item relating to security ownership of certain beneficial owners and management is included in our proxy statement for our 2010 annual meeting of stockholders under the section entitled Security Ownership of Certain Beneficial Owners and Management and is incorporated herein by reference.

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The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2009.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:			
2007 Equity Incentive Plan	4,771,825	$ 8.93(1)	1,870,814(2)
2007 Employee Stock Purchase Plan			270,694(3)
2007 Non-Employee Directors Stock Option Plan	190,000	$ 8.08	71,568(4)
Equity compensation plans not approved by security holders:			
Directors Deferred Compensation Plan	77,294(5)		(6)
Total	5,039,119		2,213,076

(1) The weighted average exercise price of outstanding options and rights under our 2007 Equity Incentive Plan, or the 2007 Plan, includes the effect of our grant of restricted stock units under the 2007 Plan, which restricted stock units were granted in consideration of services rendered to us and do not carry an exercise price. The weighted average exercise price of outstanding options under the 2007 Plan was $8.98, excluding the grant of the restricted stock units but including shares subject to options originally granted under our 2003 Equity Incentive Plan.

(2) As of December 31, 2009, an aggregate of 6,817,361 shares of common stock were reserved for issuance under the 2007 Plan, of which 1,870,814 remained available for future issuance. The number of shares reserved for issuance under the 2007 Plan includes shares subject to options originally granted under our 2003 Equity Incentive Plan. The number of shares reserved for issuance under the 2007 Plan automatically increases on each January 1, from January 1, 2008 through January 1, 2017, by the lesser of (a) 4.5% of the total number of shares of our common stock outstanding on December 31 of the preceding year or (b) 3,000,000 shares, (or such lesser amount as may be approved by our board of directors). On January 1, 2010, the number of shares reserved for issuance under the 2007 Plan increased by 1,406,487 shares pursuant to this automatic share increase provision.

(3) As of December 31, 2009, an aggregate of 1,050,000 shares of common stock were reserved for issuance under our 2007 Employee Stock Purchase Plan, or the 2007 ESPP, of which 270,694 remained available for future issuance under the 2007 ESPP with up to a maximum of 260,000 shares that could be purchased in the current purchase period and for the following two purchase periods. Subsequently, the aggregate number of shares available for issuance in any six month purchase period will be 175,000. The number of shares reserved for issuance under the 2007 ESPP automatically increases on each January 1, from January 1, 2008 through January 1, 2017, by the lesser of (a) 1.5% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year or (b) 350,000 shares, (or such lesser amount as may be approved by our board of directors). On January 1, 2010, the number of shares reserved for issuance under the 2007 ESPP increased by 350,000 shares pursuant to this automatic share increase provision.

(4) As of December 31, 2009, an aggregate of 345,531 shares of common stock were reserved for issuance under our 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Plan, of which 71,568 remained available for future issuance. The number of shares remaining available for issuance under the 2007 Directors Plan as shown in the table above is reduced by the number of shares credited to our non-employee directors stock accounts under our Director Deferred Compensation Plan, or the Directors Deferred Plan. The number of shares reserved for issuance under the 2007 Directors Plan automatically increases on each January 1, from January 1, 2008 through January 1, 2017, by the sum of (a) the excess of (i) the number of shares of common stock subject to options granted during the preceding calendar year under the 2007 Directors Plan, over (ii) the number of shares added back to the share reserve under the 2007 Directors Plan during the preceding calendar year and (b) the aggregate number of shares credited to our non-employee directors stock accounts under the Directors Deferred Plan (or such lesser amount as may be approved by our board of directors). In no event may the amount of any such annual increase exceed 200,000 shares. On January 1, 2010, the number of shares reserved for issuance under the 2007 Directors Plan

increased by 128,432 shares pursuant to this automatic share increase provision.

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(5) Represents shares credited to individual non-employee director stock accounts as of December 31, 2009 under the Directors Deferred Plan. There is no exercise price for these shares.

(6) Distributions in shares of our common stock under the Directors Deferred Plan are funded with the shares reserved under the 2007 Directors Plan. Accordingly, no shares are shown remaining available for issuance under the Directors Deferred Plan in the above table. The aggregate number of shares credited to our non-employee directors stock accounts during a calendar year are automatically added to the share reserve under the 2007 Directors Plan on January 1st of the following year as set forth in note (4) above.

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

The information required by this item is included in our proxy statement for our 2010 annual meeting of stockholders under the sections entitled Certain Relationships and Related Transactions and Corporate Governance and Board Matters Independence of Jazz Pharmaceuticals Board of Directors and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to the information included in our proxy statement for our 2010 annual meeting of stockholders under the section entitled Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

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

1. Index to Financial Statements:

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

2. Financial Statement Schedules:

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

Schedule II: Valuation and Qualifying Accounts

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

(b) Exhibits The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.(15)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(3)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(4)
4.3A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between the Registrant and the other parties named therein.(13)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(38)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(48)
4.3D	Waiver and Amendment Agreement, dated as of July 6, 2009 by and between the Registrant and the other parties named therein.(73)
4.6	Form of Series BB Preferred Stock Warrant of the Registrant.(14)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(39)
4.5A	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein.(40)

4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(41)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(42)
4.5D	Form of Common Stock Warrant of the Registrant.(43)
4.5E	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(44)
4.5F	Amendment and Waiver Agreement, dated as of November 10, 2009, by and among the Registrant, JPI Commercial, LLC and the other parties named therein.(76)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(49)

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Exhibit Number	Description of Document
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(50)
4.6C	Amendment Agreement No. 1, dated as of November 20, 2009, by and between the Registrant and Kingsbridge Capital Limited.(77)
4.7	Form of Registered Direct Common Stock Warrant.(55)
4.8	NOL Preservation Lock-Up Agreement, effective as of July 7, 2009, by and between the Registrant and the other parties named therein.(68)
4.9A	Form of Common Stock Warrant of the Registrant issued on July 7, 2009.(69)
4.9B	Investor Rights Agreement, dated July 7, 2009 by and between the Registrant and the other parties named therein.(75)
10.1+	2003 Equity Incentive Plan, as amended.(5)
10.2+	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.(6)
10.3+	2007 Equity Incentive Plan.(7)
10.4+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.(16)
10.5+	2007 Non-Employee Directors Stock Option Plan.(8)
10.6+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.(9)
10.7+	2007 Employee Stock Purchase Plan.(10)
10.8+	Form of 2007 Employee Stock Purchase Plan Offering Document.(11)
10.9	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.(22)
10.10	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(17)
10.11	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.(18)
10.12	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.(23)
10.13	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(24)
10.14	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(19)
10.15	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(20)
10.16	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc. and Elan Pharma International Limited.(28)
10.17	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(25)
10.18	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(29)
10.19	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(30)
10.20	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.(26)

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Exhibit Number	Description of Document
10.21	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(27)
10.22	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(31)
10.23	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.(32)
10.24	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.(21)
10.25+	Directors Deferred Compensation Plan.(12)
10.26+	Non-Employee Director Compensation Arrangements, as modified on August 14, 2008.(57)
10.27A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(33)
10.27B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and the Registrant.(34)
10.27C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.(35)
10.27D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and the Registrant.(36)
10.28+	Form of Letter, amending outstanding options granted under the Registrant s 2003 Equity Incentive Plan.(2)
10.29+	Form of Restricted Stock Unit Award under the Registrant s 2007 Equity Incentive Plan.(37)
10.30	Amendment Number 4 to Development, License and Supply Agreement, dated as of October 26, 2007, by and between the Registrant and Elan Pharma International, Inc.(45)
10.31	Amendment No. 1 to Amended and Restated Xyrem License and Distribution Agreement, dated as of December 21, 2007, by and between the Registrant and UCB Pharma Limited.(46)
10.32	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.(47)
10.33	Common Stock Purchase Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(51)
10.34+	Amended Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(52)
10.35+	Form of Stock Award Grant Notice and Stock Award Agreement under the Registrant s 2007 Equity Incentive Plan.(53)
10.36	Master Services Agreement dated May 6, 2008, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and CuraScript, Inc.(54)
10.37	Amendment No. 2 to Amended and Restated Xyrem License and Distribution Agreement, dated July 23, 2008, by and between the Registrant and UCB Pharma Limited.(56)
10.38	Amendment No. 2 to License Agreement, dated as of October 17, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(58)
10.39	Amendment No. 3 to License Agreement, dated as of December 19, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(60)
10.40	Amendment No. 4 to License Agreement, dated as of February 5, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(61)
10.41+	Directors Deferred Compensation Plan, as amended.(62)

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Exhibit Number	Description of Document
10.42+	Amended and Restated Executive Change in Control and Severance Benefit Plan.(63)
10.43	Revision of Payment Terms of the Plea Agreement dated as of July 17, 2007 between the U.S. Attorney for the Eastern District of New York and Orphan Medical, Inc.(64)
10.44	Amendment to Settlement Agreement, signed by the Company on February 6, 2009, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(65)
10.45	Form of Registered Direct Subscription Agreement.(59)
10.46	Consulting Agreement dated April 3, 2009 by and between the Registrant and Samuel R. Saks, MD(66)
10.47	First Amendment of Lease, dated June 1, 2009, by and between the Registrant and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University.(67)
10.48	Securities Purchase Agreement, dated July 6, 2009, by and between the Registrant and the purchasers listed on the signature pages thereto.(70)
10.49	2009 Executive Officer Compensation Arrangements.(72)
10.50	Form of Amended and Restated Indemnification Agreement between the Registrant and its officers and directors.(71)
10.51	Amendment No. 5 to License Agreement, dated as of June 23, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(74)
10.52	Amendment No. 5 to License Agreement, dated as of October 23, 2009, by and between the Registrant and Elan Pharma International Limited.(78)
10.53	Offer Letter from the Registrant to Kathryn Falberg.(79)
12.1	Ratio of Earnings to Fixed Charges and computation of ratios of earnings to fixed charges.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereto).
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

+ Indicates management contract or compensatory plan.

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

(1) Incorporated herein by reference to exhibit 3.1 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.

(2) Incorporated herein by reference to exhibit 10.60 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.

(3) Incorporated herein by reference to exhibit 3.4 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(4) Incorporated herein by reference to exhibit 4.2 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(5) Incorporated herein by reference to exhibit 10.21 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(6)

Incorporated herein by reference to exhibit 10.22 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(7) Incorporated herein by reference to exhibit 10.23 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

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(8) Incorporated herein by reference to exhibit 10.25 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
(9) Incorporated herein by reference to exhibit 10.26 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
(10) Incorporated herein by reference to exhibit 10.27 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
(11) Incorporated herein by reference to exhibit 10.28 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
(12) Incorporated herein by reference to exhibit 10.55 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.
(13) Incorporated herein by reference to exhibit 4.3A in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.
(14) Incorporated by reference to exhibit 4.6 to the Registrant s registration statement on Form S-1 (File No. 333-141164), as filed with the SEC on March 9, 2007.
(15) Incorporated by reference to exhibit 2.1 in the Registrant s registration statement on Form S-1 (File No. 333-141164), as filed with the SEC on March 9, 2007.
(16) Incorporated herein by reference to exhibit 10.24 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.
(17) Incorporated herein by reference to exhibit 10.31 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.
(18) Incorporated herein by reference to exhibit 10.32 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.
(19) Incorporated herein by reference to exhibit 10.43 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.
(20) Incorporated herein by reference to exhibit 10.44 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.
(21) Incorporated herein by reference to exhibit 10.54 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.
(22) Incorporated herein by reference to exhibit 10.30 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(23) Incorporated herein by reference to exhibit 10.41 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(24) Incorporated herein by reference to exhibit 10.42 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(25) Incorporated herein by reference to exhibit 10.46 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(26) Incorporated herein by reference to exhibit 10.49 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(27) Incorporated herein by reference to exhibit 10.50 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(28) Incorporated herein by reference to exhibit 10.45 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(29) Incorporated herein by reference to exhibit 10.47 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(30) Incorporated herein by reference to exhibit 10.48 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(31) Incorporated herein by reference to exhibit 10.51 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(32) Incorporated herein by reference to exhibit 10.52 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(33) Incorporated herein by reference to exhibit 10.57A in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
(34) Incorporated herein by reference to exhibit 10.57B in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
(35) Incorporated herein by reference to exhibit 10.57C in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.

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(36) Incorporated herein by reference to exhibit 10.57D in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
(37) Incorporated herein by reference to exhibit 10.64 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
(38) Incorporated herein by reference to exhibit 4.3B in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(39) Incorporated herein by reference to exhibit 4.4B in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(40) Incorporated herein by reference to exhibit 4.5A in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(41) Incorporated herein by reference to exhibit 4.5B in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(42) Incorporated herein by reference to exhibit 4.5C in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(43) Incorporated herein by reference to exhibit 4.5D in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(44) Incorporated herein by reference to exhibit 4.5E in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(45) Incorporated herein by reference to exhibit 10.66 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(46) Incorporated herein by reference to exhibit 10.68 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(47) Incorporated herein by reference to exhibit 10.69 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(48) Incorporated herein by reference to exhibit 4.3C in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
(49) Incorporated herein by reference to exhibit 4.6A in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
(50) Incorporated herein by reference to exhibit 4.6B in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
(51) Incorporated herein by reference to exhibit 10.70 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
(52) Incorporated herein by reference to exhibit 10.71 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.
(53) Incorporated herein by reference to exhibit 10.73 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.
(54) Incorporated herein by reference to exhibit 10.74 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.
(55) Incorporated herein by reference to exhibit 4.7 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
(56) Incorporated herein by reference to exhibit 10.75 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 24, 2008.
(57) Incorporated herein by reference to exhibit 10.56 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2008, as filed with the SEC on November 14, 2008.
(58) Incorporated herein by reference to exhibit 10.77 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2008, as filed with the SEC on November 14, 2008.
(59) Incorporated by reference to exhibit 10.1 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
(60) Incorporated herein by reference to exhibit 10.78 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(61) Incorporated herein by reference to exhibit 10.79 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(62) Incorporated herein by reference to exhibit 10.80 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(63) Incorporated herein by reference to exhibit 10.81 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.

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(64) Incorporated herein by reference to exhibit 10.82 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(65) Incorporated herein by reference to exhibit 10.83 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(66) Incorporated herein by reference to exhibit 10.85 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
(67) Incorporated herein by reference to exhibit 10.86 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 4, 2009.
(68) Incorporated herein by reference to exhibit 4.8 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(69) Incorporated herein by reference to exhibit 4.9A in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(70) Incorporated herein by reference to exhibit 10.87 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(71) Incorporated herein by reference to exhibit 10.89 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(72) Incorporated herein by reference to exhibit 10.84 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
(73) Incorporated herein by reference to exhibit 4.3D in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009.
(74) Incorporated herein by reference to exhibit 10.90 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009.
(75) Incorporated herein by reference to exhibit 4.9B in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(76) Incorporated by reference to exhibit 4.5F in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on November 10, 2009.
(77) Incorporated by reference to exhibit 4.6C in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on November 23, 2009.
(78) Incorporated by reference to exhibit 10.91 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2009, as filed with the SEC on November 6, 2009.
(79) Incorporated herein by reference to exhibit 10.92 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on December 3, 2009.

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

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SIGNATURES

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

Date: March 3, 2010

Jazz Pharmaceuticals, Inc.
(Registrant)

/s/ Bruce C. Cozadd
Bruce C. Cozadd
Chairman and Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Kathryn E. Falberg
Kathryn E. Falberg
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

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POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Bruce C. Cozadd	Chairman, Chief Executive Officer and Director	March 3, 2010
Bruce C. Cozadd	*(Principal Executive Officer)*	
/s/ Kathryn E. Falberg	Senior Vice President and Chief Financial Officer	March 3, 2010
Kathryn E. Falberg	*(Principal Financial Officer)*	
/s/ Joan E. Colligan	Controller and Principal Accounting Officer	March 3, 2010
Joan E. Colligan	*(Principal Accounting Officer)*	
/s/ Samuel D. Colella	Director	March 3, 2010
Samuel D. Colella		
/s/ Bryan C. Cressey	Director	March 3, 2010
Bryan C. Cressey		
/s/ Patrick G. Enright	Director	March 3, 2010
Patrick G. Enright		
/s/ Michael W. Michelson	Director	March 3, 2010
Michael W. Michelson		
/s/ James C. Momtazee	Director	March 3, 2010
James C. Momtazee		
/s/ Robert M. Myers	Director	March 3, 2010
Robert M. Myers		
/s/ Kenneth W. O keefe	Director	March 3, 2010

	Kenneth W. O Keefe		
/s/	ALAN M. SEBULSKY	Director	March 3, 2010
	Alan M. Sebulsky		
/s/	JAMES B. TANANBAUM, M.D.	Director	March 3, 2010
	James B. Tananbaum, M.D.		
/s/	NATHANIEL M. ZILKHA	Director	March 3, 2010
	Nathaniel M. Zilkha		

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Jazz Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule listed in the Index at Item 15(a)2. These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of the internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Jazz Pharmaceuticals, Inc. at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Palo Alto, California

March 3, 2010

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,595	$ 24,903
Restricted cash	2,988	1,913
Marketable securities		1,004
Accounts receivable, net of allowances of $288 and $176 at December 31, 2009 and 2008, respectively	12,313	6,643
Inventories	3,426	4,294
Prepaid expenses	1,653	2,366
Other current assets	979	2,876
Total current assets	36,954	43,999
Property and equipment, net	1,124	2,514
Intangible assets, net	29,858	32,526
Goodwill	38,213	38,213
Other long-term assets	1,247	246
Total assets	$ 107,396	$ 117,498
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Line of credit	$ 9,399	$ 3,875
Accounts payable	2,158	5,736
Accrued liabilities	14,296	16,491
Senior secured notes (including $1,355 and $6,747 pertaining to a related party at December 31, 2009 and 2008)	23,759	118,534
Purchased product rights liability	4,000	14,000
Liability under government settlement	2,954	2,533
Deferred revenue	2,675	12,322
Total current liabilities	59,241	173,491
Deferred rent	29	
Deferred revenue, non-current	10,191	11,330
Purchased product rights liability, non-current	9,000	
Liability under government settlement, non-current	10,658	13,063
Senior secured notes (including $5,196 pertaining to a related party at December 31, 2009)	91,107	
Common stock subject to repurchase		12,492
Commitments and contingencies (Note 7)		
Stockholders deficit:		
Preferred stock, $0.0001 par value; 20,000,000 shares authorized at December 31, 2009 and 2008; no shares issued and outstanding at December 31, 2009 and 2008, respectively		
Common stock, $0.0001 par value; 150,000,000 shares authorized at December 31, 2009 and 2008; 31,255,274 and 28,925,117 shares issued and outstanding at December 31, 2009 and 2008, respectively	3	3
Additional paid-in capital	434,811	407,923
Accumulated other comprehensive income		4
Accumulated deficit	(507,644)	(500,808)

Total stockholders deficit	(72,830)	(92,878)
Total liabilities and stockholders deficit	$ 107,396	$ 117,498

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

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2009	2008	2007
Revenues:			
Product sales, net	$ 115,108	$ 64,637	$ 53,536
Royalties	2,203	1,739	1,156
Contract revenues	11,138	1,138	10,611
Total revenues	128,449	67,514	65,303
Operating expenses:			
Cost of product sales (excluding amortization of acquired developed technology and intangible asset impairment)	9,638	13,924	8,903
Research and development	36,561	69,963	69,792
Selling, general and administrative	58,652	111,401	78,540
Intangible asset amortization	7,668	12,828	9,217
Intangible asset impairment		29,763	20,160
Provision for government settlement			17,469
Total operating expenses	112,519	237,879	204,081
Income (loss) from operations	15,930	(170,365)	(138,778)
Interest income	34	1,834	5,942
Interest expense (including $1,183, $1,179 and $4,104 for the years ended December 31, 2009, 2008 and 2007, respectively, pertaining to a related party)	(22,796)	(19,742)	(13,647)
Other (expense) income	(4)	16	1,797
Gain on sale of product rights		3,918	5,860
Net loss	$ (6,836)	$ (184,339)	$ (138,826)
Net loss per share, basic and diluted	$ (0.23)	$ (7.19)	$ (10.04)
Weighted-average common shares used in computing net loss per share, basic and diluted	30,018	25,646	13,829

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

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF

STOCKHOLDERS EQUITY (DEFICIT)

(In thousands, except share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balance at January 1, 2007	623,986	$	$ 1,335	$ 12	$ (177,643)	$ (176,296)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements			50			50
Vesting of common stock subject to repurchase			(834)			(834)
Conversion of convertible preferred stock to common stock and common stock subject to repurchase in conjunction with initial public offering	17,921,551	2	259,646			259,648
Conversion of preferred stock warrant liability to equity in conjunction with initial public offering			6,675			6,675
Issuance of common stock for cash in conjunction with initial public offering, net of issuance costs	6,000,000		97,488			97,488
Stock issuable under directors deferred compensation plan			211			211
Issuance of common stock for cash in conjunction with exercise of stock options	5,617		77			77
Issuance of common stock for cash under employee stock purchase plan	69,675		918			918
Stock-based compensation			5,874			5,874
Comprehensive loss:						
Net loss					(138,826)	(138,826)
Unrealized gain on available-for-sale securities				7		7
Comprehensive loss						(138,819)
Balance at December 31, 2007	24,620,829	2	371,440	19	(316,469)	54,992
Lapse of repurchase rights to shares issued under restricted stock purchase agreements			30			30
Warrants to purchase common stock issued in conjunction with senior secured notes			1,928			1,928
Stock issued/issuable under directors deferred compensation plan	2,843		237			237
Issuance of common stock in conjunction with exercise of stock options for cash and restricted stock units	153,400		1,001			1,001
Issuance of common stock for cash under employee stock purchase plan	299,756		1,166			1,166
Issuance of common stock and warrants for cash in conjunction with registered direct public offering, net of issuance costs	3,848,289	1	24,513			24,514
Stock-based compensation			6,859			6,859
Conversion of common stock subject to repurchase to common stock			749			749

Comprehensive loss:						
Net loss					(184,339)	(184,339)
Unrealized loss on available-for-sale securities				(15)		(15)
Comprehensive loss						(184,354)
Balance at December 31, 2008	28,925,117	3	407,923	4	(500,808)	(92,878)

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF

STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands, except share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balance at December 31, 2008	28,925,117	3	407,923	4	(500,808)	(92,878)
Lapse of repurchase rights to shares issued under employment agreements			12,492			12,492
Modification of warrants to purchase common stock issued in conjunction with amended senior secured notes			1,254			1,254
Stock issued/issuable under directors deferred compensation plan	3,826		243			243
Issuance of common stock in conjunction with exercise of stock options for cash and restricted stock units	20,722		40			40
Issuance of common stock for cash under employee stock purchase plan	409,875		348			348
Issuance of common stock and warrants for cash in conjunction with private placement offering, net of issuance costs	1,895,734		6,782			6,782
Stock-based compensation			5,729			5,729
Comprehensive loss:						
Net loss					(6,836)	(6,836)
Unrealized loss on available-for-sale securities				(4)		(4)
Comprehensive loss						(6,840)
Balance at December 31, 2009	31,255,274	$ 3	$ 434,811	$	$ (507,644)	$ (72,830)

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

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2009	**2008**	**2007**
Operating activities			
Net loss	$ (6,836)	$ (184,339)	$ (138,826)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,429	2,198	1,309
Amortization of intangible assets	7,668	12,828	9,217
Intangible asset impairment		29,763	20,160
Loss on disposal of property and equipment	14	968	6
Fair value adjustment to acquired finished goods			54
Revaluation of preferred stock warrant liability			(1,846)
Stock-based compensation expense	5,957	8,106	6,060
Gain on sale of product rights		(3,918)	(5,860)
Changes in assets and liabilities:			
Accounts receivable	(5,670)	(1,254)	(250)
Inventories	883	(2,180)	499
Prepaid expenses and other current assets	2,610	237	289
Other assets	(1,005)	551	285
Accounts payable	(3,578)	2,880	(2,587)
Accrued liabilities	(2,195)	(10,430)	13,874
Senior secured notes	(2,414)	5,922	833
Deferred revenue	(10,786)	9,690	(955)
Deferred rent	29		(203)
Liability under government settlement	(1,984)	(1,254)	16,850
Net cash used in operating activities	(15,878)	(130,232)	(81,091)
Investing activities			
Purchases of property and equipment	(53)	(1,739)	(3,149)
Purchase of product rights	(6,000)	(27,000)	
(Increase) decrease in restricted cash and investments	(1,075)	12,026	(1,664)
Transfer of restricted cash to marketable securities		(4,440)	
Purchases of marketable securities			(10,848)
Proceeds from maturities of marketable securities	1,004	3,436	10,848
Proceeds from sale of product rights		5,775	10,150
Net cash (used in) provided by investing activities	(6,124)	(11,942)	5,337
Financing activities			
Proceeds from employee stock purchases and exercise of stock options	388	1,168	995
Proceeds from offerings of common stock, net of issuance costs	6,782	24,514	97,488
Net proceeds from line of credit	5,524	416	1,268
Proceeds from sale of senior secured notes and warrants, net of issuance costs		38,538	
Repayment of senior secured notes (including $327 paid to a related party)		(504)	
Net cash provided by financing activities	12,694	64,132	99,751
Net (decrease) increase in cash and cash equivalents	(9,308)	(78,042)	23,997
Cash and cash equivalents, at beginning of period	24,903	102,945	78,948
Cash and cash equivalents, at end of period	$ 15,595	$ 24,903	$ 102,945
Supplemental disclosure of cash flow information:			
	$ 24,488	$ 12,802	$ 12,000

Cash paid for interest (including $1,349, $796 and $3,750 for the years ended December 31, 2009, 2008 and 2007, respectively, paid to a related party)			
Supplemental disclosure of non-cash investing and financing activities:			
Liability for purchase of product rights	$ 5,000	$ 14,000	$
Warrants to purchase common stock issued in conjunction with unregistered sales of equity securities	$ 2,700	$	
Warrants to purchase common stock issued in conjunction with registered direct public offering	$	$ 6,400	$
Warrants to purchase common stock issued in conjunction with senior secured notes	$	$ 2,000	$
Modification to warrants to purchase common stock issued in conjunction with senior secured notes	$ 1,254	$	$
Warrants to purchase common stock issued in conjunction with equity financing facility	$	$ 850	$

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

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

We were incorporated in California in March 2003 and reincorporated in Delaware in January 2004. We are a specialty pharmaceutical company that, since our inception, has focused on the development and commercialization of pharmaceutical products to meet important unmet medical needs in neurology and psychiatry. With our JZP-6 product candidate for the treatment of fibromyalgia, for which we submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in December 2009, and which NDA was filed by the FDA in February 2010, we expanded our development activities to include rheumatology and pain management. We currently market two products: Xyrem (sodium oxybate) for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy; and Luvox CR (fluvoxamine maleate) for the treatment of both obsessive compulsive disorder and social anxiety disorder. We are building a portfolio of products through a combination of internal development, acquisition and in-licensing activities, and we utilize our specialty sales force to promote our products in our target markets. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes our two marketed products, which generated net product sales of $115.1 million in 2009, our late-stage JZP-6 product candidate, and several product candidates in various stages of clinical development.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Jazz Pharmaceuticals, Inc. and its wholly-owned subsidiaries, Orphan Medical, LLC, formerly Orphan Medical, Inc., (Orphan Medical) and JPI Commercial, LLC (JPIC), after elimination of intercompany transactions and balances.

Certain amounts in the consolidated statements of cash flows for the years ended December 31, 2008 and 2007 and in the consolidated balance sheet for the year ended December 31, 2008 have been reclassified to conform to the presentation for the year ended December 31, 2009. Amounts previously reported as non-cash interest expense have been reclassified to senior secured notes and other assets in the consolidated statements of cash flows. The current portion of the liability under government settlement which was previously reported in accrued liabilities is now reported separately on the consolidated balance sheets and the current and noncurrent portions of the government liability have been combined on the consolidated statements of cash flows. In addition, deferred cost of goods sold which was previously recorded in inventories has been reclassified to other current assets.

Significant Risks and Uncertainties

We have incurred significant losses since inception including losses of $6.8 million, $184.3 million and $138.8 million in the three years ended December 31, 2009, 2008 and 2007, respectively. Under the agreement with the holders of our senior secured notes, or Senior Notes, we are required to repay principal of $3.0 million, $6.0 million, $9.0 million and $10.0 million, on March 31, 2010, June 30, 2010, September 30, 2010 and December 31, 2010, respectively. On March 31, 2011, a $12.0 million principal payment is due on the Senior Notes, and the remaining balance on the Senior Notes is due in full on June 24, 2011. Through at least December 31, 2010, we believe our existing cash balances and cash generated from operations will be sufficient to fund our operations and meet all of our obligations, including obligations under our Senior Notes, as they become due. As available, we also plan to borrow under our revolving bank line of credit which expires in May 2010.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts and disclosures reported in the consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Concentration of Credit Risks

Financial instruments that potentially subject us to concentrations of credit risk consist of cash equivalents, restricted cash, marketable securities and accounts receivable. Our investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies and institutions with investment-grade credit ratings and places restrictions on maturities and concentration by type and issuer. We are exposed

to credit risk in the event of a default by the financial institutions holding our cash and cash equivalents and issuers of investments to the extent recorded on the balance sheet.

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We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to Express Scripts Specialty Distribution Services, or Express Scripts, which is our sole customer for Xyrem in the United States and to pharmaceutical wholesale distributors who distribute Luvox CR and to our ex-U.S. licensees. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced significant credit losses on our accounts receivable. Our five largest customers accounted for an aggregate of approximately 99%, 97% and 93% of gross accounts receivable as of December 31, 2009, 2008 and 2007, respectively.

Fair Value of Financial Instruments

Effective January 1, 2008, we adopted authoritative guidance for financial assets and liabilities and any other assets and liabilities carried at fair value. The guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs (i.e. inputs that reflect the reporting entity s own assumptions about the assumptions that market participants would use in estimating the fair value of an asset or liability) are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

Cash Equivalents, Restricted Cash and Marketable Securities

We consider all highly liquid investments, readily convertible to cash, that mature within three months or less from date of purchase to be cash equivalents. Restricted cash is restricted either by contract or agreement. At December 31, 2009, we held restricted cash of $3.0 million, $2.0 million of which was held in our bank account pending application against our revolving bank line of credit, $650,000 of which was in the form of a certificate of deposit required to secure our leased automobiles and $301,000 of which was in the form of a certificate of deposit required to secure spending on credit cards used by employees.

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

Inventories

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. If the estimate of future demand is too high, we may have to increase the reserve for excess inventory for that product and record a charge to cost of product sales. For product candidates that have not been approved by the FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. For products that have been approved by the FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the clinical trial. Prior to receiving FDA approval of Luvox CR in February 2008, all costs related to purchases of the active pharmaceutical ingredient and the manufacturing of the product were recorded as research and development expense. All direct manufacturing costs incurred after approval have been capitalized into inventory.

Property and Equipment

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

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Goodwill and Intangible Assets

Goodwill

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then in the second step, the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. Management tests goodwill for impairment annually in October and whenever events or changes in circumstances indicate that the carrying value may not be recoverable.

Intangible Assets

Intangible assets consist primarily of purchased developed technology, agreements not to compete and trademarks. Intangible assets are amortized on a straight-line basis over their estimated useful lives, which range from three to ten years. The estimated useful lives associated with intangible assets are consistent with underlying agreements, or the estimated lives of the products and may be modified when circumstances warrant. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. We evaluate purchased intangibles and other long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. See Note 5 for additional information regarding intangible asset impairment charges.

Preferred Stock Warrant Liability

In June 2005, in connection with the issuance of senior secured notes by Orphan Medical, which were subsequently exchanged for the same principal amount of our Senior Notes, we issued warrants to purchase shares of convertible preferred stock which were recorded as a preferred stock warrant liability. See Note 6 for additional information regarding the Senior Notes. Prior to our initial public offering, the preferred stock warrant liability was revalued at the end of each reporting period to fair value. On June 6, 2007, upon completion of our initial public offering, the warrants became exercisable for common stock and the liability was reclassified to stockholders equity at its then fair value. We recorded a benefit of $1.8 million in other income during the year ended December 31, 2007 to reflect the change in the fair value of the preferred stock warrant liability.

Revenue Recognition

Revenues are recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. In evaluating arrangements with multiple elements we consider whether components of the arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. This evaluation requires subjective determinations and requires management to make judgments about the fair value of individual elements and whether such elements are separable from other aspects of the contractual relationship. The consideration received in such arrangements is allocated among the separate units of accounting based on their respective fair values when there is reliable evidence of fair value for all elements of the arrangement. If there is no evidence of fair value for all the elements of the arrangement, consideration is allocated based on the residual method for the delivered elements. Under the residual method, the amount of revenues allocated to the delivered elements equals the total arrangement consideration less the aggregate fair value of any undelivered elements. The applicable revenue recognition criteria are applied to each of the separate units. Payments received in advance of work performed or milestones achieved are recorded as deferred revenues and recognized when the service is provided or the milestone is achieved, as applicable.

Product Sales, Net

We sell Xyrem in the United States to a single source specialty pharmaceutical distributor, Express Scripts. We recognize revenues from sales of Xyrem within the United States upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment directly to a patient.

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We accept returns from Express Scripts of any product returned by patients to Express Scripts with defects that were not reasonably discoverable upon receipt of the consigned product by Express Scripts. Based on our experience over the past five years since we acquired the rights to Xyrem, product returns to Express Scripts are extremely rare once product is shipped to patients. We provide Express Scripts with a credit for product returned by patients. During the year ended December 31, 2009 we issued credits for returned product totaling less than $10,000.

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

Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder and social anxiety disorder in February 2008. We shipped initial stocking orders of Luvox CR to our wholesaler customers in March 2008 and began promoting Luvox CR through our specialty sales force in April 2008. We grant rights to our wholesaler customers to return product six months prior to and up to twelve months after product expiration and issue credits which may be applied against existing or future invoices. Given our limited history of selling Luvox CR and the lengthy return period, we have not been able to reliably estimate expected returns of Luvox CR at the time of shipment, and therefore we recognize revenue when units are dispensed through prescriptions, at which point, the product is not subject to return. We do not accept product returns of Luvox CR that have been dispensed to patients. In order to estimate units dispensed, we purchase dispensing data from an independent prescription tracking service. We believe this data to be reasonably accurate and reliable and not subject to material adjustments. In 2009 and in 2008, we recorded revenue of $18.3 million and $5.7 million, respectively, related to Luvox CR, net of estimated wholesaler fees, discounts, chargebacks and rebates. As of December 31, 2009, we had recorded a deferred revenue liability related to shipments of Luvox CR of $1.5 million, which represented amounts paid by wholesaler customers in excess of revenue recognized, net of estimated wholesaler fees, discounts, chargebacks and certain rebates.

Prior to the sale of our rights to Antizol® (fomepizole) and Antizol-Vet® in August 2008, Antizol and Antizol-Vet were shipped to our wholesaler customers in the United States with free on board destination shipping terms, and we recognized revenues when delivery occurred.

Revenues from sales of products within the United States are recorded net of estimated allowances for specialty distributor fees, wholesaler fees, prompt payment discounts, Medicaid rebates, TRICARE rebates, government chargebacks and patient rebates. Calculating certain of these items involves estimates and judgments based on sales or invoice data and historical experience. Adjustments to estimates for allowances have not been material. In 2009, we recorded, as a reduction of revenues, a reserve of $1.4 million as a result of a final rule issued by the Department of Defense in March 2009 for potential rebates due for drugs sold by retail pharmacies to TRICARE beneficiaries on or after January 28, 2008. We requested a waiver from the Department of Defense for approximately $999,000 of the $1.4 million amount reserved and have not yet received a response. Of the total amount requested in our waiver, $596,000 relates to product sales in 2008. Except for and to the extent that our waiver is granted, we do not anticipate that changes to our estimated allowance for TRICARE rebates for Xyrem and Luvox CR will have a material impact on product sales.

Royalties, Net

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

Contract Revenues

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

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Cost of Product Sales and Concentrations of Supply Risk

Cost of product sales includes third party manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability and cargo insurance, FDA user fees, freight, shipping, handling and storage costs, fair value of inventory acquired and salaries and related costs of employees involved with production. During the year ended December 31, 2009, we recorded charges to cost of product sales related to Luvox CR totaling $82,000 for inventory we judged to be in excess of expected requirements. During the year ended December 31, 2008, we recorded charges to cost of product sales related to Luvox CR totaling $4.2 million, which was composed of a reserve for inventory we judged to be in excess of expected requirements in the amount of $3.5 million and a $671,000 liability to a contract manufacturer for cancelled production orders. Excluded from cost of product sales, as shown on the consolidated statements of operations, is amortization of acquired developed technology of $6.6 million, $11.5 million and $7.5 million for the years ended December 31, 2009, 2008 and 2007, respectively. Also excluded from cost of product sales are intangible asset impairment charges of $29.8 million related to Luvox CR and $20.2 million related to Antizol for the years ended December 31, 2008 and 2007, respectively. See Note 5 for additional information regarding impairment charges.

We rely on certain sole suppliers for drug substance and certain sole manufacturing partners for each of our marketed products and certain of our product candidates. We attempt to mitigate this risk by establishing contractual relationships where appropriate.

Research and Development

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

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses for the years ended December 31, 2009, 2008 and 2007 were $448,000, $11.0 million and $7.3 million, respectively.

Income Taxes

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

Comprehensive Loss

Comprehensive loss includes net loss and all changes in stockholders deficit during a period, except for those changes resulting from investments by stockholders or distributions to stockholders. For each of the years ended December 31, 2009, 2008 and 2007, the difference between comprehensive loss and net loss represented net unrealized gains or losses on available-for-sale securities.

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Net Loss Per Common Share

Basic and diluted net loss per common share is computed using the weighted-average number of shares of common stock outstanding during the period. Potentially dilutive securities consisting of stock options, common stock subject to repurchase and warrants were not included in the diluted net loss per share for all periods presented because the inclusion of such shares would have had an antidilutive effect.

	Year Ended December 31,		
	2009	2008	2007
	(In thousands, except per share data)		
Numerator:			
Net loss	$ (6,836)	$ (184,339)	$ (138,826)
Denominator:			
Weighted-average common shares outstanding	30,018	26,524	14,594
Less: weighted-average common shares outstanding subject to repurchase		(878)	(765)
Weighted-average common shares used in computing net loss per share, basic and diluted	30,018	25,646	13,829
Net loss per share, basic and diluted	$ (0.23)	$ (7.19)	$ (10.04)

The following table shows certain items that were excluded from the computation of diluted net loss per share for the periods presented because including them would have an antidilutive effect (in thousands):

	Year Ended December 31,		
	2009	2008	2007
Warrants to purchase common stock (as if exercised)	3,759	2,144	489
Options to purchase common stock	2,843	3,687	1,693
Common stock subject to repurchase		828	879
Restricted stock units	38	94	

As of December 31, 2009, we had warrants outstanding as follows:

	No. of Shares	Expiration Date	Exercise Price
Warrants issued in conjunction with:			
$80.0 million senior secured notes	785,728	June 2012	$ 9.34
$40.0 million senior secured notes	562,192	March 2013	$ 9.34
Equity financing facility	220,000	November 2013	$ 9.20
Public offering	1,731,724	July 2014	$ 7.37
Private offering	947,867	July 2016	$ 4.00

Stock-Based Compensation

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

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Recent Accounting Pronouncements

In October 2009, the FASB issued authoritative guidance which amends the revenue recognition guidance to require companies to allocate revenue in multiple-element arrangements based on an element s estimated selling price if vendor-specific or other third-party evidence is not available. The guidance is effective beginning January 1, 2011. Earlier adoption is permitted. We are currently evaluating the effect that the adoption of this guidance will have on our results of operations and financial position.

In January 2010, the FASB issued additional guidance for improving disclosures about fair value measurements. Under this guidance, two new disclosures are required: (1) transfers in and out of Level 1 and 2 measurements and the reasons for the transfers, and (2) a gross presentation of activity within the Level 3 roll forward. This guidance also includes clarifications to existing disclosure requirements on the level of disaggregation and disclosures regarding inputs and valuation techniques. This guidance applies to all entities required to make disclosures about recurring and nonrecurring fair value measurements. The guidance is effective for interim and annual reporting periods beginning after December 15, 2009. We do not expect that our adoption of the guidance will have an impact on our results of operations or financial position.

3. Fair Value Measurement

Available-for-sale investments consisted of the following as of December 31, 2009 and 2008 (in thousands):

	2009				2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Other debt securities, primarily money market funds	$ 5,072	$	$	$ 5,072	$ 24,880	$	$	$ 24,880
Obligations of U.S. government agencies					1,000	4		1,004
Total	$ 5,072	$	$	$ 5,072	$ 25,880	$ 4	$	$ 25,884

	2009	2008
Available-for-sale investments	$ 5,072	$ 25,884
Cash	10,523	23
Restricted cash	2,988	1,913
Total	$ 18,583	$ 27,820

Reported as	2009	2008
Amounts classified as cash and cash equivalents	$ 15,595	$ 24,903
Amounts classified as restricted cash	2,988	1,913
Amounts classified as marketable securities		1,004
Total	$ 18,583	$ 27,820

Since inception, there have been no material realized gains or losses on cash equivalents or marketable securities.

All marketable securities, which consist of obligations of U.S. government agencies, held as of December 31, 2008, had contractual maturities of less than one year and had no unrealized losses.

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

	December 31, 2009		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Money market funds	$ 5,072	$	$ 5,072
Total	$ 5,072	$	$ 5,072

	December 31, 2008		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Obligations of U.S. government agencies	$	$ 1,004	$ 1,004
Money market funds	24,880		24,880
Total	$ 24,880	$ 1,004	$ 25,884

As of December 31, 2009, the carrying amount of our $119.5 million principal amount Senior Notes was $114.9 million and the estimated fair value was $123.6 million. The fair value was estimated using a discounted cash flow analysis based on our estimated incremental borrowing rates for similar types of borrowing arrangements. It was not practicable to estimate the fair value of our Senior Notes at December 31, 2008 because it was difficult to estimate the timing of cash flows and an appropriate discount rate due to the then existing default under our agreement with the holders of our Senior Notes.

4. Certain Balance Sheet Items

Inventories consist of the following (in thousands):

	December 31,	
	2009	2008
Raw materials	$ 1,245	$ 2,175
Work in process	676	156
Finished goods	1,505	1,963
Total inventories	$ 3,426	$ 4,294

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

	December 31, 2009	2008
Leasehold improvements	$ 704	$ 704
Computer equipment	1,479	1,469
Computer software	3,715	3,607
Furniture and fixtures	586	586
Construction-in-progress	28	133
Total	6,512	6,499
Less accumulated depreciation and amortization	(5,388)	(3,985)
Property and equipment, net	$ 1,124	$ 2,514

Accrued liabilities consist of the following (in thousands):

	December 31, 2009	2008
Accrued research and development expense	$ 2,862	$ 7,735
Accrued personnel expense	6,545	4,445
Accrued selling, general and administrative expense	891	1,117
Medicaid rebates reserve	828	171
TRICARE rebate reserve	1,425	
Other	1,745	3,023
Total accrued liabilities	$ 14,296	$ 16,491

5. Goodwill and Intangible Assets

The gross carrying amount of goodwill was $38.2 million as of December 31, 2009 and 2008. The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	December 31, 2009			December 31, 2008		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology - Xyrem	$ 39,700	$ 18,842	$ 20,858	$ 39,700	$ 14,670	$ 25,030
Developed technology - Luvox CR	9,700	2,443	7,257	4,700		4,700
Agreements not to compete	3,900	3,523	377	3,900	2,743	1,157
Trademarks	2,600	1,234	1,366	2,600	961	1,639
Total	$ 55,900	$ 26,042	$ 29,858	$ 50,900	$ 18,374	$ 32,526

Future amortization costs per year for our existing intangible assets other than goodwill as of December 31, 2009 are estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2010	$ 7,825
2011	7,448
2012	5,696
2013	4,445
2014	4,445

In February 2009, we amended our product license agreement with Solvay for the rights to market Luvox CR and Luvox in the United States such that the existing $14.0 million current payment obligation, a $5.0 million obligation related to a milestone of uninterrupted supply of Luvox CR and future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million. As a result, we recorded an increase of $5.0 million in the value of the intangible asset associated with Luvox CR in 2009.

We tested the intangible asset related to Luvox CR developed technology for impairment in September 2009, in response to a notice we received in August 2009 of the filing of an abbreviated new drug application with the FDA by a third party for a generic version of Luvox CR. Based on the estimated undiscounted cash flows related to the asset, we determined at that time that the asset was not impaired, but that its remaining estimated useful life should be shortened to 2.7 years from 4.0 years.

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In December 2008, as a result of lower than anticipated sales of Luvox CR, we evaluated the intangible asset associated with Luvox CR for impairment and reduced the gross carrying amount and accumulated amortization of this intangible asset by $36.3 million and $6.5 million, respectively, which resulted in a $29.8 million intangible asset impairment charge for the year ended December 31, 2008. The most significant input used in the calculation of the fair value of the intangible asset associated with Luvox CR was projected net sales of Luvox CR which were estimated by extrapolating the current growth trends of the product and applying judgment as to the appropriate future growth rate among other factors. Selection of a risk appropriate discount rate also involves significant judgment. We used a discount rate of 20% to estimate fair value in December 2008.

In December 2007, a generic product competitive to Antizol was introduced and, as a result, we evaluated the intangible asset associated with Antizol for impairment and reduced the gross carrying amount and accumulated amortization of this intangible asset by $28.4 million and $8.2 million, respectively, which resulted in a $20.2 million intangible asset impairment charge for the year ended December 31, 2007. The most significant input used in the calculation of the fair value of the Antizol asset was expected revenues which were estimated by reviewing the impact of generic products on revenues of other branded products. In August 2008, we sold our rights to and interests in Antizol and Antizol-Vet, associated product registrations, commercial inventory and trademarks for cash consideration of $5.8 million and we recorded a gain of $3.9 million. As a result of the sale, we reduced the gross carrying amount and accumulated amortization of this intangible asset by $2.7 million and $792,000, respectively.

In March 2007, we sold our rights to Cystadane, associated product registrations, commercial inventory and trademarks for cash consideration of $9.0 million and recorded a gain of $5.1 million. As a result of the sale, we reduced the gross carrying amount and accumulated amortization of the intangible asset associated with Cystadane by $4.3 million and $761,000, respectively.

6. Debt and Financing Obligations

Senior Secured Notes

In March 2008, JPIC sold $40.0 million aggregate principal amount of our Senior Notes and issued warrants to purchase 562,192 shares of our common stock with an exercise price of $14.23 per share which expire in March 2013. The $2.0 million fair value of the warrants issued in March 2008 was recorded in stockholders deficit and was estimated using the Black-Scholes option pricing model with the following assumptions: a risk-free rate 2.2%, volatility 51%, a term of 5.0 years and a dividend yield of 0.0%. The notes generally bear interest at 15% per annum, payable quarterly in arrears, and are due on June 24, 2011. In addition, in March 2008, a total of $80.0 million aggregate principal amount of senior secured notes of Orphan Medical issued in June 2005 that bore interest at 15% per annum, due on June 24, 2011 were exchanged for the same principal amount of our Senior Notes. The effective interest rate on our Senior Notes newly issued and the Senior Notes exchanged for Orphan Medical senior secured notes in March 2008 was 19.8% and 19.2%, respectively. As a result of these transactions, a total of $120.0 million aggregate principal amount of Senior Notes issued by JPIC was outstanding. We refer to the agreement governing all of the Senior Notes as the Senior Note Agreement. Under the Senior Note Agreement, we guaranteed the repayment obligations of JPIC, we granted the holders of the Senior Notes a security interest in all of our assets and those of our wholly-owned subsidiaries other than accounts receivable and inventory, and we gave the holders the right to accelerate payment of the principal amount of the Senior Notes upon a change in control. We are required to maintain a restricted cash balance equal to 15% of the then outstanding principal amount of Senior Notes if our quarterly net sales are less than $25.0 million. The Senior Note Agreement includes restrictions on working capital borrowings, dividends and certain other payments. Under the terms of the Senior Note Agreement we may borrow from other sources up to $15.0 million secured by our accounts receivable and inventory. We had $9.4 million outstanding at December 31, 2009, under our revolving bank line of credit subject to these terms. See Line of Credit below.

Under the terms of the Senior Note Agreement, we are obligated to pay the holders of the Senior Notes the proceeds from any future sale of our rights to Xyrem, Luvox CR and JZP-6 if the holders so elect. In August 2008, we paid certain holders of the Senior Notes $504,000 aggregate principal amount as their pro rata share of the proceeds from the sale of our rights to Antizol and Antizol-Vet.

We did not timely pay quarterly interest of $4.5 million, $5.1 million and $5.1 million due on December 31, 2008, March 31, 2009 and June 30, 2009 to the holders of the Senior Notes, and we did not maintain a required restricted cash account beginning in May 2009, which constituted events of default under our Senior Note Agreement and permitted LB I Group Inc., as the holder of more than 50% of the principal amount of the Senior Notes, to accelerate payment of the Senior Notes. As a result of the defaults, interest on the Senior Notes accrued on the outstanding principal amount at an annual default rate of 17% (instead of 15%) effective January 1, 2009 through July 7, 2009. On July 7, 2009, we paid $14.6 million to the holders of the Senior Notes, which represented all of the accrued and unpaid interest as of June 30, 2009, and we timely paid quarterly interest of $4.5 million due on each of September 30, 2009 and December 31, 2009. In addition since June 30, 2009 we have not been required under the terms of the Senior Note Agreement to maintain a restricted cash balance because our quarterly net sales have been more than $25.0 million.

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In November 2009, we amended the Senior Note Agreement in connection with that amendment we reduced the exercise price of warrants to purchase 1,347,920 shares of common stock, previously issued to the holders of the Senior Notes, to $9.34 per share. Under the terms of the amended Senior Note Agreement we are required to repay principal of $3.0 million, $6.0 million, $9.0 million, $10.0 million and $12.0 million on March 31, 2010, June 30, 2010, September 30, 2010, December 31, 2010 and March 31, 2011, respectively, without prepayment penalty. The principal amount of $79.5 million remaining after giving effect to the required quarterly payments is due on June 24, 2011 if not paid earlier. Under the amended Senior Note Agreement we are also required to pay a $500,000 fee on the maturity date, or upon earlier repayment in full, of the Senior Notes. In addition, if the outstanding principal amount of the Senior Notes decreases to below $80.0 million, the minimum cash balance we are required to maintain if our quarterly net sales are less than $25.0 million will be reduced to 7.5% of the then outstanding principal amount. Under the amended Senior Note Agreement, in the event of default, or if we prepay the notes before they are due, or upon acceleration of the notes following a change in control, we are obligated to pay a prepayment penalty which was 9.9% as of December 31, 2009 and reduces ratably to zero through June 24, 2011.

We determined that the amendment of the Senior Note Agreement should be accounted for as a modification of the existing Senior Notes. The $1.3 million fair value of the warrant modification was recorded as a debt discount and in stockholders deficit. The fair value was estimated using the Black-Scholes option pricing model with the following assumptions for the warrant to purchase 785,728 shares of common stock at $20.36 per share issued in connection with the Senior Notes issued by JPIC; a risk-free rate of 1.2%, volatility of 90%, an expected term of 2.6 years, and a dividend yield of 0.0% and the following assumptions for the warrant to purchase 562,192 shares of common stock at $14.23 per share issued in connection with the Senior Notes issued by Orphan Medical; risk-free rate of 1.6%, volatility of 90%, an expected term of 3.3 years, and a dividend yield of 0.0%.

The $119.5 million principal amount of the Senior Notes is recorded net of a debt discount of $4.6 million and $5.4 million as of December 31, 2009 and 2008, respectively. The current portion of the carrying amount of the Senior Notes was $23.8 million and $118.5 million as of December 31, 2009 and 2008, respectively, which included unpaid interest of $4.5 million as of December 31, 2008. Interest expense associated with the Senior Notes is recorded using the interest method and includes non-cash interest related to the debt discount and debt issuance costs. The effective interest rate on the Senior Notes subsequent to the amendment to the Senior Note Agreement in November 2009 was 21.2%.

Revolving Bank Line of Credit

On September 30, 2009, we amended our existing revolving bank line of credit agreement and, as a result, subject to certain limitations, we may borrow up to the lesser of 75% of eligible accounts receivable, with a maximum borrowing of $15.0 million. Borrowings under the revolving bank line of credit are secured by a first priority security interest in our accounts receivable and inventory and bear interest at a variable rate. As of December 31, 2009 and 2008, $9.4 million and $3.9 million, respectively, were outstanding under the revolving bank line of credit. These amounts bore interest at 6.5% and 5.5% at December 31, 2009 and 2008, respectively. The amended agreement provides for a minimum monthly interest payment of $14,000 and a collateral monitoring fee up to 0.15% per month on the outstanding principal amount. The revolving bank line of credit expires in May 2010.

7. Commitments and Contingencies

Indemnification

In the normal course of business, we enter into agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. Our exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against us. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations, except as set forth in the description of legal proceedings below.

We have agreed to indemnify our officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under this indemnification is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we have not recognized any liabilities relating to these obligations as of December 31, 2009 and 2008. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

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Lease and Other Commitments

In June 2009, we amended our noncancelable operating lease for our corporate office building located in Palo Alto, California. Under the amendment, the term of the lease was extended by 36 months through September 2012 and the monthly base rent, which is subject to an annual rent escalation clause after September 2010, was adjusted. The lease is renewable through 2016. We are also obligated to make payments under noncancelable operating leases for automobiles used by our sales force. Rent expense under all operating leases was $2.7 million, $5.2 million and $2.0 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Future minimum lease payments under our noncancelable operating leases at December 31, 2009, were as follows (in thousands):

Year ending December 31,	Lease Payments
2010	$ 1,995
2011	1,426
2012	768
2013	38
2014	
Total	$ 4,227

As of December 31, 2009 and 2008, we had $3.6 million and $6.3 million, respectively, of noncancelable purchase commitments due within one year under agreements with contract manufacturers.

The FDA approval of Luvox CR included a commitment for two Phase IV clinical trials, one in adolescent patients with social anxiety disorder and one a long-term duration of effect study in patients with social anxiety disorder. We are in the process of planning these studies, and we are in discussion with the FDA concerning the studies. The cost of these Phase IV clinical trials is significant.

Legal Proceedings

In April 2006, we and Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. In July 2007, we and Orphan Medical entered into agreements with various parties to settle this matter pursuant to which we paid $2.5 million, $2.0 million, $1.0 million in the years ended December 31, 2009, 2008 and 2007, respectively and agreed to pay $3.0 million, $3.0 million and $8.5 million in 2010, 2011 and 2012, respectively, some of which may be accelerated in certain circumstances. Related to the settlement, we recorded a charge of $17.5 million during the year ended December 31, 2007, which represented the present value of the settlement payments discounted at an interest rate of 4.6%. As of December 31, 2009 and 2008, the non-current portion of this provision was $10.7 million and $13.1 million, respectively, and the current portion was $3.0 million and $2.5 million, respectively.

In August 2009, we received a Paragraph IV Patent Certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an abbreviated new drug application, or ANDA, with the FDA seeking approval to market a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen Pharmaceuticals, Inc., or Anchen, advising that Anchen has filed an ANDA with the FDA seeking approval to market a generic version of Luvox CR. We have not been informed as to the timing or status of the FDA s review of either party s filing, or whether either filer has complied with FDA requirements for proving bioequivalence. Actavis Paragraph IV Certification alleges that Elan s U.S. Patent No. 7,465,462, or the 462 patent, is invalid on the basis that the inventions claimed therein were obvious. Anchen s Paragraph IV Certification alleges that the 462 patent will not be infringed by Anchen s manufacture, use or sale of the generic product for which the ANDA was submitted and that the 462 patent is invalid on the basis that the inventions claimed therein were obvious. On October 6, 2009, we and Elan, as plaintiffs, filed a lawsuit against Actavis, Anchen, and Anchen Incorporated, the parent of Anchen, in the United States District Court for the District of Delaware claiming infringement of the 462 patent by the defendants in response to the Paragraph IV Certifications filed by Actavis and Anchen. We are seeking a permanent injunction that prevents Actavis and Anchen from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. On October 27, 2009, Anchen and Anchen Incorporated filed a motion to dismiss for lack of jurisdiction. On November 16, 2009, we and Elan filed our response. On January 14, 2010, we and Elan filed a motion to enjoin the later-filed duplicative proceeding in the United States District Court for the Central District of California referenced below. On February 1, 2010, Anchen and Anchen Incorporated responded. The court has not ruled on either motion and no hearing dates are scheduled. We cannot predict or determine the outcome of this matter.

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On October 14, 2009, we and Elan, as plaintiffs, also filed a lawsuit in the United States District Court for the Central District of California against Anchen and Anchen Incorporated claiming infringement of the 462 patent based upon Anchen s Paragraph IV Certification. The plaintiffs are seeking a permanent injunction that prevents Anchen from introducing a generic version of Luvox CR prior to the expiration of the 462 patent. Since Anchen is incorporated in California, the additional protective lawsuit was filed in California in an effort to both ensure jurisdiction over Anchen in the event that the United States District Court for the District of Delaware finds that it does not have jurisdiction over Anchen in Delaware, and to prevent the FDA from approving the ANDA filed by Anchen until the earliest of 30 months following the filing of the lawsuit, expiration of the 462 patent, settlement of the lawsuit or a decision in the infringement case that is favorable to Anchen in California. On December 14, 2009, the court in the United States District Court for the Central District of California held a scheduling conference to discuss the status of the case and the Delaware case. Following the conference and submission of scheduling proposals by both parties, the court scheduled a patent claim construction or *Markman* hearing for June 1, 2010. Following a ruling in that hearing, the court indicated that it will set the remaining schedule following consultation with both parties. We cannot predict or determine the outcome of this matter.

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

8. In-Licensing Agreements

In January 2007, we entered into a product license agreement with Solvay for the rights to market Luvox CR and Luvox in the United States which agreement was subsequently amended a number of times. Under the amended agreement we paid $6.0 million, $27.0 million and $2.0 million in the years ended December 31, 2009, 2008 and 2007, respectively and agreed to pay $4.0 million, $4.5 million and $5.0 million in 2010, 2011 and 2012, respectively. If we pay these amounts when due, the payment due in 2012 will decrease to $4.5 million. In addition, we agreed to pay Solvay $5.0 million in 2015 if net sales of Luvox CR have reached a cumulative amount of $100.0 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the United States as of December 31, 2014.

In October 2004, we entered into an agreement with GlaxoSmithKline to purchase worldwide rights to the active pharmaceutical ingredient in JZP-4. We agreed to pay up to $113.5 million upon the achievement of future development and commercial milestones and royalties at specified rates based on net sales. A payment of $5.0 million will be due to GlaxoSmithKline upon the enrollment of the first patient in a JZP-4 Phase II clinical trial.

9. Out-Licensing Agreements

In June 2006, we entered into an agreement with UCB that amended and restated a prior agreement between Orphan Medical and a predecessor of UCB. Under the terms of the amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia in 54 countries outside of the United States. UCB made nonrefundable milestone payments to us related to Xyrem for the treatment of narcolepsy of $2.0 million which was due and recognized as revenue in March 2007 when the milestone was achieved. UCB has also made payments to us related to JZP-6 for the treatment of fibromyalgia totaling $32.5 million, which included an upfront payment of $5.0 million upon execution of the amended agreement in June 2006, an additional upfront payment of $10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia, a nonrefundable milestone payment of $7.5 million due and recognized as revenue in September 2007, and a $10.0 million nonrefundable milestone payment received in July 2008, recognized as revenue in April 2009 upon the completion of the last patient in our second Phase III pivotal clinical trial of JZP-6 for the treatment of fibromyalgia.

We recognized contract revenues of $1.1 million during each of the years ended December 31, 2009, 2008, and 2007 related to the two upfront payments totaling $15.0 million related to JZP-6. The remaining $11.3 million was recorded as deferred revenues as of December 31, 2009 and is being recognized ratably through 2019, the end of the expected performance period under the agreement. There has been no change in the expected performance period under our agreement with UCB since its establishment in 2006 at the time of the initial upfront payment.

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10. Restructuring Expense

As part of a strategic decision in 2008 to focus on our commercial products and JZP-6 and lower operating expenses, we recorded restructuring charges of $3.5 million during the year ended December 31, 2008, of which $186,000 was reversed in 2009. $2.7 million of the total charge during the year ended December 31, 2008, was recorded as part of selling, general and administrative expense and the remainder included in research and development expense.

The following table represents activity in our restructuring accrual (in thousands):

	Employee Expenses(1)	Auto Lease Expenses(2)	Facility Expenses(3)	Total
Balance as of January 1, 2008	$	$	$	$
Charges incurred	2,139	374	950	3,463
Non-cash settlements	(13)		(830)	(843)
Cash payments	(1,147)			(1,147)
Balance as of December 31, 2008	979	374	120	1,473
Cash payments	(896)	(271)	(120)	(1,287)
Adjustment to charges incurred in prior periods	(83)	(103)		(186)
Balance as of December 31, 2009	$	$	$	$

(1) Includes employee severance, health insurance premium and outplacement assistance expenses.
(2) Includes auto lease termination expenses.
(3) Includes excess facilities, property and equipment expenses.

11. Common Stock

Committed Equity Financing Facility

In May 2008 we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge which expires in December 2012. We have not yet utilized the CEFF; however, in November 2009 we amended it to increase the number of shares we could sell at any one point in time, to reduce the discount we give to Kingsbridge when it purchases shares of common stock, and to reduce the minimum stock price above which we are eligible to utilize the CEFF. In exchange for the changes in the CEFF we reduced the exercise price of a warrant to purchase 220,000 shares of common stock previously issued to Kingsbridge from $11.20 to $9.20 per share. Under the amended CEFF we can require Kingsbridge to purchase shares of our common stock at varying discounts to its then market price, subject to a limit of the lesser of $75.0 million, or 4,922,064 shares of common stock, and certain other conditions and limitations, including a requirement to maintain an effective registration statement with the SEC. As of December 31, 2009, we had an effective registration statement covering 3,726,727 shares related to the CEFF. There are no minimum commitments or minimum use penalties.

The $850,000 fair value of the warrant to purchase 220,000 shares of common stock at $11.20 per share issued in May 2008 was recorded in stockholders deficit and was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free rate of 3.2%, volatility of 52%, a term of 5.5 years and a dividend yield of 0%. The $58,000 fair value of the modification of the warrant in November 2009 was recorded in stockholders deficit and was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free rate of 1.7%, volatility of 92%, a term of 4.0 years and a dividend yield of 0%.

Unregistered Sales of Equity Securities

In 2009, we completed a private placement of units consisting of an aggregate of 1,895,734 shares of common stock and warrants to purchase an aggregate of 947,867 shares of our common stock at a price of $3.6925 per unit for net proceeds of $6.8 million. The warrants are exercisable for $4.00 per share of common stock at any time through July 2016, subject to certain restrictions. The $2.7 million fair value of the warrants was recorded in stockholders deficit and was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free

rate of 3.1%, volatility of 92%, a term of 7.0 years and a dividend yield of 0%.

Employee Stock Purchase Plan, Stock Option Exercises, Vested Restricted Stock Units and Stock Bonus

During 2009, we issued 409,875 shares of our common stock for proceeds of $348,000 under our Employee Stock Purchase Plan, or ESPP, 6,371 shares of our common stock as a result of stock option exercises for proceeds of $40,000 and 14,116 shares of our common stock as a result of the vesting of restricted stock units.

In May 2008, we issued 125,532 shares of common stock with a fair value of $999,000 to employees under our employee bonus plan.

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Common Stock Subject to Repurchase

In February 2004, each of our then executive officers entered into an employment agreement with us which permitted the executive officer or the officer s estate to require us to repurchase vested shares at fair market value upon termination of the executive officer s employment due to death or disability. The fair value of vested shares held by our executive officers as of the date of such agreements (the Agreement Date Fair Value) was recorded as common stock subject to repurchase, and following the date of such agreements, the Agreement Date Fair Value of shares held by our executive officers was recorded as common stock subject to repurchase as such shares vested. The excess of the Agreement Date Fair Value over the original purchase price paid for such shares was charged against additional paid-in capital or, to the extent additional paid-in capital was insufficient, as an increase to stockholders deficit as such shares vested. In addition, upon completion of our initial public offering in 2007, 278,609 shares of preferred stock held by five of our executive officers, which were also subject to their employment agreements, were reclassified from preferred stock to common stock subject to repurchase. In December 2008, as a result of the resignation of an executive officer covered by an employment agreement, $749,000 related to 49,697 shares of common stock was reclassified from common stock subject to repurchase to additional paid-in capital. As of December 31, 2008, common stock subject to repurchase was $12.5 million. In February 2009, as a result of the expiration of the employment contracts with our executive officers, $12.5 million related to 827,761 shares of common stock was reclassified from common stock subject to repurchase to additional paid-in capital. As of December 31, 2009, there was no common stock subject to repurchase.

Registered Direct Public Offering

In 2008, we completed a registered direct public offering of units consisting of an aggregate of 3,848,289 shares of common stock and warrants to purchase an aggregate of 1,731,724 shares of our common stock at a price of $6.75625 per unit for net proceeds of $24.5 million. The warrants are exercisable for $7.37 per share of common stock at any time prior to July 2014. The $6.4 million fair value of the warrants was recorded in stockholders deficit and was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free rate of 3.62%, volatility of 58%, a term of 6.5 years and a dividend yield of 0%.

Authorized But Unissued Common Stock

We have reserved the following shares of authorized but unissued common stock:

	As of December 31, 2009
2007 Equity Incentive Plan	6,642,639
2007 Employee Stock Purchase Plan	270,694
2007 Non-Employee Directors Stock Option Plan	338,862
Exercise of warrants	4,247,511
Total reserved shares of common stock	11,499,706

12. Stock-Based Compensation

2007 Equity Incentive Plan

In May 2007, our board of directors adopted, and our stockholders approved, the 2007 Equity Incentive Plan, or the 2007 Plan, which provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, or RSUs, stock appreciation rights, performance stock awards and other forms of equity compensation to employees, including officers, non-employee directors and consultants. All of the grants under the 2007 Plan were granted to employees and vest ratably over service periods of three to five years and expire no more than ten years after the date of grant. The aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2007 Plan as of December 31, 2009, is 6,817,361 shares. The number of shares of our common stock reserved for issuance automatically increases on January 1 of each year, from January 1, 2008 to January 1, 2017, by the lesser of (a) 4.5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or (b) 3,000,000 shares, or a lesser amount determined by our board of directors. On January 1, 2010, shares reserved for issuance under the 2007 Plan increased by 1,406,487 shares pursuant to this automatic share increase provision.

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2007 Employee Stock Purchase Plan

Effective upon our initial public offering in June 2007, employees became eligible to participate in the ESPP. The ESPP allows eligible employee participants to purchase shares of our common stock at a discount of 15% through payroll deductions. The ESPP consists of a fixed offering period, generally 24 months, with four purchase periods within each offering period. In September 2009, the compensation committee of our board of directors approved an increase in the number of shares available for issuance under our ESPP during any six month purchase period from 150,000 to 260,000 effective with the purchase period that began on June 1, 2009 and for the following three purchase periods. In subsequent purchase periods 175,000 shares will be available for issuance. A total of 1,050,000 shares of our common stock have been authorized for issuance under the ESPP. The number of shares reserved for issuance under the 2007 ESPP automatically increases on each January 1 each year, from January 1, 2008 to January 1, 2017, by the lesser of (a) 1.5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or (b) 350,000, or a lesser amount determined by our board of directors. On January 1, 2010, the number of shares reserved for issuance under the 2007 ESPP increased by 350,000 shares pursuant to this automatic share increase provision.

2007 Non-Employee Directors Stock Option Plan

In May 2007, our board of directors adopted, and our stockholders approved, the 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Option Plan. The 2007 Directors Option Plan provides for the automatic grant of nonstatutory stock options to purchase shares of our common stock to our non-employee directors which generally vest over a period of one to three years. In addition, the 2007 Directors Option Plan provides the source of shares to fund distributions under the Directors Deferred Compensation Plan described below. A total of 345,531 shares of our common stock have been authorized for issuance under the 2007 Directors Option Plan. The number of shares of common stock reserved for issuance automatically increases on January 1 of each year by the number used during the previous year. On January 1, 2010, the number of shares reserved for issuance under the 2007 Directors Option Plan increased by 128,432 shares pursuant to this automatic share increase provision.

Directors Deferred Compensation Plan

In May 2007, our board of directors adopted the Directors Deferred Compensation Plan, the Directors Plan. The Directors Plan allows each non-employee director to elect to defer receipt of all or a portion of his or her annual retainer fees to a future date or dates. Amounts deferred are credited as shares of common stock to a phantom stock account the number of which are based on the amount of the retainer fees deferred divided by the market value of our common stock on the date the retainer fees are deemed earned. We recorded expense of $243,000, $236,000 and $211,000 related to retainer fees earned and deferred in 2009, 2008 and 2007, respectively. Upon termination of a director s service, the deferred shares are issued. We issued 3,826 and 2,843 shares of common stock during the years ended December 31, 2009 and 2008, respectively. As of December 31, 2009, 77,294 shares of common stock were unissued related to retainer fees deferred.

Stock Based Compensation

We use the Black-Scholes option pricing model to calculate the fair value of stock options which were estimated at the grant date using the following assumptions:

	Year Ended December 31,		
	2009	**2008**	**2007**
Weighted-average volatility for options	91%	60%	56%
Weighted-average expected term (years) for options	6.1	6.1	6.1
Range of risk-free rates	1.8-3.1%	2.7-3.4%	3.4-4.9%
Expected dividend yield	0.0%	0.0%	0.0%

The weighted-average grant date fair value per share of employee stock options granted during the years ended December 31, 2009, 2008 and 2007 was $1.34, $4.82, and $8.42, respectively.

We completed our initial public offering in June 2007 and, as such, our common stock has a limited trading history. A public market for options to purchase our common stock did not exist before June 2009 and the market that does exist is not very liquid, particularly for options with more than one year to expiration. Through 2008, due to the limited trading history of our common stock, we used the historic volatility of the common stock of a peer group to estimate future volatility of our common stock for our stock option grants and we used the historic and implied volatility of the common stock of a peer group in addition to the historic volatility of our common stock to estimate volatility of our common stock for

grants under our ESPP. In 2009, we used the historic volatility of the common stock of a peer group and the historic volatility of our own common stock to estimate future volatility of our common stock for stock option grants. To estimate the fair value of the most recent grants under our ESPP we relied exclusively on the implied volatility of our common stock.

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We have limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. As a result, for stock option grants made during each of the years ended December 31, 2009, 2008 and 2007, the expected term was estimated by assuming stock options would be exercised at the mid-point between the vest date and the contractual term.

The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of our stock option grants. The expected dividend yield assumption was based on our history and expectation of dividend payouts.

As of December 31, 2009, total compensation cost related to awards under the ESPP not yet recognized was $2.1 million, which is expected to be allocated to expense and production costs over a weighted-average period of one year and includes $1.4 million related to the increase in the number of shares available for issuance under our ESPP during any six month purchase period beginning with the purchase period that began on June 1, 2009.

Stock-based compensation expense related to stock options, restricted stock units, or RSUs, shares of common stock credited to each director s phantom stock account under the Directors Plan and awards under our ESPP was as follows (in thousands):

	Year Ended December 31,		
	2009	2008	2007
Selling, general and administrative	$ 4,400	$ 5,712	$ 4,600
Research and development	1,456	2,207	1,419
Cost of product sales	101	187	41
Total stock-based compensation expense	$ 5,957	$ 8,106	$ 6,060

No income tax benefit related to stock-based compensation was recognized in the statement of operations for the years ended December 31, 2009, 2008 and 2007. Employee stock-based compensation costs of $46,000 and $31,000 as of December 31, 2009 and 2008, respectively, were capitalized as a component of inventory and included in the consolidated balance sheets.

The total compensation cost related to unvested stock option grants not yet recognized as of December 31, 2009 was $7.8 million, which is expected to be recognized over a weighted-average period of 2.1 years.

The following table summarizes information as of December, 31, 2009 and activity during the year ended December 31, 2009, related to stock option plans:

	Shares Subject to Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2009	3,442,848	$ 16.41		
Options granted	2,865,000	1.80		
Options exercised	(6,371)	6.26		
Options forfeited	(715,467)	6.16		
Options expired	(651,633)	20.01		
Outstanding at December 31, 2009	4,934,377	8.95	7.8	$ 14,892
Vested and expected to vest at December 31, 2009	4,018,783	9.73	7.7	11,333
Exercisable at December 31, 2009	1,614,109	18.27	5.8	85

Aggregate intrinsic value shown in the table above is equal to the difference between the exercise price of the underlying stock options and the fair value of our common stock for stock options that were in the money. The aggregate intrinsic value of stock options exercised was $18,000, $18,000 and $16,000, during the years ended December 2009, 2008 and 2007, respectively.

We do not currently expect to repurchase shares of common stock in future years to reserve for issuance upon exercise of stock options.

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Restricted Stock Units

We granted RSUs equivalent to 123,991 shares of common stock vesting over three years with a weighted average grant date fair value of $13.25 per share, during the year ended December 31, 2007 and accelerated the vesting of RSUs equivalent to 1,874 shares of common stock during the year ended December 31, 2008. No RSUs were granted during the years ended December 31, 2009 and 2008. As of December 31, 2009, the total remaining unrecognized compensation cost related to non-vested RSUs was $369,000, which is expected to be recognized over a period of 1.6 years. The total fair value of shares vested during the years ended December 31, 2009 and 2008 was $96,000 and $220,000, respectively. No RSUs vested prior to 2008.

The following table summarizes information as of December 31, 2009, and activity during the year ended December 31, 2009, related to RSUs:

	Number of Retricted Stock Units	Weighted-Average Grant-Date Fair Value	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2009	55,130	$ 13.25		
RSUs granted				
RSUs exercised	(14,116)	13.25		
RSUs forfeited	(13,566)	13.25		
RSUs expired				
Outstanding at December 31, 2009	27,448	13.25	1.1	$ 216
Vested and expected to vest at December 31, 2009	15,592	13.25	1.1	123

13. Income Taxes

We have a history of losses and therefore have made no provision for income taxes. All of our losses result from domestic operations.

Deferred income taxes reflect the tax effects of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes.

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

	December 31, 2009	2008
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 134,368	$ 132,990
Federal and state tax credit carryforwards	14,525	14,182
Deferred contract revenues	4,802	8,958
Intangible assets	2,721	174
Other	6,245	8,443
Total deferred tax assets	162,661	164,747
Valuation allowance	(162,661)	(164,747)
Net deferred tax assets	$	$

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence, management believes it more likely than not that our deferred tax assets are not recognizable and will not be recognizable until we have sufficient taxable income. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by $2.1 million for the year ended December 31, 2009, and increased by $59.1 million

and $50.1 million for the years ended December 31, 2008 and 2007, respectively.

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At December 31, 2009, we had net operating loss carryforwards for federal income tax purposes of approximately $369.1 million, which expire in the period from 2011 to 2029, and federal tax credits of approximately $15.4 million, which expire in the period from 2011 to 2029. Approximately $0.8 million of federal net operating losses and $1.0 million of federal tax credits expire in the next five years. We also have state net operating loss carryforwards of approximately $223.0 million, that expire beginning in 2010 and state tax credits of approximately $5.1 million that have no expiration date. Utilization of our net operating loss carryforwards and tax credit carryforwards is subject to annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of the net operating loss before utilization. Because our acquisition of Orphan Medical in 2005 triggered an ownership change, approximately $38.0 million of the acquired Orphan Medical net operating loss carryforward is only available ratably through 2019 based upon the annual limitation under Section 382 of the Internal Revenue Code. Similarly, approximately $5.0 million of acquired Orphan Medical tax credits are available only from 2019 to 2024. We have completed detailed reviews of our ownership changes in accordance with the Internal Revenue Code, and we have confirmed that it is more likely than not that we have not experienced an ownership change from the time of the acquisition of Orphan Medical in June 2005 through December 31, 2009.

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have reduced our gross deferred tax assets by $4.7 million, $4.0 million and $2.1 million at December 31, 2009, 2008 and 2007, respectively; for certain tax benefits which we judge may not be sustained upon examination, and we have provided an offset through equal reductions in our deferred tax asset valuation allowance. A reconciliation of our unrecognized tax benefits follows (in thousands):

	2009	2008	2007
Balance at the beginning of the year	$ 4,010	$ 2,060	$ 1,500
Additions based on tax positions related to the current year	560	871	560
Additions for tax positions of prior years	147	1,110	
Lapse of applicable statute of limitations	(6)	(31)	
Balance at the end of the year	$ 4,711	$ 4,010	$ 2,060

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

14. Related Party Transactions

In August 2008, in connection with the sale of our rights to Antizol and Antizol-Vet pursuant to the terms of the agreement governing the Senior Note, or the Senior Note Agreement, we paid $327,000 to an entity affiliated with Kohlberg, Kravis & Roberts & Co. L.P., or KKR, a significant stockholder, as partial prepayment of the outstanding principal of the Senior Notes held by it.

As of December 31, 2008, an entity affiliated with KKR held Senior Notes with an aggregate principal amount of $6.8 million and warrants to purchase 70,156 shares of common stock exercisable at $20.36 per share. The exercise price of these warrants was reduced to $9.34 per share when we amended our Senior Note Agreement in November 2009. As of December 31, 2009, an entity affiliated with KKR held Senior Notes with an aggregate principal amount of $6.8 million and warrants to purchase 70,156 shares of common stock exercisable at $9.34 per share.

Cash paid for interest with respect to notes held by entities affiliated with KKR during the years ended December 31, 2009, 2008 and 2007 was $1.3 million, $796,000 and $3.8 million, respectively.

In the registered direct public offering that was completed in July 2008, a total of 60% of the investment was made by certain of our existing stockholders with which certain members of our board of directors are affiliated and/or associated; the remaining units were purchased by third party institutional investors on the same terms and conditions. Entities affiliated with KKR purchased 1,328,527 shares of common stock in this offering and warrants to purchase 597,837 shares of common stock exercisable at $7.37 per share through July 2014.

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15. 401(k) Plan

We provide a qualified 401(k) savings plan for our employees. All employees are eligible to participate, provided they meet the requirements of the plan. While we may elect to match employee contributions; no such matching contributions have been made through December 31, 2009.

16. Segment and Other Information

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

The following is a summary of our product sales, net (in thousands):

	Year Ended December 31,		
	2009	2008	2007
Xyrem	$ 96,763	$ 53,803	$ 39,018
Luvox CR	18,345	5,728	
Antizol(1)		5,106	14,153
Cystadane(2)			365
Total	$ 115,108	$ 64,637	$ 53,536

(1) We sold our rights to and interests in Antizol and Antizol-Vet in August 2008.
(2) We sold our rights to Cystadane to a third party in March 2007.

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

	Year Ended December 31,		
	2009	2008	2007
United States	$ 114,080	$ 62,894	$ 53,132
Europe	14,011	2,860	11,856
All other	358	1,760	315
Total	$ 128,449	$ 67,514	$ 65,303

The following table presents a summary of revenues from significant customers as a percentage of our total revenues:

	Year Ended December 31,		
	2009	2008	2007
Express Scripts	75%	79%	59%
UCB(1)	11%	*	18%

(1) In 2009, we recognized, as revenue, a $10.0 million nonrefundable milestone payment received from UCB in July 2008. See Note 9 for additional information.
* Represented less than 10% of our total revenues.

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17. Quarterly Financial Data (Unaudited)

The following interim financial information presents our 2009 and 2008 results of operations on a quarterly basis (in thousands, except per share amounts):

	2009			
	March 31	June 30	September 30	December 31
Revenues	$ 22,076	$ 37,280	$ 30,809	$ 38,284
Gross margin(1)	19,376	23,903	27,654	34,537
Net (loss) income	(12,988)	2,171	(1,672)	5,653
Net (loss) income per share, basic	(0.45)	0.07	(0.05)	0.18
Net (loss) income per share, diluted	(0.45)	0.07	(0.05)	0.17

	2008			
	March 31	June 30	September 30	December 31
Revenues	$ 14,634	$ 15,539	$ 17,746	$ 19,595
Gross margin(2)	11,686	11,955	11,497	15,575
Net loss	(46,710)	(51,880)	(28,809)	(56,940)
Net loss per share, basic and diluted	(1.97)	(2.17)	(1.07)	(2.04)

(1) Gross margin excludes amortization of acquired developed technology of $1.5 million, $1.6 million, $1.8 million and $1.8 million in the three months ended March 31, 2009, June 30, 2009, September 30, 2009 and December 31, 2009, respectively.

(2) Gross margin excludes amortization of acquired developed technology of $1.7 million, $3.5 million, $3.2 million and $3.1 million in the three months ended March 31, 2008, June 30, 2008, September 30, 2008 and December 31, 2008, respectively. Gross margin also excludes a charge of $29.8 million related to the impairment of the intangible asset associated with Luvox CR recorded in the three months ended December 31, 2008.

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

Contract revenues of $10.0 million related to the achievement of a development milestone recorded in the three months ended June 30, 2009;

A gain of $3.9 million on the sale of the rights to Antizol and Antizol-Vet recorded in the three months ended September 30, 2008, and,

A charge of $29.8 million related to the impairment of the intangible asset associated with Luvox CR recorded in the three months ended December 31, 2008.

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Schedule II

Valuation and Qualifying Accounts

(In thousands)

		Balance at beginning of period	Additions	Additions charged to costs and expenses (3)	Deductions	Balance at end of period
For the year ended December 31, 2009						
Allowance for doubtful accounts	(1)	$ 50	$	$ 111	$ (111)	$ 50
Allowance for sales discounts	(1)	126		2,068	(1,956)	238
Allowance for wholesaler fees	(2)	426	43	4,362	(4,218)	613
Allowance for government rebates	(2)	171		3,777	(1,678)	2,270
For the year ended December 31, 2008						
Allowance for doubtful accounts	(1)	$ 50	$	$ 30	$ (30)	$ 50
Allowance for sales discounts	(1)	101		1,375	(1,350)	126
Allowance for chargebacks	(1)	13		208	(221)	
Allowance for customer rebates	(1)	12		21	(33)	
Allowance for wholesaler fees	(2)	43		4,040	(3,657)	426
Allowance for government rebates	(2)	64		503	(396)	171
For the year ended December 31, 2007						
Allowance for doubtful accounts	(1)	$ 50	$	$ 15	$ (15)	$ 50
Allowance for sales discounts	(1)	94		1,111	(1,104)	101
Allowance for chargebacks	(1)	5		285	(277)	13
Allowance for customer rebates	(1)	18		14	(20)	12
Allowance for wholesaler fees	(1)	31		147	(135)	43
Allowance for government rebates	(2)	63		263	(262)	64

Notes

(1) Shown as a reduction of accounts receivable
(2) Included in accrued liabilities
(3) All charges except doubtful accounts are reflected as a reduction of revenue

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EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.(15)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(3)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(4)
4.3A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between the Registrant and the other parties named therein.(13)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(38)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(48)
4.3D	Waiver and Amendment Agreement, dated as of July 6, 2009 by and between the Registrant and the other parties named therein.(73)
4.6	Form of Series BB Preferred Stock Warrant of the Registrant.(14)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(39)
4.5A	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein.(40)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(41)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(42)
4.5D	Form of Common Stock Warrant of the Registrant.(43)
4.5E	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(44)
4.5F	Amendment and Waiver Agreement, dated as of November 10, 2009, by and among the Registrant, JPI Commercial, LLC and the other parties named therein.(76)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(49)
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(50)
4.6C	Amendment Agreement No. 1, dated as of November 20, 2009, by and between the Registrant and Kingsbridge Capital Limited.(77)
4.7	Form of Registered Direct Common Stock Warrant.(55)
4.8	NOL Preservation Lock-Up Agreement, effective as of July 7, 2009, by and between the Registrant and the other parties named therein.(68)
4.9A	Form of Common Stock Warrant of the Registrant issued on July 7, 2009.(69)
4.9B	Investor Rights Agreement, dated July 7, 2009 by and between the Registrant and the other parties named therein.(75)
10.1+	2003 Equity Incentive Plan, as amended.(5)
10.2+	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.(6)
10.3+	2007 Equity Incentive Plan.(7)
10.4+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.(16)

10.5+ 2007 Non-Employee Directors Stock Option Plan.(8)

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Exhibit Number	Description of Document
10.6+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.(9)
10.7+	2007 Employee Stock Purchase Plan.(10)
10.8+	Form of 2007 Employee Stock Purchase Plan Offering Document.(11)
10.9	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.(22)
10.10	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(17)
10.11	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.(18)
10.12	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.(23)
10.13	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(24)
10.14	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(19)
10.15	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(20)
10.16	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc. and Elan Pharma International Limited.(28)
10.17	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(25)
10.18	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(29)
10.19	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(30)
10.20	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.(26)
10.21	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(27)
10.22	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(31)
10.23	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.(32)
10.24	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.(21)
10.25+	Directors Deferred Compensation Plan.(12)
10.26+	Non-Employee Director Compensation Arrangements, as modified on August 14, 2008.(57)
10.27A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(33)
10.27B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and the Registrant.(34)
10.27C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.(35)
10.27D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and the Registrant.(36)

10.28+ Form of Letter, amending outstanding options granted under the Registrant s 2003 Equity Incentive Plan.(2)

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Exhibit Number	Description of Document
10.29+	Form of Restricted Stock Unit Award under the Registrant s 2007 Equity Incentive Plan.(37)
10.30	Amendment Number 4 to Development, License and Supply Agreement, dated as of October 26, 2007, by and between the Registrant and Elan Pharma International, Inc.(45)
10.31	Amendment No. 1 to Amended and Restated Xyrem License and Distribution Agreement, dated as of December 21, 2007, by and between the Registrant and UCB Pharma Limited.(46)
10.32	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.(47)
10.33	Common Stock Purchase Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(51)
10.34+	Amended Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(52)
10.35+	Form of Stock Award Grant Notice and Stock Award Agreement under the Registrant s 2007 Equity Incentive Plan.(53)
10.36	Master Services Agreement dated May 6, 2008, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and CuraScript, Inc.(54)
10.37	Amendment No. 2 to Amended and Restated Xyrem License and Distribution Agreement, dated July 23, 2008, by and between the Registrant and UCB Pharma Limited.(56)
10.38	Amendment No. 2 to License Agreement, dated as of October 17, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(58)
10.39	Amendment No. 3 to License Agreement, dated as of December 19, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(60)
10.40	Amendment No. 4 to License Agreement, dated as of February 5, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(61)
10.41+	Directors Deferred Compensation Plan, as amended.(62)
10.42+	Amended and Restated Executive Change in Control and Severance Benefit Plan.(63)
10.43	Revision of Payment Terms of the Plea Agreement dated as of July 17, 2007 between the U.S. Attorney for the Eastern District of New York and Orphan Medical, Inc.(64)
10.44	Amendment to Settlement Agreement, signed by the Company on February 6, 2009, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(65)
10.45	Form of Registered Direct Subscription Agreement.(59)
10.46	Consulting Agreement dated April 3, 2009 by and between the Registrant and Samuel R. Saks, MD(66)
10.47	First Amendment of Lease, dated June 1, 2009, by and between the Registrant and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University.(67)
10.48	Securities Purchase Agreement, dated July 6, 2009, by and between the Registrant and the purchasers listed on the signature pages thereto.(70)
10.49	2009 Executive Officer Compensation Arrangements.(72)
10.50	Form of Amended and Restated Indemnification Agreement between the Registrant and its officers and directors.(71)
10.51	Amendment No. 5 to License Agreement, dated as of June 23, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(74)
10.52	Amendment No. 5 to License Agreement, dated as of October 23, 2009, by and between the Registrant and Elan Pharma International Limited.(78)
10.53	Offer Letter from the Registrant to Kathryn Falberg.(79)
12.1	Ratio of Earnings to Fixed Charges and computation of ratios of earnings to fixed charges.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page hereto).

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Exhibit Number	Description of Document
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

+ Indicates management contract or compensatory plan.

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

(1) Incorporated herein by reference to exhibit 3.1 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.

(2) Incorporated herein by reference to exhibit 10.60 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.

(3) Incorporated herein by reference to exhibit 3.4 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(4) Incorporated herein by reference to exhibit 4.2 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(5) Incorporated herein by reference to exhibit 10.21 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(6) Incorporated herein by reference to exhibit 10.22 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(7) Incorporated herein by reference to exhibit 10.23 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(8) Incorporated herein by reference to exhibit 10.25 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(9) Incorporated herein by reference to exhibit 10.26 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(10) Incorporated herein by reference to exhibit 10.27 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(11) Incorporated herein by reference to exhibit 10.28 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(12) Incorporated herein by reference to exhibit 10.55 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(13) Incorporated herein by reference to exhibit 4.3A in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.

(14) Incorporated by reference to exhibit 4.6 to the Registrant s registration statement on Form S-1 (File No. 333-141164), as filed with the SEC on March 9, 2007.

(15) Incorporated by reference to exhibit 2.1 in the Registrant s registration statement on Form S-1 (File No. 333-141164), as filed with the SEC on March 9, 2007.

(16) Incorporated herein by reference to exhibit 10.24 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.

(17) Incorporated herein by reference to exhibit 10.31 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.

(18) Incorporated herein by reference to exhibit 10.32 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.

(19) Incorporated herein by reference to exhibit 10.43 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.

(20) Incorporated herein by reference to exhibit 10.44 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.

(21) Incorporated herein by reference to exhibit 10.54 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 24, 2007.

(22) Incorporated herein by reference to exhibit 10.30 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.

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(23) Incorporated herein by reference to exhibit 10.41 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(24) Incorporated herein by reference to exhibit 10.42 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(25) Incorporated herein by reference to exhibit 10.46 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(26) Incorporated herein by reference to exhibit 10.49 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(27) Incorporated herein by reference to exhibit 10.50 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
(28) Incorporated herein by reference to exhibit 10.45 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(29) Incorporated herein by reference to exhibit 10.47 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(30) Incorporated herein by reference to exhibit 10.48 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(31) Incorporated herein by reference to exhibit 10.51 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(32) Incorporated herein by reference to exhibit 10.52 in the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
(33) Incorporated herein by reference to exhibit 10.57A in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
(34) Incorporated herein by reference to exhibit 10.57B in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
(35) Incorporated herein by reference to exhibit 10.57C in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
(36) Incorporated herein by reference to exhibit 10.57D in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
(37) Incorporated herein by reference to exhibit 10.64 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
(38) Incorporated herein by reference to exhibit 4.3B in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(39) Incorporated herein by reference to exhibit 4.4B in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(40) Incorporated herein by reference to exhibit 4.5A in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(41) Incorporated herein by reference to exhibit 4.5B in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(42) Incorporated herein by reference to exhibit 4.5C in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(43) Incorporated herein by reference to exhibit 4.5D in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(44) Incorporated herein by reference to exhibit 4.5E in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(45) Incorporated herein by reference to exhibit 10.66 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(46) Incorporated herein by reference to exhibit 10.68 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(47) Incorporated herein by reference to exhibit 10.69 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.
(48) Incorporated herein by reference to exhibit 4.3C in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
(49) Incorporated herein by reference to exhibit 4.6A in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
(50) Incorporated herein by reference to exhibit 4.6B in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
(51) Incorporated herein by reference to exhibit 10.70 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.

(52) Incorporated herein by reference to exhibit 10.71 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.

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(53) Incorporated herein by reference to exhibit 10.73 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.
(54) Incorporated herein by reference to exhibit 10.74 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.
(55) Incorporated herein by reference to exhibit 4.7 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
(56) Incorporated herein by reference to exhibit 10.75 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 24, 2008.
(57) Incorporated herein by reference to exhibit 10.56 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2008, as filed with the SEC on November 14, 2008.
(58) Incorporated herein by reference to exhibit 10.77 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2008, as filed with the SEC on November 14, 2008.
(59) Incorporated by reference to exhibit 10.1 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
(60) Incorporated herein by reference to exhibit 10.78 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(61) Incorporated herein by reference to exhibit 10.79 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(62) Incorporated herein by reference to exhibit 10.80 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(63) Incorporated herein by reference to exhibit 10.81 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(64) Incorporated herein by reference to exhibit 10.82 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(65) Incorporated herein by reference to exhibit 10.83 in the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2008, as filed with the SEC on March 26, 2009.
(66) Incorporated herein by reference to exhibit 10.85 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
(67) Incorporated herein by reference to exhibit 10.86 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on June 4, 2009.
(68) Incorporated herein by reference to exhibit 4.8 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(69) Incorporated herein by reference to exhibit 4.9A in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(70) Incorporated herein by reference to exhibit 10.87 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(71) Incorporated herein by reference to exhibit 10.89 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(72) Incorporated herein by reference to exhibit 10.84 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
(73) Incorporated herein by reference to exhibit 4.3D in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009.
(74) Incorporated herein by reference to exhibit 10.90 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2009, as filed with the SEC on August 14, 2009.
(75) Incorporated herein by reference to exhibit 4.9B in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
(76) Incorporated by reference to exhibit 4.5F in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on November 10, 2009.
(77) Incorporated by reference to exhibit 4.6C in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on November 23, 2009.
(78) Incorporated by reference to exhibit 10.91 in the Registrant s quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2009, as filed with the SEC on November 6, 2009.
(79) Incorporated herein by reference to exhibit 10.92 in the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on December 3, 2009.

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

the Securities Exchange Act of 1934, as amended.