JAZZ PHARMACEUTICALS INC
Form 10-K
March 26, 2009
Table of Contents

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, 2008

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 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. x

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, 2008, based upon the last sale price reported for such date on the NASDAQ Global Market, was $70,678,403. The calculation of the aggregate market value of voting and

non-voting stock excludes 15,360,755 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 March 20, 2009, a total of 28,925,352 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 2009 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.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

2008 ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

Table of Contents

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, 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 these 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 focused on developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development, acquisition and in-licensing activities, and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and to compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of $59.5 million in 2008, one product candidate in late Phase III clinical development 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 U.S. Food and Drug Administration, or 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 U.S. are affected by narcolepsy. We promote Xyrem in the U.S. 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 U.S. to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 13 countries. In 2008, our Xyrem net sales were $53.8 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 on February 28, 2008. We shipped initial stocking orders of Luvox CR to our wholesaler customers in March 2008 and began promoting the product 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. SSRIs are used in the treatment of depression, anxiety disorders and some personality disorders. We promote Luvox CR in the U.S. for its FDA-approved indications to certain general practitioners and psychiatrists through our specialty sales force. 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 U.S., 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 U.S. from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the U.S. In 2008, our Luvox CR net sales were $5.7 million.

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, between two and four percent of the U.S. population suffers from fibromyalgia. The product is currently in Phase III clinical development; the program includes two Phase III pivotal clinical trials and a long term safety trial. In November 2008, we announced positive preliminary top-line results from the first of the two Phase III pivotal clinical trials. The randomized, double-blind, placebo-controlled study achieved its primary endpoints, demonstrating that JZP-6 significantly decreased pain and

Table of Contents

fatigue, and improved daily function, in patients with fibromyalgia. We expect preliminary data from the second Phase III pivotal clinical trial, for which we have completed enrollment, in mid-2009. Subject to successful completion of the remaining Phase III pivotal clinical trial, we plan to submit to the FDA a new drug application, or NDA, for JZP-6 in the fourth quarter of 2009. If our NDA is approved by the FDA, we expect to market JZP-6 in the U.S. to specialists who treat fibromyalgia patients, through an expanded specialty sales force and/or in partnerships with third parties. We do not promote Xyrem for use in fibromyalgia. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the U.S.

Our other product candidates in clinical development are 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 (sodium and calcium channel antagonist), 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 do not anticipate significant additional development progress on JZP-8, JZP-4 or JZP-7 unless or until we partner a program or otherwise obtain financing that we believe is sufficient to continue their development.

During the second half of 2008, we significantly reduced our ongoing expenses. We are also seeking to raise additional funds. We are currently operating the company in a manner that we believe maximizes the value of our business for our creditors and stockholders by focusing on selling and marketing Xyrem and Luvox CR, continuing our JZP-6 clinical program, with respect to which we expect to obtain the preliminary results of a second Phase III pivotal clinical trial in mid-2009, and looking for additional ways to reduce our operating expenses. As of December 31, 2008, we had cash, cash equivalents and marketable securities of $25.9 million (excluding restricted cash of $1.9 million). On December 31, 2008, we did not make the $4.5 million quarterly interest payment that was due with respect to our senior secured notes, and in early January 2009, we received a notice of default. We are currently in discussions with our senior lenders with respect to our payment default and the status of our senior debt. If we are unable to resolve our situation with our senior debt and/or to raise sufficient additional funds, we would be required to further reduce operating expenses, by, among other things, curtailing significantly or delaying or eliminating part or all of our development programs including JZP-6 and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

Marketed Products and Late-Stage Product Candidate

Xyrem (sodium oxybate) oral solution

Xyrem is a sodium oxybate oral solution approved in the U.S. 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 γ-hydroxybutyrate, an endogenous neurotransmitter and metabolite of γ-aminobutyric acid. In June 2005, we obtained the rights to Xyrem as a result of our acquisition of Orphan Medical, Inc., or Orphan Medical. 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 2008, our net product sales of Xyrem were $53.8 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 U.S. 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).

Table of Contents

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. In the Journal *SLEEP* in December 2007, the American Academy of Sleep Medicine recommended Xyrem as a standard of care for the treatment of both excessive daytime sleepiness and cataplexy associated with narcolepsy.

Commercialization

We promote Xyrem in the U.S. 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 throughout Europe, South America, the Middle East and Asia in exchange for milestone and royalty payments to us. UCB currently markets the product in 13 countries. We are entitled to additional commercial milestone payments of up to $6.0 million specifically associated with the sale of Xyrem for the treatment of narcolepsy and royalties on all commercial sales of Xyrem by UCB. In October 2005, the European Agency for the Evaluation of Medical Products, or EMEA, approved Xyrem for the treatment of cataplexy in adult patients with narcolepsy, and in March 2007, the EMEA 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 EMEA approval to commercially promote and distribute Xyrem for the treatment of narcolepsy, subject to automatic extension unless and until UCB terminates the agreement upon not less than 12 months notice. Under the terms of an amendment to our license and distribution agreement with UCB entered in July 2008, 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 exclusivity in the U.S. for both excessive daytime sleepiness and cataplexy in patients with narcolepsy. This provides marketing exclusivity in the U.S. until July 2009 for the cataplexy indication and November 2012 for the excessive daytime sleepiness indication. In addition to orphan drug exclusivity, Xyrem is covered by two formulation patents that are listed in the FDA s approved drug products with therapeutic equivalence evaluation document, or Orange Book. The patents will expire in 2020. 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 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. Patent applications covering Xyrem s distribution system are currently pending, and the patents, if issued, would expire in 2022. In addition, we believe that the strict manufacturing and distribution controls on sodium oxybate and Xyrem, and the complicated risk management procedures required to market and sell the product, may make it difficult for other companies to manufacture and market generic formulations of Xyrem.

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 must be distributed through a single central pharmacy. The central pharmacy we use is Express Scripts Specialty Distribution Services, or Express Scripts, with whom we have an exclusive relationship. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about 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 must verify the prescription and obtain additional information by contacting the patient s insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign for the package. The initial shipment may only be for a one-month supply and physicians may only prescribe up to six months of supply of Xyrem at one time.

Pursuant to our exclusive agreement 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 U.S. 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.

Table of Contents

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. 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. We must 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.

Competition

As an alternative to Xyrem, cataplexy is 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). Xyrem and Provigil are both approved for the treatment of excessive daytime sleepiness in patients with narcolepsy, but Xyrem is also approved for the treatment of cataplexy. Provigil is 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 is a pill that is usually taken once in the morning for excessive daytime sleepiness by patients with narcolepsy. Provigil is distributed by numerous pharmacies. Xyrem s REMS requires that it be distributed in the U.S. 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 Provigil, which is 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 launched Luvox CR in March 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 U.S. Solvay retained the rights to market and distribute Luvox CR outside of the U.S. 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. The approval of Luvox CR includes a post marketing commitment to conduct a safety and efficacy study in adolescent patients with social anxiety disorder and 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 U.S. 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. While these patients often realize that their obsessions and compulsions are irrational or excessive, they frequently have little or no control over them. Typical obsessions include concerns with dirt, germs and contamination, fear of acting on violent or aggressive impulses or feeling overly responsible for the safety of others. Rituals adopted by obsessive compulsive disorder patients may provide them with transient relief from anxiety, but the rituals do not provide sustained comfort. Frequently, the rituals become so overwhelming that patients are unable to function normally in their daily lives. Symptoms of obsessive compulsive disorder typically appear in childhood, adolescence or early adulthood. According to an article published in the *Journal of Clinical Psychiatry*, a significant portion of obsessive compulsive disorder patients are believed to have one or more concomitant psychiatric disorders, such as depression or social anxiety disorder.

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 U.S. Despite the prevalence of the disorder, social anxiety disorder remains underdiagnosed and undertreated by clinicians. Social anxiety disorder patients have anticipatory anxiety about these situations, and this anxiety can become so pronounced that patients cannot function normally in their daily lives. Social anxieties can be limited to a particular situation or apply to a variety of situations. In addition to anxiety, patients experience physical symptoms including blushing, sweating, trembling and

nausea. Symptoms of social anxiety disorder typically appear in

Table of Contents

childhood or adolescence with a mean age of onset of approximately 13 years, and the symptoms are often preceded by a history of social inhibition or shyness. According to an article published in the *Journal of Clinical Psychiatry*, mood and other anxiety disorders are prevalent among social anxiety disorder patients.

Attributes of Luvox CR

We believe that there is a market opportunity for prescriptions for Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder, and that Luvox CR offers an opportunity to improve upon the immediate-release formulation of fluvoxamine, the active pharmaceutical ingredient in Luvox CR, in treating these disorders. 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 significantly improves compliance and patient 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 launched Luvox CR in the first quarter of 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 U.S., and Solvay retained the rights to market and distribute Luvox CR outside of the U.S. 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 U.S. If Solvay decides not to market Luvox CR in any countries to which it has rights, we have a right of first offer with respect to any license of rights to market and distribute Luvox CR in those countries. 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 will be responsible for satisfying Solvay s commercial requirements of Luvox CR outside of the U.S. in exchange for supply price payments to us. 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. On February 5, 2009, we amended the agreement again, 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, which we expected would be met in April 2009 as well as the future royalty and other obligations were replaced with an obligation to pay a total of $19.0 million. Under that most recent amendment, we paid Solvay $1.0 million on March 15, 2009, and we owe Solvay an additional $5.0 million in 2009 in three quarterly installments of $1.0 million, $2.0 million and $2.0 million on or before June 15, 2009, September 15, 2009 and December 15, 2009 respectively, $4.0 million in 2010, $4.5 million in 2011, $5.0 million in 2012. We also agreed to pay Solvay $5.0 million in 2015 if 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 U.S. 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. Failure to promptly conduct these Phase IV clinical trials could result in the FDA s withdrawal of approval for Luvox CR.

Table of Contents

Luvox CR has three years of marketing exclusivity beginning on February 28, 2008, the date Luvox CR was approved by the FDA. In addition, a patent covering the orally administered formulation of extended-release fluvoxamine, requiring the release of fluvoxamine over a period of not less than 12 hours, has issued to Elan. In the U.S., the patent expires in 2020. The patent has also issued in Europe, Australia South Africa, Ukraine and Russia and is pending in seven other countries.

Competition

Selective serotonin reuptake inhibitors, or SSRIs, have become the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. According to the Pharmaceutical Audit Suite published by Wolters Kluwer Health, more than 152 million total prescriptions were written for SSRIs and serotonin-norepinephrine reuptake inhibitors, or SNRIs, in the U.S. in 2008, accounting for approximately $20.8 billion in sales. Serotonin-norepinephrine reuptake inhibitors are a class of antidepressants used in the treatment of clinical depression and sometimes used to treat anxiety disorders, including obsessive compulsive disorder, social anxiety disorder and other conditions. Since the approval of Prozac® (fluoxetine) in the U.S. in 1987, the use of SSRIs and SNRIs has increased dramatically due to their efficacy and reduced side effect profile relative to previously approved antidepressants. Based on available market data, we estimate that the majority of SSRI and SNRI prescriptions are for the treatment of depression and that obsessive compulsive disorder and social anxiety disorder constitute approximately three percent of total SSRI and SNRI prescriptions.

Six branded products in addition to Luvox CR are currently approved by the FDA for the treatment of obsessive compulsive disorder, including five SSRIs: Paxil® (paroxetine HCl), which is marketed by GlaxoSmithKline, Zoloft® (sertraline HCl), which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly, Pexeva® (paroxetine mesylate) which is marketed by Noven Therapeutics and Luvox® (fluvoxamine) which is not currently marketed. The sixth branded product is Anafranil® (clomipramine hydrochloride), a tricyclic antidepressant marketed by Mallinckrodt in the U.S. The relative use of each of these products for the treatment of obsessive compulsive disorder has varied over the past ten years, and each currently has generic equivalents and is not actively promoted. Generic products are generally sold at significantly lower prices than branded products, tending both to take market share away from branded products and to put downward pricing pressure on branded products.

The market for drugs to treat obsessive compulsive disorder is extremely fragmented. Based on data for 2008 from IMS NPA Market Dynamics, we estimate that Paxil, Zoloft, Prozac and Anafranil, and their generic equivalents, and fluvoxamine accounted for 50% of the total drug usage for the treatment of obsessive compulsive disorder in 2008. Although they are not FDA-approved for the treatment of obsessive compulsive disorder, based on data for 2008 from IMS NPA Market Dynamics, we estimate that the currently marketed branded products, Lexapro®, Celexa®, Effexor XR® and Cymbalta®, and their generic equivalents, accounted for approximately an additional 45% of total drug usage for the treatment of obsessive compulsive disorder in 2008, with more than five other drugs making up the remaining 5%.

Four branded products in addition to Luvox CR are currently approved by the FDA for the treatment of social anxiety disorder, including three SSRIs: Zoloft, Paxil and Paxil CR, an extended-release version of Paxil, and one SNRI, Effexor XR. Effexor XR, Paxil, Paxil CR and Zoloft have generic equivalents.

The market for drugs to treat social anxiety disorder is also extremely fragmented. Based on data for 2008 from IMS NPA Market Dynamics, we estimate that Zoloft, Paxil, Paxil CR and Effexor XR, and their generic equivalents, in the aggregate accounted for approximately 42% of the total drug usage for the treatment of social anxiety disorder in 2008. Although they are not approved for the treatment of social anxiety disorder, based on data for 2008 from IMS NPA Market Dynamics, we estimate that the currently marketed products Lexapro, Celexa and Cymbalta, and their generic equivalents, accounted for 39% of total drug usage for the treatment of social anxiety disorder in 2008, with ten other drugs making up the remaining 19%. 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 social anxiety disorder. Zoloft, Paxil, Paxil CR and Effexor XR are approved for additional psychiatric disorders such as major depressive disorder, in addition to social anxiety disorder, which may give them broader recognition and use by physicians and patients.

The currently approved SSRI products, including Luvox CR, all have significant adverse side effects and a black box 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, we announced positive preliminary top-line results from the first of two Phase III pivotal clinical trials of JZP-6 for the treatment of fibromyalgia. The randomized, double-blind, placebo-controlled study achieved its primary endpoints, demonstrating that JZP-6 significantly decreased pain and fatigue, and improved daily function, in patients with fibromyalgia. We expect preliminary data from the second Phase III pivotal clinical

trial, for which we have completed patient enrollment, in mid-2009.

Table of Contents

Market Opportunity

Fibromyalgia is a chronic condition characterized by widespread pain. According to the American College of Rheumatology, between two and 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.

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), approved in January 2009, 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 12.5 million total prescriptions were written to treat fibromyalgia symptoms in 2008. Of these, approximately 27% were for antidepressants, 27% for anti-epileptics (gabapentin and pregabalin), 17% for analgesics, 13% for muscle relaxants and 16% 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 syndrome and many of its related symptoms.

Attributes of JZP-6

We are developing 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 provide significant advantages over current treatments by offering improvements in three important fibromyalgia symptoms: pain, fatigue and sleep disturbances.

The primary endpoint for our Phase III pivotal clinical trials measuring the efficacy of JZP-6 is the change from baseline in pain based on the pain visual analog scale. In the U.S., an efficacious response by a patient in the trial is defined as a greater than or equal to 30% reduction in the pain visual analog scale. The FDA has accepted the Pain Visual Analog Scale as the acceptable primary endpoint to obtain an indication for the treatment of fibromyalgia. The European Agency for the Evaluation of Medicinal Products, or EMEA, has stated that a pain reduction of at least 30% should be targeted, as well as a positive result in either the Fibromyalgia Impact Questionnaire or the Patient Global Impression of Change.

Product Development

Phase III Clinical Trial Results. In November 2008, we announced results of the first of two Phase III pivotal clinical trials. The 14-week study 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 primary outcome measure, viewed by both the FDA and the EMEA 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 EMEA has indicated that the Fibromyalgia Impact Questionnaire data is equally relevant, while FDA considers it supportive data.

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 on 4.5 grams of sodium oxybate nightly and 39.3 % of patients on 6 grams of sodium oxybate nightly reported this level of pain relief as measured by the Pain Visual Analog Scale, compared with 27.3 % of patients on placebo. These results were highly statistically significant. The Pain Visual Analog Scale is a well-accepted tool for the measurement of pain, in which patients track and report their level of discomfort, ranging from none to worst imaginable.

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 significantly different from placebo for the 4.5 grams of sodium oxybate nightly dose and approached significance for the 6 grams of sodium oxybate per night. The Fibromyalgia Impact Questionnaire is a 20 item questionnaire that asks patients to assess their ability to complete activities of daily living such as shopping, preparing a meal, visiting or doing housework. 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.

9

Table of Contents

Patients receiving sodium oxybate at both dosage levels in our first Phase III clinical pivotal clinical trial also reported significant improvement in fatigue, another common symptom of fibromyalgia.

Adverse events for our study patients were similar to those seen in previous experience with sodium oxybate. The most common adverse events, with incidence greater than or equal to 5 percent and at least twice the rate of placebo, were headache, nausea, dizziness, vomiting, diarrhea, anxiety and sinusitis. Sodium oxybate was generally well tolerated, with the majority of adverse events reported being mild to moderate in nature.

Ongoing Phase III Clinical Trials. We have completed enrollment in the second of our two Phase III pivotal clinical trials, with 578 patients, of whom 197 reside in Europe and 381 reside in the U.S. This second trial has the same endpoints and dosages as the first Phase III trial and is also a double blind, placebo controlled study. We expect to report top-line results for the second Phase III pivotal clinical trial in mid-2009. We are also conducting an open-label continuation trial to provide long-term safety data; this trial is open to patients who complete one of the two Phase III pivotal clinical trials.

If the second Phase III pivotal clinical trial is successful, we currently anticipate submission of an NDA for this product candidate in the fourth quarter of 2009. UCB has informed us that it anticipates filing the European Union equivalent of an NDA with the EMEA shortly after we submit our NDA.

Commercialization Strategy

If JZP-6 is approved by the FDA, we believe that the majority of prescriptions for the product to treat fibromyalgia will be written by physicians such as pain specialists, rheumatologists, neurologists, psychiatrists and sleep specialists. Because the number of pain specialists and rheumatologists in the U.S. is relatively small, we expect to be able to expand our specialty sales force and/or to develop partnerships with third parties to promote JZP-6 in the U.S. We may also identify one or more pharmaceutical company partners or a contract sales organization to promote JZP-6 to other physicians, including primary care physicians who are treating patients with fibromyalgia.

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 throughout Europe, South America, the Middle East and Asia, 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, UCB has paid us $32.5 million, which includes a nonrefundable $10.0 million payment made to us in July 2008 in lieu of the $7.5 million payment that would have been due prior to the amendment upon completion of the study by the last patient in our second Phase III pivotal clinical trial. Under the terms of the amendment, we are obligated to use commercially reasonable efforts to enroll at least 185 patients in the clinical trial from countries within the European Union, an obligation that we achieved in December 2008. We are entitled to up to $25.0 million in additional development milestone payments associated with JZP-6, and additional commercial milestone payments of up to $100.0 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 EMEA 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 commercial quantities of 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 to manufacture the product for us. 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. We must 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 to complete our clinical trials and, if it is approved, to commercialize JZP-6. We believe that we currently have enough quota to complete the current JZP-6 Phase III clinical trials. 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. These restrictions and risk management policies may present a meaningful obstacle to introduction of generic versions of JZP-6.

We expect that our patents 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 28 other countries which expire in 2018, that cover the use of sodium oxybate for the treatment of fibromyalgia.

Table of Contents

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 the second cohort of 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 are currently evaluating the data from the first two cohorts of the Phase II clinical trial in preparation for dosing additional patients, assuming we are able to partner or otherwise secure funding for 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 U.S. suffer from epilepsy, and according to the National Institute of Mental Health, approximately 5.7 million people in the U.S. are affected by bipolar disorder. We are currently conducting product formulation activities in preparation for initiation of a Phase II clinical program for JZP-4. A Phase II program will be initiated when we are able to partner or otherwise secure funding for 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 pre-clinical activities conducted in preparation for the initiation of a Phase III clinical program for JZP-7 which would be initiated when we are able to partner or otherwise secure funding for this program.

Early Stage Development

We have identified several product candidates through our new product candidate identification and development program, including the use of sodium oxybate for the treatment of movement disorders and the development of an oral tablet form of sodium oxybate. We do not anticipate significant development progress on these or any additional product candidates in 2009 unless we partner a program or otherwise obtain sufficient financing to continue a program s development.

Sales and Marketing

As of March 16, 2009, we had a specialty sales force consisting of approximately 120 full-time sales professionals, which includes our Specialty Sales Consultants, Regional Sales Managers, and Area Business Director, who currently promote Xyrem and Luvox CR. Our Specialty Sales Consultants are experienced, with an average of nine years of specialty pharmaceutical selling experience. Our Regional Sales Management team has an average of nine years of specialty sales management experience and 17 years of industry experience. Our sales force calls primarily on psychiatrists, neurologists, pulmonologists, sleep specialists and certain general practitioners. If JZP-6 is approved by the FDA, we may need to expand our specialty sales force to include additional sales professionals who would focus on specialists treating fibromyalgia.

We have established marketing and commercial operations departments to support our sales efforts. Our marketing and commercial operations departments consist of marketing professionals who are responsible for brand management and market research, and commercial operations professionals who are responsible for business analytics and commercial technology, sales administration, training and development, pharmacy relations and patient affairs. Our marketing team develops and implements brand strategies to maximize product uptake and adoption with our target physician audiences in accordance with our approval labeling. 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.

11

Table of Contents

Customers and Financial Information about Geographic Areas

In the U.S., Xyrem is sold to one specialty pharmacy which ships Xyrem directly to patients. Our other products in the U.S. are sold primarily to distributors who distribute our product to pharmacies. During the year ended December 31, 2008, the specialty pharmacy for Xyrem was Express Scripts, and the principal distributors for Luvox CR in the U.S. were Cardinal Health, McKesson and AmerisourceBergen. Outside the U.S., UCB Pharma is our primary distributor for Xyrem. Luvox CR is not sold outside the U.S.

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 will continue until August 1, 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. 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 DEA quota is a difficult and time consuming process which may provide a meaningful obstacle for the introduction of generic formulations of Xyrem and the eventual introduction of generic versions of JZP-6. We believe that the quota granted by the DEA for 2009 will be sufficient to satisfy our commercial and clinical needs in 2009. In the future, in cooperation with our procurement and manufacturing partners, we will continue to seek increased quotas to satisfy our clinical and commercial 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 for the marketplace or JZP-6 for use in our clinical studies or for commercial use, or both.

Pursuant to 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. 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 U.S. in exchange for supply price payments to us.

We believe that qualified suppliers and manufacturers for our marketed products will continue to be available in the future, at a reasonable cost to us, although there can be no assurance that this will be the case.

We are also seeking, have identified or have entered into manufacturing and supply arrangements for our product candidates. We have contracted with our contract manufacturers of Xyrem for the active pharmaceutical ingredient and drug product for our clinical requirements of JZP-6. As with Xyrem, we will be responsible for supplying JZP-6 to UCB.

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.

12

Table of Contents

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 U.S. and in other countries. In the U.S., 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 U.S. 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.

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.

Table of Contents

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 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. In addition, the FDA recently announced that, in light of staffing issues, it has given its managers discretion to miss PDUFA deadlines for completing reviews of NDAs.

If the FDA s evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue a complete response letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA s evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter. Sponsors that receive either a complete response letter or a not approvable letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. 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 drug candidates will qualify for any of these programs, or that, if a drug 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.

14

Table of Contents

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 Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits the applicant to rely upon the FDA s findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug product for all or some of the label indications for which the referenced product has been approved, or for a new indication sought by the Section 505(b)(2) applicant.

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

Table of Contents

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.

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, depending on our ability to meet certain legal requirements permitting such 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 and execute required REMS for Xyrem, and will work with the FDA if the agency determines that REMS are necessary for Luvox CR or for our product candidates.

16

Table of Contents

Orphan Drug Designation and Exclusivity

Some jurisdictions, including Europe and the U.S., 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 U.S. or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. In the U.S., 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 periods of orphan drug exclusivity expire in July 2009 and November 2012, respectively, for cataplexy and excessive daytime sleepiness in patients with narcolepsy. 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 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.

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

Table of Contents

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 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 foreign regulations governing clinical trials and the marketing of other products. Outside of the U.S., our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above. A World Health Organization (WHO) subcommittee plans to begin the process of evaluating the scheduling of sodium oxybate in 2009, which could result in Xyrem being placed in a more restrictive schedule in Europe than its current Schedule IV controlled substance status and in a more restrictive schedule in the U.S. than its current Schedule III controlled substance status. The WHO review process is often long and complicated and the 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 U.S., 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 U.S. 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;
- controls on healthcare providers;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- changes of drug importation laws; and

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

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

Table of Contents

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 eight 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 17 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. Our Xyrem formulation patent has issued in 17 other countries and will expire on December 22, 2019. It is currently pending in two additional countries. Xyrem is also covered by a U.S. patent that covers a process for preparing the formulation that expires on December 22, 2019. We also have filed a U.S. patent application with claims covering the method for distributing sodium oxybate using a centralized distribution system that, if issued, would expire on December 17, 2022.

Luvox CR. Luvox CR is covered by a U.S. 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. 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 U.S. A continuation application is pending in the U.S.

JZP-6. We expect that our current 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 U.S. on August 29, 2017 and in 29 other countries on August 27, 2018.

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.

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

Table of Contents

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 U.S. and 22 registered trademarks and service marks in other countries. We also have 5 pending trademark and service mark applications in the U.S. and seven pending trademark and service mark applications in other countries. 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.

Competition

The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies, such as Pfizer 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, a wakefulness promoting agent and the only other FDA-approved product for the treatment of excessive daytime sleepiness in patients with narcolepsy.

Luvox CR. We believe that the primary competitors for Luvox CR in the treatment of obsessive compulsive disorder are Prozac, Zoloft and Paxil, and their generic equivalents. In the treatment of social anxiety disorder, we believe that Luvox CR s primary competitors are Paxil CR and Effexor XR.

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 of current products that compete with 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;

Table of Contents

product acceptance by physicians and other health care providers;

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 March 16, 2009, we had approximately 216 full-time employees. Of the full-time employees, approximately 145 were engaged in sales and marketing, 43 were engaged in manufacturing, product development and clinical activities, and 28 were engaged in general and administrative activities. We had workforce reductions of 33 employees in June 2008, primarily from the research and development and administrative areas, 67 employees in November 2008, primarily from the specialty sales force, and 71 employees in December 2008 from all areas other than the specialty sales force.

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.

Executive Officers of the Registrant

The following table sets forth certain information concerning our executive officers as of March 16, 2009:

Name	Age	Position
Bruce C. Cozadd	45	Executive Chairman and Director
Samuel R. Saks, M.D.	54	Chief Executive Officer and Director
Robert M. Myers	45	President
Carol A. Gamble	56	Senior Vice President, General Counsel and Corporate Secretary
Janne L.T. Wissel	53	Senior Vice President, Chief Regulatory and Compliance Officer
Joan E. Colligan	58	Controller and Acting Principal Financial Officer

Bruce C. Cozadd is a co-founder and has served as our Executive Chairman since 2003. 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.

Samuel R. Saks, M.D. is a co-founder and has served as our Chief Executive Officer since 2003. From 2001 until 2003, he was Company Group Chairman of ALZA Corporation and served as a member of the Johnson & Johnson Pharmaceutical Group Operating Committee. From 1992 until 2001, he held various positions with ALZA Corporation, most recently as its Chief Medical Officer and Group Vice President, where he was responsible for clinical and commercial activities. He serves on the boards of Cougar Biotechnology and Trubion Pharmaceuticals, biopharmaceutical companies. He received a B.S. and an M.D. from the University of Illinois.

Robert M. Myers is a co-founder and was appointed as our President in March 2007. 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 Corporation from 1992 to 2001, most recently as its Senior Vice President, Commercial Development. In this role, he was responsible for ALZA Corporation s corporate development, mergers and acquisitions, new product planning and corporate planning. He received B.S. and M.S. degrees from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

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 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.

Table of Contents

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 acting principal financial officer. 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.

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.

Table of Contents

Item 1A. Risk Factors

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

Risks Relating to Our Financial Condition

We have defaulted on our senior debt and our lenders have the right to accelerate our obligations at any time, which raises substantial doubt about our ability to continue as a going concern.

On December 31, 2008, we did not make the $4.5 million interest payment that was due to the holders of our $119.5 million principal amount of senior secured notes, or the Senior Notes. In early January, we received a notice of default on behalf of the holders of the Senior Notes. We are currently seeking a number of financing and strategic alternatives and are in discussions with our holders of the Senior Notes, including in particular LB I Group Inc., an affiliate of Lehman Brothers Holdings, Inc., which holds approximately 75% of the principal amount of the Senior Notes, with respect to our December 31, 2008 payment default and the status of the Senior Notes. There can be no assurance that we can reach such resolution, obtain sufficient financing or enter into other transactions to satisfy our Senior Note obligations in a timely manner, or at all.

At any time, the holders of 50% of more of the principal amount of the Senior Notes can accelerate our obligations under the Senior Notes and require payment of the full principal amount of the Senior Notes, plus interest and a prepayment penalty. We do not have sufficient cash resources to pay the amount that would become payable in the event of an acceleration of the Senior Notes, and even if we could obtain additional financing, it is unlikely that we could obtain an amount sufficient to repay the Senior Notes in full. Our independent registered public accounting firm has issued an opinion on our consolidated financial statements that states that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern.

The holders of the Senior Notes could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code, and in that event, it is unlikely that stockholders would receive any value for their shares.

The holders of the Senior Notes have a first priority security interest in all of our assets other than our inventory and accounts receivable and, in the event of an acceleration of our obligations and our failure to pay the amount that would then become due, the noteholders could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code.

In that event, we could seek to reorganize our business, or we or a trustee appointed by the court could be required to liquidate our assets. In either of these events, whether the stockholders receive any value for their shares is highly uncertain. If we needed to liquidate our assets, we might realize significantly less from them than the value that could be obtained in a transaction outside of a bankruptcy proceeding. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to secured and unsecured creditors, including the holders of the Senior Notes, before any funds would be available to pay our stockholders. If we were required to liquidate under the federal bankruptcy laws, it is unlikely that stockholders would receive any value for their shares.

Our operations have resulted in negative cash flows, we are seeking to raise additional funds to fund our operating expenses and debt obligations as soon as possible, which could cause us to have to accept terms that are harmful to our business, dilutive to our stockholders or otherwise disadvantageous to our existing stockholders, and if we are unable to secure additional funding, we may be required to significantly scale back our operations, significantly reduce our headcount, seek protection under the provisions of the U.S. Bankruptcy Code, and/or discontinue many of our activities which could negatively affect our business and prospects.

As of December 31, 2008, we had cash, cash equivalents and marketable securities of $25.9 million. While we believe that our current cash resources, together with anticipated revenues from product sales, would be sufficient to fund our operations, they are not sufficient to fund both our operations and any payment of interest or repayment of principal on the Senior Notes. In addition, we have based the estimate related to funding our operations on assumptions that may prove to be wrong, including assumptions with respect to the level of revenues from sales of Xyrem and Luvox CR, and we could exhaust our available financial resources sooner than we currently expect.

In light of the circumstances described above, including our default under our Senior Notes and discussions with the noteholders, we are seeking to raise funds as soon as possible. We may seek to raise additional funds through collaborations, partnering arrangements, development financings, or public or private debt or equity financings. It is likely that the consent of the holders of the Senior Notes would be required for some of these capital raising transactions. We cannot assure you that the Senior Note holders would consent to any transactions that we might propose. Because the holders of the Senior Notes currently have a first

23

Table of Contents

priority security interest in our assets, they may be unwilling to consent to any transaction that limits their rights or impacts the protection of their security interest. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing would likely be substantially dilutive to our stockholders, particularly given the prices at which our common stock has been recently trading. In addition, if we raise additional 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 would otherwise seek 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, particularly in light of the current illiquidity and instability in the global financial markets.

If we are unable to raise sufficient additional funds when needed, we would be required to further reduce operating expenses by, among other things, curtailing significantly or delaying or eliminating part or all of our development programs, including JZP-6, and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

We have reduced the net cash used in our operations by implementing three reductions in force in 2008 and focusing our efforts on our commercial products and JZP-6, and we are continuing to review our operations in order to identify additional measures to further reduce spending. 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 have taken and may take in the future may not be sufficient to enable us to meet our cash requirements or for us to reach profitability, and they may negatively affect our business and prospects.

We have a substantial amount of debt, on which we are in default, which may adversely affect our ability to operate our business.

There is currently outstanding $119.5 million principal amount of the Senior Notes on which we are in default.

Even if the holders of the Senior Notes do not accelerate our obligations under the Senior Notes, that debt, combined with our other financial obligations and contractual commitments, could have other important negative consequences. For example, it could:

- make us more vulnerable to adverse changes in general U.S. and worldwide economic, industry and competitive conditions and adverse changes in government regulation;
- 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 , and important corporate activities;
- 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 and execution of our business strategy.

Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects.

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

Even if we are able to resolve the default under our Senior Notes, our business may be subject to a number of limitations. The terms of our Senior Notes currently contain, and any future indebtedness would likely 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. Our existing debt

includes covenants, including requirements that we:

- generally not borrow additional amounts without the approval of our lenders;
- dispose of certain assets only in accordance with the terms of our existing senior secured debt;
- not impair our lenders security interests in our assets; and
- repay a portion of the debt early under certain circumstances.

In addition, under the existing terms of our Senior Notes, we expect that we will be required to maintain restricted cash balances equal to 15% of the then outstanding principal amount of Senior Notes after the quarter ending March 31, 2009, which we may not be able to do, particularly if we are unable to obtain sufficient additional funding. If we are not able to maintain any required restricted cash balance under the terms of the Senior Notes or to change the terms of the Senior Notes, the holders of the Senior Notes may exercise their rights and remedies under the notes, which may include the acceleration of the indebtedness.

Table of Contents

We have a history of net losses, which may continue for the next few years and, if we are to grow our business in the future, we will need to commit substantial resources, which could increase the extent of any future losses.

We have a limited operating history and have incurred significant net losses since our inception in 2003, and we may continue to incur net losses for the next few years. Our net loss for the twelve months ended December 31, 2008 was $184.3 million and we had an accumulated deficit of $500.8 million at December 31, 2008.

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 U.S.;
- revenues from current and potential future development and/or commercial collaboration partners;
- the results from our second Phase III pivotal clinical trial for JZP-6;
- 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;
- 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.

Risks Related to Our Business

We may not be able to successfully increase sales of Xyrem or Luvox CR in the U.S., which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

An increase in revenue from sales of our commercial products in 2009 is a critical part of our budget for 2009 and affects our negotiations with the holders of our Senior Notes and potential future sources of financing. We cannot assure you that Xyrem or Luvox CR prescriptions will increase at the level estimated in our budget, or at all. Sales and prescriptions of Xyrem increased in 2008; 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. Sales of and prescriptions for Luvox CR have been lower than anticipated since its launch. On February 5, 2009, we amended our Luvox CR license agreement with Solvay. Under the terms of the amendment, we are required to pay Solvay $6.0 million in 2009, $4.0 million in 2010, $4.5 in 2011 and other payments thereafter. If sales of Luvox CR do not increase, they may not cover these payments plus the cost to manufacture, market and sell the product and our Phase IV clinical trial commitment to the FDA. If sales of Xyrem and Luvox CR do not increase as expected, we may be required to further reduce our operating expenses, and our ability to raise additional funds would likely be adversely affected, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Table of Contents

Our only product candidate currently in Phase III clinical trials is JZP-6 for the treatment of fibromyalgia. The Phase III clinical trials may not show JZP-6 to be safe and effective for the treatment of fibromyalgia or the FDA or foreign regulatory authorities may not approve JZP-6 for marketing, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We are currently developing JZP-6 for the treatment of fibromyalgia. Our Phase III clinical program for JZP-6 includes two Phase III pivotal clinical trials, both of which must have statistically significant positive results before we can submit an NDA to the FDA seeking approval of JZP-6 for the treatment of fibromyalgia. Although we received favorable results from the first Phase III pivotal clinical trial in November 2008, these results may not be indicative of the clinical results from the second Phase III pivotal clinical trial. Our Phase III clinical program for JZP-6 is costly, and we do not expect to have preliminary results from our second Phase III pivotal clinical trial until mid-2009. We do not know if the second Phase III pivotal clinical trial will show JZP-6 to be safe and effective for the treatment of fibromyalgia, or if the FDA or other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia. Further, 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. An unsuccessful second Phase III pivotal clinical trial or a failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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.

There are currently no approved fibromyalgia treatments in the European Union. We cannot be sure that the EMEA will approve any treatment, or JZP-6 in particular, for fibromyalgia. For example, in October 2008 a panel of European regulators recommended against approving Cymbalta as a treatment for fibromyalgia.

Even if the FDA approves JZP-6 for the treatment of fibromyalgia, the FDA may require us to have a REMS similar to the one we use for Xyrem. Under the Xyrem REMS, Xyrem must be distributed through a single central pharmacy. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about 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 must verify the prescription and obtain additional information by contacting the patient s insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign 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.

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 may be approved for the treatment of fibromyalgia, which could limit potential sales of JZP-6.

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

Table of Contents

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 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 depend upon UCB to market and promote Xyrem outside the U.S., 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 U.S.

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the U.S. 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. If UCB terminates its relationship with us, we would need to find another party or parties to commercialize Xyrem in UCB s licensed territories. We may be unable to find another party or parties on acceptable terms, or at all, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. 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 that UCB has the right to market and promote Xyrem for patients with narcolepsy. We have relied in part on milestone payments from UCB to offset our development costs of JZP-6. 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 JZP-6 in UCB s territories and may need to execute alternative financing plans to help fund our development of JZP-6. We may be unable to do either of these on acceptable terms, or at all. There are currently no approved fibromyalgia treatments in the European Union. We cannot be sure that the EMEA will approve any treatment, or JZP-6 in particular, for fibromyalgia. For example, a panel of European regulators recently recommended against approving Cymbalta as a treatment for fibromyalgia.

We depend on one central pharmacy distributor for Xyrem sales in the U.S. 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 U.S. must be shipped directly to patients through a central pharmacy. The process under which patients receive Xyrem under our Xyrem REMS is cumbersome. While we have an agreement with the central pharmacy for Xyrem, 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. The 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, including 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 U.S.

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 and II controlled substances that may be produced in the U.S. 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. In cooperation with our manufacturing partners, we sought and received significant increases in their 2007 quotas from the DEA for sodium oxybate, Xyrem and JZP-6 to satisfy the forecasted demand for Xyrem and to conduct our clinical studies of JZP-6. We did not succeed in obtaining the entire quota we requested for 2007. The quota our suppliers received from the DEA for 2008 was greater than what was issued for 2007, but was less

27

Table of Contents

than what we requested for 2008. We believe, although we cannot assure you, that our quota for 2009 will be sufficient to meet our commercial, clinical and development needs. In the future and in cooperation with our procurement and manufacturing partners, we will continue to seek increased quotas to satisfy our clinical and commercial 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 or sodium oxybate 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 recent deterioration in worldwide economic conditions and the recent disruption to the credit and financial markets in the U.S. 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 is dependent 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 for the marketplace.

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.

Lonza is our sole supplier of sodium oxybate, the active pharmaceutical ingredient in Xyrem and, through Solvay, for fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR. We expect Lonza will continue to be our sole supplier of sodium oxybate and fluvoxamine maleate for the foreseeable future. We cannot assure you that Lonza can or will continue to supply, in the time we need, sufficient quantities of active pharmaceutical ingredient to enable Elan and Patheon to manufacture the quantities of Luvox CR and Xyrem, respectively, that we need.

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.

28

Table of Contents

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

Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects. For example, if Lonza is unable to timely provide fluvoxamine maleate in the quantities we need there could be an interruption in the supply of Luvox CR to the market. 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.

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;
- 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.

As an example, sales of Luvox CR have been significantly less than we had anticipated at the time of the acquisition of the rights to this product and prior to its launch in the first quarter of 2008.

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 have the anticipated revenues from that product candidate to fund our operations, and we will not receive any return on our investment in 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;

Table of Contents

- 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, policy and guidelines;
- varying interpretation of data by the FDA or foreign regulatory agencies; and
- insufficient funds to complete the trials.

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 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 U.S. 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 and because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Because sodium oxybate is a derivative of GHB, patients, physicians and regulators may view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of the 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.

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 U.S., 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 $20.0 million in civil and criminal payments is required to be paid in connection with this matter, of which $1.0 million was paid in July 2007, $2.0 million was paid in January 2008, and $2.5 million is due in October 2009; the remaining will be due over the next three 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.

Table of Contents

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 box warning regarding the risk of abuse. A box 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 box 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, the only other product approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, does not have a box warning and can be advertised with reminder ads. In addition, Xyrem s type of 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 was not approved under the FDA s Subpart H regulations and is not subject to the pre-review requirements. Accordingly, promotional materials for Provigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

Since 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 box warning. The FDA has approved products for the treatment of fibromyalgia. One of these products is not, and future competing products may not be, subject to this restriction, and the box 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, 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 (modafinil), the only other FDA-approved product for the treatment of excessive daytime sleepiness in patients with narcolepsy.

We are marketing Luvox CR in the U.S. for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors 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, including five selective serotonin reuptake inhibitors: Paxil, which is marketed by GlaxoSmithKline, Zoloft, which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly, Pexeva, which is a branded generic marketed by Noven Therapeutics and Luvox, which is not currently marketed. Anafranil, the sixth other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the U.S. Each of these products currently has 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, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended-release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR. Each of these products have generic competitors.

We are developing JZP-6 for the treatment of fibromyalgia. In June 2007, the FDA approved Lyrica, an anticonvulsant marketed by Pfizer for the treatment of partial seizures, post herpetic neuralgia and diabetic peripheral neuropathy, for the treatment of fibromyalgia. In June 2008, the FDA approved Cymbalta, a selective serotonin and norepinephrine reuptake inhibitor marketed by Eli Lilly for the treatment of major depressive disorder and generalized anxiety disorder, and diabetic peripheral neuropathic pain, for the treatment of fibromyalgia. In January 2009, the FDA approved Savella, a selective serotonin and norepinephrine reuptake inhibitor marketed by Forest Laboratories for the treatment of fibromyalgia. There are currently no other products approved by the FDA for the treatment of fibromyalgia. 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.

31

Table of Contents

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. In addition, we have undertaken several cost-cutting measures that may affect our ability to compete with other companies and due to our financial condition we may be required to take additional cost-cutting measures in the future.

Our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may. For example, other major pharmaceutical companies have completed or we believe are close to completing Phase III clinical trials of product candidates for the treatment of fibromyalgia, and these are large pharmaceutical companies with far greater resources than we have. Three of these product candidates have received FDA approval and have already reached the market. These treatments, as well as other product candidates that may reach the market before JZP-6, may be better accepted by physicians and patients. Thus, even if we successfully complete our Phase III pivotal clinical trials for JZP-6 for the treatment of fibromyalgia and achieve FDA approval, JZP-6 may not result in significant commercial revenues for us.

Our competitors 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 because there is no proprietary protection for some of our products or because our protection has expired or is not sufficiently broad. The FDA has granted orphan drug exclusivity for Xyrem until July 2009 for cataplexy in patients with narcolepsy, and until November 2012 for excessive daytime sleepiness in patients with narcolepsy. Once our orphan drug exclusivity periods for Xyrem expire, other companies could introduce generic equivalents of Xyrem if the generic equivalents do not infringe our existing patents covering Xyrem. Once our orphan drug exclusivity period for Xyrem for the treatment of cataplexy expires in July 2009, prescriptions for Xyrem for excessive daytime sleepiness in patients with narcolepsy, or if approved by the FDA, JZP-6, could possibly be filled with generic equivalents that have been approved for the treatment of cataplexy in patients with narcolepsy, even if the patient is diagnosed with excessive daytime sleepiness or fibromyalgia.

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. Although Xyrem is covered by patents expiring in 2019 and 2020 with claims covering the formula and process for manufacturing our commercial formulation of Xyrem and Luvox CR is covered by a patent covering the orally administered formulation of extended-release fluvoxamine, it is possible that other companies could manufacture generic equivalents of Xyrem and Luvox CR in ways that are not covered by the claims of these patents.

Part of our business strategy includes the ongoing development of proprietary product improvements to Xyrem, including new and enhanced dosage forms. However, we may not be successful in developing or obtaining FDA and other regulatory approvals of these improvements. Although the active pharmaceutical ingredient in Xyrem and JZP-6 is a DEA scheduled compound for which a quota is required and the FDA has required a REMS for its distribution, and therefore generic competition may be more difficult and expensive than it might be for other products not requiring a similar REMS for distribution, our competitors will not be prevented from introducing a generic equivalent. We have filed a patent application with claims covering the method for distributing sodium oxybate using a centralized distribution system, but we cannot assure you that this patent will issue or, if issued, whether it will provide any significant protection of Xyrem from generic competition.

Luvox CR is covered by a patent owned by Elan with claims covering the orally administered extended-release formulation of fluvoxamine. It is possible that other companies could manufacture similar or therapeutically equivalent products in ways that are not covered by the claims of the patent. There may be other patents that we are not aware of that cover some aspect of the Luvox CR formulation and that would prevent us from continuing to commercialize Luvox CR or that would require us to pay royalties or other forms of consideration.

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 U.S. allows for, and in a few instances in the absence of specific instructions from the prescribing physician mandates, the use of generic products rather than branded products where a generic equivalent is available. Generic competition for our products earlier than expected 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 or in-license additional products or product candidates to grow our business.

In order to grow our business, we will need to acquire or in-license additional products and product candidates that we believe have significant commercial potential. We do not believe we will be able to acquire or in-license additional products and product candidates until our financial condition improves. Any growth through acquisitions or in-licensing will be dependent upon the

Table of Contents

continued availability of suitable acquisition or in-license products and product candidates at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify products or product candidates suitable for potential acquisition or in-licensing, or we may not have the financial resources necessary to pursue such 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.

In November 2008, we reduced the size of our sales force as a result of the lower than expected demand for Luvox CR. Each of our remaining sales representatives is now responsible for a larger territory than he or she was responsible for prior to the reduction in force. We cannot predict if the smaller sales force will be effective at promoting our commercial products or if having a smaller sales force will negatively affect sales.

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 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. 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 negatively affect sales of our products. If we elect to rely on third parties to sell our products in the U.S., 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. 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. In December 2008, Matthew K. Fust, our Executive Vice President and Chief Financial Officer, left the company and we have not filled this position.

In June 2008, we reduced the number of non-sales employees in our company in connection with efforts to focus, in the near term, on our commercial products and later-stage product candidates. In November 2008, we significantly reduced the number of sales representatives. In December 2008, we further reduced the number of non-sales employees in our company. These reductions in force may negatively affect our ability to retain or attract talented employees. Competition for qualified personnel in the life sciences industry remains 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 current financial uncertainty adds to the risk of our loss of or our inability to recruit needed employees.

If we need to accelerate our activities or expand our business, and cannot recruit qualified employees when we need them, our key activities could be delayed. 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.

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.

33

Table of Contents

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 is dependent upon 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 U.S. 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. 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.

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 U.S. 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.

Table of Contents

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.

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;
- 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 U.S.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. 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 U.S. 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 U.S. and other countries, and regulations differ from country to country. Approval in the U.S., 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 products. We are not permitted to market our product candidates in the U.S. 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

Table of Contents

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.

Earlier 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. If the FDA were to miss a PDUFA deadline for one of our products, delaying the approval and launch, the delay could have a material adverse effect on our business.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

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 marketability of the product or otherwise reduce the size of the potential market for that product. Following any regulatory approval of our products, we will be subject to continuing 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, if the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with any of our products in the U.S. 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 and 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 and promotion. Our manufacturing partners are subject to 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.

Federal false claims laws prohibit 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.

Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. 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 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

Table of Contents

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 the reporting of gifts to individual physicians in the states. Other states require the posting of information relating to clinical studies. In addition, California requires pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for or payments to individual prescribers. 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 customer. The rebate amount also includes an inflation adjustment, if necessary.

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 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 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 Services pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The Public Health Services 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 Services, as well as hospitals that serve a disproportionate share of poor patients and children.

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 U.S., 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 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.

Table of Contents

There have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for some medical treatments or subject the pricing of drugs to government control. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides a new Medicare prescription drug benefit that became effective in January 2006, and mandates other reforms. Although we cannot predict the full effect on our business of the implementation of this new legislation, it is possible that the new benefit, which is managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues. Currently, there are legislative proposals that would permit the U.S. Secretary of Health and Human Services to negotiate directly with pharmaceutical companies to obtain lower prices for drugs covered under Medicare Part D.

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. During the recent presidential election campaign, the candidates discussed healthcare reform proposals which, if enacted, could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

Sales of our products in the U.S. may be adversely affected by consolidation among wholesale drug distributors and the growth of large retail drug store chains.

The market participants to whom we sell Luvox CR, and the market participants to whom we expect to sell most of our future products, have undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drugstore chains has decreased. In addition, excess inventory levels held by large distributors can lead to periodic and unanticipated reductions in our revenues and cash flows. Consolidation of drug wholesalers and retailers, as well as any increased pricing pressure that those entities face from their customers, including the U.S. government, may increase pricing pressure and place other competitive pressures on drug manufacturers, including us.

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 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 U.S. 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 U.S. 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 will permit pharmacists and wholesalers to import prescription drugs into the U.S. 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 U.S. to be imported or reimported to the U.S. from Canada, Europe and other countries. In addition, there have been indications that the new 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.

We licensed Xyrem to Valeant to distribute in Canada. Due to government price regulation in Canada, products are generally sold in Canada for lower prices than in the U.S. Due to the REMS for Xyrem and our agreement with Valeant, we believe that it is unlikely that Xyrem will be imported from Canada to the U.S. Luvox CR is not approved in Canada.

38

Table of Contents

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. Our products and product candidates are designed to affect important bodily functions and processes. Side effects of, or manufacturing defects in, the products sold by us could result in exacerbation of a patient s condition, further deterioration of a patient s condition 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 selective serotonin reuptake inhibitors, 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 selective serotonin reuptake inhibitor 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 selective serotonin reuptake inhibitors 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.

Risks Relating to Ownership of Our Common Stock

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

Our stock has 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. If we were to file for bankruptcy protection, it is likely that our common stock would have little or no value.

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.

Investors who purchase our common stock may not be able to sell their shares at or above the purchase price. The following factors, in addition to other risks described herein, may have a significant effect on our common stock market price:

- our financial situation, including our default under our senior notes;
- our ability or inability to raise additional capital in early 2009 and the terms on which we raise it;
- conditions or trends in the pharmaceutical industry, the credit and financial markets or the U.S. and worldwide economy in general;

the success of Luvox CR in the U.S.;

the success of our development efforts and clinical trials, including in particular with respect to JZP-6;

negative publicity concerning one of our products or product candidates;

announcement of FDA approval or non-approval of our product candidates, or specific label indications for their use, or delays in the FDA review process;

the failure or delay by the DEA in providing sufficient quotas for sodium oxybate, Xyrem or JZP-6;

Table of Contents

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;

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;

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.

Our common stock is currently at risk for delisting from The NASDAQ Global Market. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease, and our ability to obtain adequate financing for the continuation of our operations would be substantially impaired.

Our common stock is currently listed on The NASDAQ Global Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Global Market. These requirements include maintaining a minimum closing bid price of $1.00 per share, and the closing bid price of our common stock on March 20, 2009 was $0.91 per share. These requirements also include maintaining a minimum market value of publicly held shares, and, as of March 20, 2009, we did not meet this minimum requirement. Although NASDAQ has temporarily suspended the minimum closing bid price and minimum market value of publicly held shares requirements until July 20, 2009, there can be no assurance that we will meet these requirements after such date, and it is possible that NASDAQ may notify us prior to July 20, 2009 that we have failed to meet the minimum listing requirements that have not been suspended and initiate the delisting process. If our common stock is delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease, and our ability to obtain adequate financing for the continuation of our operations would be substantially impaired.

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 December 31, 2008, we had 28,925,117 shares of common stock outstanding, all of which shares, less shares subject to a repurchase option in our favor tied to the holders continued service to us (which will be eligible for sale upon lapse of the repurchase option), were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144.

As of March 20, 2009, the holders of up to approximately 19,306,128 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

Table of Contents

exercise of their registration rights, these sales may impair our ability to raise capital. On March 17, 2008, we entered into a registration rights agreement pursuant to which we agreed to file a registration statement covering the resale of the 562,192 shares underlying the warrants that we issued in connection with the expansion of our senior secured debt in March 2008. In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, 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. 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 requires that we use commercially reasonable efforts to ensure that the registration statement in connection with the CEFF remains effective for the term of such agreement. Kingsbridge will not be obligated to purchase shares of our common stock under the CEFF unless certain conditions are met. These conditions include a minimum trading price of $4.50 for our common stock, and our common stock has recently been trading well below that minimum.

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 March 20, 2009, our executive officers and directors, together with their respective affiliates, beneficially owned 63.3% of our capital stock, of which 6.4% was beneficially owned by our executive officers. Accordingly, our executive officers and directors together with their respective affiliates 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 this annual report on Form 10-K, 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, 2009. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we have hired and will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. 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.

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.

41

Table of Contents

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 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.

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

Our business requires significant funding, and we currently invest more in product development than we earn from sales of our products. In addition, the agreements governing our debt restrict our ability to pay dividends on our common stock. Therefore, 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. 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 August 2009 are approximately $816,000. We are currently negotiating an extension of our lease with the landlord.

Item 3. Legal Proceedings

From time to time we are involved in legal proceedings arising in the ordinary course of business. We currently have no ongoing litigation and are not aware of any pending litigation that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

Item 4. Submission of Matters to a Vote of Security Holders

None

Table of Contents

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 sales prices of our common stock, par value $.0001, on the Nasdaq Global Market under the symbol JAZZ from June 1, 2007 the day our common stock commenced trading, through December 31, 2008 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 - 2007		
Second Quarter (beginning June 1, 2007)	$ 18.00	$ 15.50
Third Quarter	$ 17.11	$ 11.20
Fourth Quarter	$ 17.14	$ 11.30

On March 20, 2009, the last reported sales price per share of our common stock was $0.91 per share.

Holders of Common Stock

As of March 20, 2009, there were 52 holders of record of our common stock.

Use of Proceeds from the Sale of Registered Securities

On May 31, 2007, our registration statement on Form S-1/A (Registration No. 333-141164) was declared effective by the SEC for our initial public offering, pursuant to which we registered 6,000,000 shares of common stock to be sold by us. The stock was offered at a public offering price of $18.00 per share. Our common stock commenced trading on June 1, 2007. The offering closed on June 6, 2007 after the sale of all securities registered, and we received net proceeds of $97.5 million after underwriters discounts of $7.6 million and other expenses of $2.9 million.

As of December 31, 2008, we have used all of the net proceeds from our initial public offering to fund the planned U.S. launch and commercialization of Luvox CR, to fund our Phase III pivotal clinical trials of JZP-6 and to fund development activities for our other product candidates. No payments were made to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers and to non-employee directors as compensation for their services.

Dividends

Under the terms of our senior secured note and warrant purchase agreement, 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.

Table of Contents

Performance Measurement Comparison(1)

The following graph shows the total stockholder return 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, 2008. 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 19 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.

Table of Contents

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, 2008, 2007 and 2006 and the consolidated balance sheet data as of December 31, 2008 and 2007 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, 2005 and 2004, and the selected consolidated balance sheet data as of December 31, 2006, 2005, and 2004 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2008(1)	2007(1)	2006(1)	2005(2)	2004
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net	$ 64,637	$ 53,536	$ 43,299	$ 18,796	$
Royalties, net	1,739	1,156	594	146	
Contract revenues	1,138	10,611	963	2,500	
Total revenues	67,514	65,303	44,856	21,442	
Operating expenses:					
Cost of product sales (excluding amortization and impairment of acquired developed technology)	13,924	8,903	6,968	4,292	
Research and development	69,963	69,792	54,956	45,783	17,988
Selling, general and administrative	111,401	78,540	51,384	23,551	7,459
Intangible asset amortization	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	237,879	204,081	122,908	99,886	25,447
Loss from operations	(170,365)	(138,778)	(78,052)	(78,444)	(25,447)
Interest income	1,834	5,942	2,307	1,318	643
Interest expense (including $15,082, $9,193, $9,024 and $4,595 for the years ended December 31, 2008, 2007, 2006 and 2005, respectively, pertaining to related parties)	(19,742)	(13,647)	(14,129)	(7,129)	
Other income (expense)	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	(184,339)	(138,826)	(59,391)	(85,156)	(24,804)
Beneficial conversion feature			(21,920)		
Loss attributable to common stockholders	$ (184,339)	$ (138,826)	$ (81,311)	$ (85,156)	$ (24,804)
Loss per share attributable to common stockholders, basic and diluted	$ (7.19)	$ (10.04)	$ (6,254.69)	$ (14,192.67)	$ (1,550.25)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	25,646	13,829	13	6	16

(1) Total operating expenses in 2008, 2007 and 2006 included employee stock-based compensation costs of $8.1 million, $6.1 million and $3.5 million, respectively, due to our adoption of Statement of Financial Accounting Standards No. 123(R), 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.

Table of Contents

(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,				
	2008	2007	2006	2005	2004
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 25,907	$ 102,945	$ 78,948	$ 20,614	$ 39,624
Working capital (deficit)	(129,492)	79,235	61,043	8,048	36,663
Total assets	117,498	207,554	214,571	164,781	42,850
Liability under government settlement	13,063	14,881			
Senior secured notes (including $95,548, $52,581, $51,998 and $50,620 as of December 31, 2008, 2007, 2006 and 2005, respectively, held by related parties)	118,534	75,116	74,283	73,629	
Convertible preferred stock			263,852	163,862	64,009
Common stock subject to repurchase	12,492	13,241	8,183	5,924	3,665
Accumulated deficit	(500,808)	(316,469)	(177,643)	(118,252)	(27,332)
Total stockholders equity (deficit)	(92,878)	54,992	(176,296)	(118,248)	(30,923)

Table of Contents

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and the 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. As discussed in Note 2 to the consolidated financial statements, our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. 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 focused on developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development, acquisition and in-licensing activities, and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and to compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products that generated net product sales of $59.5 million in 2008, one product candidate in late Phase III clinical trials 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 U.S. Food and Drug Administration, or 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 U.S. are affected by narcolepsy. We promote Xyrem in the U.S. 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 U.S. to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 13 countries. In 2008, our Xyrem net sales were $53.8 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 on February 28, 2008. We shipped initial stocking orders of Luvox CR to our wholesaler customers in March 2008 and began promoting the product 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. SSRIs are used in the treatment of depression, anxiety disorders and some personality disorders. 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 U.S., 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 U.S. from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the U.S. In 2008, our Luvox CR net sales were $5.7 million.

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, between two and four percent of the U.S. population suffers from fibromyalgia. The product is currently in Phase III clinical trials; the program includes two Phase III pivotal clinical trials and a long term safety trial. In November 2008, we announced positive preliminary top-line results from the first of the two Phase III pivotal clinical trials. The randomized, double-blind, placebo-controlled study achieved its primary endpoints, demonstrating that JZP-6 significantly decreased pain and fatigue, and improved daily function, in patients with fibromyalgia. We expect preliminary data from the second Phase III pivotal clinical trial, for which we have completed enrollment, in mid-2009. Subject to successful completion of the remaining Phase III pivotal clinical trial, we plan to submit a new drug application, or NDA, for JZP-6 in the

fourth quarter of 2009. If our NDA is approved by the FDA, we expect to market JZP-6 in the U.S. to specialists who treat fibromyalgia patients, through an expanded specialty sales force and/or in partnerships with third parties. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the U.S.

Our other product candidates in clinical development are 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 (sodium and calcium channel antagonist), 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 do not anticipate significant additional development progress on JZP-8, JZP-4 or JZP-7 unless or until we partner a program or otherwise obtain financing that we believe is sufficient to continue development.

Table of Contents

In late 2007 and early 2008, we incurred significant expenses in preparation for the launch of Luvox CR, including expenses in connection with an expansion of our sales force from 55 representatives to approximately 200 representatives, the manufacture of commercial launch quantities of Luvox CR and the preparation of Luvox CR marketing materials. Luvox CR was approved by the FDA in late February 2008 and was shipped to wholesalers in March 2008; our expanded sales force began promotion of Luvox CR in April 2008. To fund these activities and other aspects of our business, in March 2008 we issued an additional $40.0 million of senior secured notes by expanding our senior debt facility from $80.0 million to $120.0 million; in July 2008 we received net proceeds of approximately $24.5 million from a registered direct public offering of units consisting of common stock and warrants; and in August 2008 we sold our Antizol® and Antizol-Vet® products for cash proceeds of approximately $5.8 million.

Sales of Luvox CR in 2008 did not approach the levels that we had anticipated prior to commercial launch. Although Xyrem sales reached record levels in 2008, revenues from those sales, together with the lower than anticipated revenues from sales of Luvox CR and the proceeds that we received from the transactions described above, were not sufficient to support the operation of our business as we had planned. As a result, during the second half of 2008, we undertook efforts to significantly reduce our operating expenses. We focused our development efforts on JZP-6, our product candidate in Phase III clinical development, and slowed development work on most of our other projects. We completed three reductions in force, including one in November 2008 affecting approximately 67 employees, of which 62 were in our sales force, and one of similar size in December 2008, affecting our non-sales employees. On December 31, 2008, we did not make the $4.5 million interest payment that was due to the holders of our $119.5 million principal amount of senior secured notes, or the Senior Notes, and in early January, we received a notice of default on behalf of the holders of the Senior Notes.

We are currently operating the company in a manner that we believe maximizes the value of our business for our creditors and stockholders by focusing on selling and marketing Xyrem and Luvox CR, continuing our JZP-6 clinical program, with respect to which we expect to obtain the preliminary results of a second Phase III pivotal clinical trial in mid-2009, and looking for additional ways to reduce our operating expenses. We are also seeking to raise additional funds. If we are unable to raise sufficient additional funds when needed, we would be required to further reduce operating expenses by, among other things, curtailing significantly or delaying or eliminating part or all of our development programs, including JZP-6, and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

As of December 31, 2008, we had cash, cash equivalents and marketable securities of $25.9 million. While we believe that our current cash resources, together with anticipated revenues from product sales, would be sufficient to fund our operations, they are not sufficient to fund both our operations and any payment of interest or repayment of principal on the Senior Notes. In addition, we have based this estimate on assumptions that may prove to be wrong, including assumptions with respect to the level of revenues from product sales, and we could exhaust our available financial resources sooner than we currently expect. The sufficiency of our current cash resources, and our need for additional capital and the timing thereof, will depend on many factors, including primarily the amount of revenues that we receive from sales of Xyrem and Luvox CR, as well as other factors set forth in Item 1A of this Annual Report on Form 10-K under the heading *We have a history of net losses, which may continue for the next few years and, if we are to grow our business in the future, we will need to commit substantial resources which could increase the extent of any future losses*.

We are not able to predict the amount of revenues that we will receive from sales of Luvox CR in 2009. In early 2009, we renegotiated the payments that we owe to Solvay under the license agreement, as a result of which $6.0 million is payable to Solvay in 2009. We also have a commitment, in connection with the FDA s approval of Luvox CR, to conduct two Phase IV clinical trials of the product. We continue to monitor our sales of Luvox CR and our expenses to manufacture, market, sell and support the product, but the product may not become profitable within a commercially reasonable period, or at all. If necessary, we will decrease our efforts in support of the product.

We are currently seeking a number of financing and strategic alternatives and are in discussions with the holders of the Senior Notes, including in particular LB I Group Inc., an affiliate of Lehman Brothers Holdings, Inc., which holds approximately 75% of the principal amount of the Senior Notes, with respect to our December 31, 2008 payment default and the status of the Senior Notes. There can be no assurance that we can reach such resolution, obtain sufficient financing or enter into other transactions to satisfy our Senior Note obligations in a timely manner, or at all. At any time, the holders of 50% of more of the principal amount of the Senior Notes can accelerate our obligations under the Senior Notes and require payment of the full principal amount of the Senior Notes, plus interest and a prepayment penalty. We do not have sufficient cash resources to pay the amount that would become payable in the event of an acceleration of the Senior Notes, and even if we could obtain additional financing, it is unlikely that we could obtain an amount sufficient to repay the Senior Notes in full. The holders of the Senior Notes have a first priority security interest in all of our assets other than our inventory and accounts receivable and, in the event of an acceleration of our obligations and our failure to pay the amount that would then become due, the holders of the Senior Notes could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code.

48

Table of Contents

In the event that we were to seek protection under the provisions of the U.S. Bankruptcy Code, we could seek to reorganize our business, or we or a trustee appointed by the court could be required to liquidate our assets. In either of these events, whether the stockholders receive any value for their shares is highly uncertain. If we are required to liquidate our assets, we might realize significantly less from them than the value that could be obtained in a transaction outside of a bankruptcy proceeding. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to our secured and unsecured creditors, including the holders of the Senior Notes, before any funds would be available to pay our stockholders, and it is uncertain if there would be any amounts available for our stockholders. If we are required to liquidate under the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares.

In light of the circumstances described above, we are seeking to raise funds as soon as possible. We may seek to raise additional funds through public or private debt or equity financings, collaborations, partnering arrangements or development financings. It is likely that the consent of the holders of the Senior Notes would be required for some of these capital raising transactions. We cannot assure you that the Senior Note holders would consent to any transactions that we might propose. Because the holders of the Senior Notes currently have a first priority security interest in our assets, they may be unwilling to consent to any transaction that limits their rights or impacts the protection of their security interest. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing would likely be substantially dilutive to our stockholders, particularly in light of the prices at which our common stock has been recently trading. In addition, if we raise additional 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 would otherwise seek to develop or commercialize ourselves. The terms of any 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, particularly in light of the current illiquidity and instability in the global financial markets.

Our independent registered public accounting firm has issued an opinion on our consolidated financial statements that states that our recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. Our financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Revenues

Product Sales, Net

The following is a summary of our product sales, net for the last three fiscal years (in thousands):

	Year Ended December 31,		
	2008	**2007**	**2006**
Xyrem	$ 53,803	$ 39,018	$ 29,049
Luvox CR (1)	5,728		
Antizol (2)	5,106	14,153	12,813
Cystadane		365	1,437
Total	$ 64,637	$ 53,536	$ 43,299

(1) Includes sales of fluvoxamine maleate, the active pharmaceutical ingredient in Luvox CR, of $364,000 in 2008.

(2) Includes sales of Antizol-Vet, which were $163,000, $251,000 and $313,000 in 2008, 2007 and 2006, respectively.

Xyrem (sodium oxybate) oral solution. Revenues from sales of Xyrem primarily represent sales in the U.S. to Express Scripts Specialty Distribution Services, Inc., or Express Scripts. Revenues from sales of Xyrem under our agreements with UCB and Valeant have not been material. The FDA has granted Xyrem orphan drug exclusivity in the U.S. for both excessive daytime sleepiness and cataplexy in patients with

narcolepsy. This provides marketing exclusivity in the U.S. until July 2009 for the cataplexy indication and November 2012 for the excessive daytime sleepiness indication. In addition to orphan drug exclusivity, Xyrem is covered by two formulation patents that are listed in the FDA s approved drug products with therapeutic equivalence evaluation document, or Orange Book. The patents will expire in 2020. An additional process patent that covers the product is not listed in the Orange Book and expires in 2019.

Table of Contents

Luvox CR (fluvoxamine maleate) Extended-Release Capsules. Revenues from sales of Luvox CR primarily represent product dispensed through prescriptions in the U.S. Luvox CR has three years of marketing exclusivity beginning on February 28, 2008, the date the product was approved by the FDA. In addition, a patent covering the orally administered formulation of extended-release fluvoxamine, requiring the release of fluvoxamine over a period of not less than 12 hours, was issued to Elan. In the U.S., the patent expires in 2020.

Antizol (fomepizole). Revenues from sales of Antizol in the U.S. primarily represent sales to pharmaceutical wholesalers. Antizol is stocked by hospitals for use in emergency rooms. Our sales of Antizol to distributors outside of the U.S. have not been material. In December 2007, a generic fomepizole product was introduced. 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.

Cystadane (betaine anhydrous). Revenues from sales of Cystadane in the U.S. primarily represent sales to pharmaceutical wholesalers. 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.

Royalties, Net

We receive royalties primarily from international distributors of our products, typically based on their net sales of our products. Royalties, net was $1.7 million, $1.2 million and $594,000 in the years ended December 31, 2008, 2007 and 2006, respectively. Although we do not expect royalty revenues to comprise a substantial portion of our revenues in the near future, we expect royalty revenues to increase as sales of Xyrem by UCB increase.

Contract Revenues

Almost all of our contract revenues relate to upfront or milestone payments received from UCB. UCB made nonrefundable milestone payments to us of $500,000 in June 2006, $2.0 million in March 2007 and $7.5 million in September 2007. These payments were all recognized as revenue when the respective milestone was achieved. In July 2008, we received a payment of $10.0 million, which is nonrefundable. We expect to recognize the payment as revenue in mid-2009 when the last patient has completed or withdrawn from our second Phase III pivotal clinical trial of sodium oxybate for the treatment of fibromyalgia.

In connection with the expansion of our agreement with UCB in 2006, UCB made an upfront payment of $5.0 million and subsequently an additional payment of $10.0 million upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia. These payments are being recognized as revenue through 2019, the estimated performance period of the contract, which resulted in $1.1 million, $1.1 million and $463,000 of contract revenues during the years ended December 31, 2008, 2007 and 2006, respectively.

Significant Customers

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

	Year Ended December 31,		
	2008	2007	2006
Express Scripts	79%	59%	65%
UCB	*	18%	*
Cardinal Health	*	*	12%

* Less than 10% of our total revenues.

Research and Development Expenses

Conducting a significant amount of research and development has been central to our business model. Since our formation in 2003 through December 31, 2008, we incurred approximately $258.6 million in research and development expenses, of which $70.0 million was incurred in 2008. In the latter part of 2008, in order to preserve our cash resources, we significantly curtailed our investment in research and development programs other than JZP-6. We continue to spend significant amounts on Phase III clinical trials of our JZP-6 product candidate. Our ability to invest in research and development is dependent upon our obtaining additional cash resources.

Our research and development expenses consisted of expenses incurred in identifying, developing and testing our product candidates. These expenses consisted primarily of fees paid to contract research organizations and other third parties to assist us in managing, monitoring and analyzing 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

Table of Contents

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 in development.

We designate development projects to which we have allocated significant research and development resources with the term JZP and a unique number. Earlier-stage development and product lifecycle extension projects are included in Terminated and other projects in the following table. Early product concept feasibility studies and other research activities are included in R&D support in the following table. The expenditures summarized in the following table reflect costs directly attributable to each development candidate and to our Terminated and other projects. We do not allocate salaries, benefits or other indirect costs to our development candidates or Terminated and other projects, but include these costs in R&D support in the following table. The following table summarizes our research and development expenses for the years ended December 31, 2008, 2007 and 2006 and for JZP projects currently under development and Luvox CR from project inception through December 31, 2008 (in thousands):

	Project Inception to December 31, 2008	Year Ended December 31,		
		2008	2007	2006
JZP-6	$ 72,424	$ 33,758	$ 24,457	$ 14,209
JZP-4	22,121	2,164	9,040	6,699
Luvox CR (1)	9,676	1,242	8,434	
JZP-7	7,803	4,370	1,955	1,328
JZP-8	6,295	3,180	1,399	1,403
Terminated and other projects		4,416	2,349	17,562
R&D support		20,833	22,158	13,755
Total		$ 69,963	$ 69,792	$ 54,956

(1) Our research and development expenses for Luvox CR consisted primarily of expenses in connection with the scale-up for commercial manufacturing of Luvox CR, including the cost of inventory manufactured prior to FDA approval on February 28, 2008. Expenses subsequent to FDA approval were either expensed as part of cost of product sales as a period expense or capitalized in inventory. In 2007, expenses for Luvox CR also included a $2.0 million payment upon execution of a product license agreement.

The process of developing and obtaining FDA approval of products is costly and time consuming. Development activities and clinical trials can take years to complete, and failure can occur any time during the clinical trial process. Although we design our development programs to mitigate risk, the successful development of our product candidates is highly uncertain. Development timelines, probability of success and development costs vary widely among product candidates. As a result, we are unable to determine the time and completion costs related to the development of our product candidates or estimate when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates.

Table of Contents

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

Revenues from sales of Xyrem within the U.S. are recognized upon transfer of title, which occurs when Express Scripts removes product from our consigned inventory location at its facility for shipment to a patient.

Luvox CR was approved by the FDA for the treatment of obsessive compulsive disorder and social anxiety disorder and we shipped initial stocking orders to our wholesaler customers in the first quarter of 2008. We shipped and invoiced our wholesaler customers $8.4 million related to Luvox CR during 2008. Luvox CR is subject to rights of return six months prior to and up to twelve months after product expiration. During 2008, we could not reliably estimate expected returns of Luvox CR at the time of shipment and therefore recognized revenue when units were dispensed through prescriptions at which point the product is generally not subject to return. In order to estimate units dispensed, we purchased dispensing data from an independent prescription tracking service which we believed to be accurate and reliable and not subject to material adjustments. In 2008, we recorded revenue of $5.7 million related to Luvox CR, net of estimated wholesaler fees, discounts, chargebacks and rebates. As of December 31, 2008, we had recorded a deferred revenue liability related to shipments of Luvox CR of $944,000, which represents amounts paid by wholesaler customers in excess of revenue recognized, net of estimated wholesaler fees, discounts, chargebacks and certain rebates.

Revenues from sales of products within the U.S. are recorded net of estimated allowances for specialty distributor and wholesaler fees, prompt payment discounts, Medicaid rebates, government chargebacks and customer rebates. For Xyrem, due to the nature of the distribution system and our agreement with Express Scripts, and for Luvox CR, due to the way we recognized revenue in 2008, returns have been minimal. Calculating these items involves estimates and judgments based primarily on sales or invoice data and historical experience. Our allowances and adjustments to estimates for allowances have historically not been material.

Specialty Distributor and Wholesaler Fees. Express Scripts, our sole Xyrem distributor in the U.S., 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 our allowance related to these fees would generally increase in proportion to increases in sales. We recorded fees to Express Scripts of $2.3 million, $1.5 million and $1.4 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Our service agreements with certain U.S. wholesaler customers require us to pay them fees. Wholesaler fees totaled $198,000, $147,000 and $203,000 for the years ended December 31, 2008, 2007 and 2006, respectively. These fees are generally calculated as a percentage of product sales and consequently they vary as product sales vary. In addition, these fees may increase if we modify our agreements with wholesalers or enter into agreements with additional wholesalers.

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 take 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. We recorded prompt payment discounts of $1.4 million, $1.1 million and $880,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

Table of Contents

Medicaid Rebates. Our products are subject to state government-managed Medicaid programs under which rebates are provided 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 also examine the historical rebate trends and any expected changes to these trends. We adjust the accrual 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 allowance for Medicaid rebates for Xyrem and Luvox CR will have a material impact on their product sales, net. We recorded Medicaid rebates of $486,000, $263,000 and $229,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

Chargebacks. Our products are subject to certain programs with federal government entities under which pricing on our products is extended below U.S. wholesaler list price to participating entities. For Xyrem product sales, the lower vendor price is identified prior to our billing of Express Scripts. For Luvox CR product sales, these entities purchase our products through U.S. wholesalers at the lower vendor price, and the U.S. wholesalers charge the difference between their acquisition cost and the lower vendor price back to us. We account for chargebacks by establishing an accrual in an amount equal to our estimate of chargeback claims. We determine our estimate of the chargebacks primarily based on historical experience regarding chargebacks and current contract prices under the vendor programs. We consider vendor payments and our claim processing time lag and adjust the accrual throughout each period to reflect actual experience and any changes in business circumstances or trends. Due to estimates and assumptions inherent in determining the amount of chargebacks, the actual amount of claims for chargebacks may be slightly different from our estimates. Based on our experience with chargebacks, we do not believe that a material change to our estimated allowance for chargebacks is reasonably likely or will have a material impact on Xyrem and Luvox CR product sales, net. Chargebacks from U.S. wholesalers of $220,000, $285,000 and $212,000 were recorded for the years ended December 31, 2008, 2007 and 2006, respectively.

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 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 collection is reasonably assured. In situations where we have continuing performance obligations, nonrefundable fees are deferred and 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.

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, 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 U.S. UCB made nonrefundable milestone payments to us of $500,000 in June 2006, $2.0 million in March 2007 and $7.5 million in September 2007. These payments were all recognized as revenue when the respective milestone was achieved. UCB also made an upfront payment of $5.0 million upon execution of the amended agreement in June 2006 and an additional payment of $10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia. We recognized contract revenues of $1.1 million, $1.1 million and $463,000 during the years ended December 31, 2008, 2007 and 2006, respectively related to these two upfront payments. The remaining $12.5 million was recorded as deferred revenues as of December 31, 2008 and is being recognized ratably through 2019, 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.

We and UCB amended our agreement in July 2008. Under this amendment, UCB paid $10.0 million to us in July 2008 in lieu of a $7.5 million milestone payment which would have been due after the last patient completed or had withdrawn from our second Phase III pivotal clinical trial of JZP-6 for the treatment of fibromyalgia. Under the terms of the amendment, we are obligated to use commercially reasonable efforts to enroll at least 185 patients in the clinical trial from countries within the European Union, a

53

Table of Contents

milestone we achieved in December 2008. As of December 31, 2008, we deferred recognition of revenue related to the nonrefundable $10.0 million payment until the performance obligations under the original license and distribution agreement are met. We expect the last patient to have completed or withdrawn from our second Phase III pivotal clinical trial of JZP-6 for the treatment of fibromyalgia in the second quarter of 2009, at which point we expect to recognize the $10.0 million payment received as revenue.

The amended agreement requires UCB to make additional milestone payments of up to $131.0 million, of which up to $6.0 million relates specifically to Xyrem for the treatment of narcolepsy, up to $25.0 million relate to the development and approval of JZP-6 for the treatment of fibromyalgia and up to $100.0 million relate primarily to the commercialization of JZP-6 for the treatment of fibromyalgia as well as additional sales of Xyrem for the treatment of narcolepsy.

Goodwill and Intangible and Long-Lived 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 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 other intangible assets are consistent with underlying agreements, or the estimated lives of the products. 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.

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR in the U.S. The approval for marketing by the FDA and the subsequent launch of the product in the first quarter of 2008 triggered milestone payments due to Solvay of $41.0 million. At that time, we believed that we would receive substantially all of the benefits of our rights over a period of five years from the date the product was approved by the FDA, and therefore we selected five years as the estimated useful life of the asset. The assumptions and forecasts used to estimate these cash flows and the useful life are extremely subjective and require a high degree of judgment.

The method of amortization should reflect the pattern in which the economic benefits of the intangible asset are consumed. If that pattern cannot be reliably determined, a straight-line amortization method should be used. We do not believe we should pattern the amortization of the intangible asset using expected cash flows because they are inherently subjective and potentially unreliable and, in addition, cash flows are negative during the product launch period, which would result in periods where no amortization expense is recorded. We believe the rights we have purchased represent a consistent periodic economic benefit to us since we cannot use our right to sell Luvox CR more in one period than in any other and, accordingly, we are amortizing the asset on a straight-line basis.

As a result of lower sales of Luvox CR than we anticipated prior to launch, we evaluated the Luvox CR intangible asset for impairment in October 2008 and in December 2008. In our most recent analysis we determined that the remaining carrying value of the asset of $34.5 million exceeded the undiscounted future cash flows related to the product. As a result we estimated the fair value of the asset based on discounted cash flows to be $4.7 million and recorded an impairment charge of $29.8 million. In projecting future cash flows, the estimate that requires the most judgment relates to projected product net sales. We based our estimates of product net sales on the growth rate of the product in the latter part of 2008, among other factors. Selection of a risk appropriate discount rate also involves significant judgment particularly in the current financial environment, with the low availability and high cost of credit. We used a discount rate of 20% to estimate fair value, which is significantly higher than the discount rate we might have used in prior periods, due to the impact of the current financial crisis on the credit markets.

In December 2007, a generic fomepizole product 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. The fair value of

Table of Contents

this intangible asset was based on the discounted cash flows related to this intangible asset. The discounted cash flows were determined using the following key assumptions: (a) revised cash flow estimates and (b) a discount rate of 14%. The discount rate reflected our expectations of future cash flows related to Antizol and an appropriate risk premium.

As of December 31, 2008 we had recorded goodwill of $38.2 million and, subsequent to the Luvox CR impairment charge, intangible assets as follows:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Weighted Average Remaining Useful Life
		(In thousands)		(In years)
Developed technology Xyrem	$ 39,700	$ 14,670	$ 25,030	6.0
Developed technology Luvox CR	4,700		4,700	4.8
Agreements not to compete	3,900	2,743	1,157	1.5
Trademarks	2,600	961	1,639	6.0
Amortizable intangible assets	$ 50,900	$ 18,374	$ 32,526	

Inventory Reserves

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 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. 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 increase the reserve for excess inventory and record additional charges to cost of product sales.

Stock-Based Compensation

We account for stock-based compensation under the provisions of SFAS No. 123(R), *Share-Based Payment,* and have elected to use the Black-Scholes valuation model to calculate the fair value of stock options and are using the straight-line method to allocate compensation cost to reporting periods. During the years ended December 31, 2008, 2007 and 2006, the fair value of stock options granted was estimated using the Black-Scholes valuation model with the following assumptions:

	Year Ended December 31,		
	2008	2007	2006
Weighted-average volatility	60%	56%	61%
Weighted-average expected term (years)	6.1	6.1	6.0
Range of risk-free rates	2.7-3.4%	3.4-4.9%	4.6-5.1%
Expected dividend yield	0.0%	0.0%	0.0%

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 the year ended December 31, 2008, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 110 Share-Based Payment.

As there is limited trading history for our common stock, the expected stock price volatility for our common stock was estimated primarily by taking the median historic stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the specialty pharmaceutical industry similar in size, stage of life cycle and financial leverage. We placed some reliance on the volatility of our own stock based on its trading history since June 1, 2007. We did not rely on the implied volatilities of traded options in our industry peers common stock, because either the term of those traded options was much shorter than the expected term of our stock option grants, or the volume of activity was relatively low.

We will continue to analyze the historical stock price volatility and expected term assumptions as more historical data becomes available. 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 assumption was based on our history and expectation of dividend payouts.

Table of Contents

Prior to our initial public offering in June 2007, the fair value of our common stock, which is also an input to the Black-Scholes model, was determined by our board of directors with assistance from management. At two points in the year prior to our initial public offering the board of directors directed management to perform in-depth contemporaneous valuations of our common stock. Determining the fair value of the common stock of a private company involves a high degree of judgment and a number of different estimates.

The assumptions we used to estimate the fair value of grants under our employee stock purchase plan were similar to those used to estimate the fair value of stock option grants except that the expected term is based on the known expected term of the grants under the employee stock purchase plan and volatility is based on the implied volatility of our peer companies.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying 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 expenses 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, company personnel 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.

Table of Contents

Results of Operations

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%
Royalties, net	1,739	1,156	583	50
Contract revenues	1,138	10,611	(9,473)	(89)
Cost of product sales	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, net in 2008 as compared to 2007 was primarily due to increases of $14.8 million in Xyrem sales and the launch of Luvox CR, offset by a decrease of $9.0 million in Antizol sales as a result of the sale of our product rights in August 2008. Half the increase in Xyrem sales was due to an increase in volumes, with the remainder due to net sales price increases. Prior to the sale of our rights to Antizol in August 2008, revenues from the product had declined substantially as compared with the same period in 2007 due to competition from generic products after the expiration of Antizol s orphan drug exclusivity period.

Royalties, Net

The increase in royalties, net 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 the absence of milestones under our agreement with UCB in 2008.

Cost of Product Sales

The increase in cost of product sales in 2008 as 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 flat as compared to 2007.

Research and Development Expenses

Higher research and development expenses in 2008 as compared to 2007 resulted primarily from higher expenditures on JZP-6, partially offset by lower research and development expenditures on Luvox CR incurred in the two months prior to approval of the product by the FDA in February 2008 and, to a lesser extent, lower expenditures on JZP-4 due to the reduction in activities related to the project. Expenditures on JZP-6 are expected to comprise substantially all of our research and development expenses in 2009, unless or until we are able to partner programs or obtain other financing to fund our other programs. As a result, research and development expenses will likely be significantly lower in 2009 than

in 2008.

Selling, General and Administrative Expenses

The increase in selling, general and administrative expenses in 2008 as 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.

Table of Contents

These factors were partially offset by a decrease in legal fees associated with our response to the U.S. Attorney s investigation of activities by Orphan Medical related to the promotion of Xyrem after we reached an agreement to settle that matter in 2007.

We expect selling, general and administrative expenses to decrease significantly during 2009, primarily due to a reduction in the number of employees as a result of our three reductions in force and lower marketing expenses.

Intangible Asset Amortization

Our intangible assets consist primarily of developed technology, agreements not to compete and trademarks and are amortized on a straight-line basis over their estimated useful lives. Amortization costs in 2008 were higher, as compared to 2007, as a result of amortization of Luvox CR intangible assets beginning in March 2008. We expect amortization expense to decrease in 2009 due to lower amortization of the Luvox CR intangible asset due to the impairment charged recorded in 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 as compared to 2007 was primarily due to lower average cash balances in 2008 as compared to 2007.

Interest Expense

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

Other Income (Expense)

We recorded a benefit of $1.8 million in 2007 in other income (expense), net, 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.

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.

Table of Contents

Comparison of Years Ended December 31, 2007 and 2006

	2007	2006	Increase/ (Decrease)	Increase/ (Decrease)
		(In thousands)		
Product sales, net	$ 53,536	$ 43,299	$ 10,237	24%
Royalties, net	1,156	594	562	95
Contract revenues	10,611	963	9,648	1002
Cost of product sales	8,903	6,968	1,935	28
Research and development	69,792	54,956	14,836	27
Selling, general and administrative	78,540	51,384	27,156	53
Intangible asset amortization	9,217	9,600	(383)	(4)
Intangible asset impairment	20,160		20,160	N/A(1)
Provision for government settlement	17,469		17,469	N/A(1)
Interest income	5,942	2,307	3,635	158
Interest expense	13,647	14,129	(482)	(3)
Other income (expense)	1,797	(1,109)	2,906	N/A(1)
Gain on extinguishment of development financing obligation		31,592	(31,592)	N/A(1)
Gain on sale of product rights	5,860		5,860	N/A(1)

(1) No comparable data for prior period, or comparison to prior period is not meaningful.

Product Sales, Net

The increase in product sales, net in 2007 as compared to 2006 was primarily due to increases in Xyrem and Antizol sales which increased by $10.0 million and $1.3 million, respectively, offset by a decrease in Cystadane sales of $1.1 million. Most of the increase in Xyrem sales was due to an increase in volume of 20%, with the remainder due to net sales price increases. The increase in Antizol sales was primarily due to increases in the price we charged our wholesale customers for Antizol of 9.0% and 5.0% in August 2007 and November 2006, respectively. Sales of Cystadane decreased due to the sale of our rights to Cystadane in March 2007.

Royalties, Net

The increase in royalties, net in 2007 compared to 2006 was largely due to an increase in royalties on sales of Xyrem by UCB.

Contract Revenues

The increase in contract revenues in 2007 compared to 2006 was primarily due to a $7.5 million milestone payment from UCB triggered by enrollment of the 200th patient in the first phase III study in fibromyalgia in August 2007 and a $2.0 million milestone payment from UCB, triggered by regulatory approval of Xyrem in Europe for the treatment of narcolepsy with cataplexy in March 2007.

Cost of Product Sales

The increase in cost of product sales in 2007 as compared to 2006 was primarily due to the 24% increase in product sales, net, a charge of $485,000 recorded in December 2007 to write down Antizol inventory in excess of estimated requirements and an expense of $133,000 related to a failed production run of Antizol in 2007.

Research and Development Expenses

Higher research and development expenses in 2007 as compared to 2006 resulted from increased spending on development projects and increased headcount and related expenses. During 2007, a substantial portion of our research and development expenses were attributable to JZP-6, Luvox CR and JZP-4. Research and development expenses for Luvox CR included a $2.0 million payment

59

Table of Contents

to Solvay in January 2007 for the exclusive right to market and distribute Luvox CR in the U.S. under the terms of a product license agreement and $6.4 million of expenses in connection with the scale-up for commercial manufacturing, which includes $3.0 million for pre-launch inventory manufactured for, but in advance of, launch of the product. Research and development expenses in 2007 were partially offset by a benefit of $1.3 million as a result of a partial refund of a milestone payment we made to a third party related to a project that was terminated in 2005. During 2006, a substantial portion of our research and development expenses were attributable to a product candidate program that was terminated in 2006 and to JZP-6.

Selling, General and Administrative Expenses

The increase in selling, general and administrative expenses in 2007 as compared to 2006 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, primarily in preparation for the launch of Luvox CR;
- an increase in spending on activities related to supporting the sales force; and
- an increase in medical affairs expenses, primarily related to investigator initiated sponsored research.

These factors were partially offset by a decrease in legal fees associated with our response to the U.S. Attorney s investigation of activities by Orphan Medical related to the promotion of Xyrem.

Intangible Asset Amortization

Our intangible assets consist primarily of developed technology, agreements not to compete and trademarks, all of which were recorded as a result of the acquisition of Orphan Medical in June 2005, and are amortized on a straight-line basis over their estimated useful lives. Amortization costs in 2007 were lower, as compared to 2006, as a result of the sale of our rights to Cystadane in March 2007.

Intangible Asset Impairment

The intangible asset impairment charge recorded in 2007 resulted from the introduction of generic competition for Antizol.

Provision for Government Settlement

The charge in 2007 represents the then present value of payments we are obligated to make under a settlement with the U.S. government.

Interest Income

The increase in interest income in 2007 as compared to 2006 was primarily due to higher average cash balances as a result of our initial public offering in June 2007.

Interest Expense

Interest expense in both 2007 and 2006 related primarily to interest on our senior secured notes. Interest in 2006 was higher than in 2007 due to interest expense of $1.1 million related to the financing of a product candidate in development in 2006. In June 2006, following the analysis of the results of a Phase III clinical trial, we decided to discontinue development of the product candidate and therefore did not accrue interest related to this financing subsequent to May 31, 2006.

Other Income (Expense)

We recorded a benefit of $1.8 million in 2007 and a charge of $1.1 million in 2006, in other income (expense), net, to reflect changes in the fair value of the preferred stock warrant liability. In June 2007, upon completion of our initial public offering, the liability was reclassified to stockholders equity at its then fair value.

Gain on Extinguishment of Development Financing Obligation

In August 2005, we entered into an agreement with a third party under which the third party agreed to provide $30.0 million to fund a Phase III clinical trial of a product candidate then in development. We were obligated to repay the third party $37.5 million subject to, and conditioned upon, approval by the FDA to market the product in the U.S. In addition, we agreed to pay royalties at specified rates based on sales of the product within the U.S. Under that agreement, we received $15.0 million in 2005 and $15.0 million in 2006. In June 2006, following analysis of the results of the Phase III clinical trial, we notified the third party of our intention to discontinue development and not to seek product marketing approval from the FDA. As of the date we notified the third

Table of Contents

party of our intention to discontinue development, we had recorded $31.6 million for future possible payments as a liability on our balance sheet, of which $30.0 million related to principal and $1.6 million related to interest accrued using the effective interest method. As a result of our notification, and the subsequent formal termination of the contract in July 2006, we were not obligated to make any payments to the third party that otherwise would have been made upon regulatory approval, launch and commercialization, and we recorded a gain of $31.6 million in 2006 resulting from the extinguishment of liabilities related to this development financing.

Gain on Sale of Product Rights

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 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

Since our inception, we have incurred significant net losses and, as of December 31, 2008, we had cash, cash equivalents and marketable securities of $25.9 million (excluding restricted cash of $1.9 million).

We have reduced the net cash used in our operations by implementing three reductions in force in 2008 and focusing our efforts on our commercial products and JZP-6, and we are continuing to review our operations in order to identify additional measures to further reduce spending. In addition, we have negotiated changes in the terms of some of our liabilities. 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, which we expected would be met in April 2009 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 is payable 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 U.S. as of December 31, 2014. In the first quarter of 2009, we entered into arrangements with various government entities to postpone until October 2009 criminal and civil payments (totaling $2.5 million) that otherwise would have been due in January 2009.

On December 31, 2008, we did not make the $4.5 million interest payment that was due to the holders of the Senior Notes. In early January, we received a notice of default on behalf of the holders of the Senior Notes. We are currently seeking a number of financing and strategic alternatives and are in discussions with the holders of the Senior Notes, including in particular LB I Group Inc., an affiliate of Lehman Brothers Holdings, Inc., which holds approximately 75% of the principal amount of the Senior Notes, with respect to our December 31, 2008 payment default and the status of the Senior Notes. There can be no assurance that we can reach such resolution, obtain sufficient financing or enter into other transactions to satisfy our Senior Note obligations in a timely manner, or at all. At any time, the holders of 50% or more of the principal amount of the Senior Notes can accelerate our obligations under the Senior Notes and require payment of the full principal amount of the Senior Notes, plus interest and a prepayment penalty. We do not have sufficient cash resources to pay the amount that would become payable in the event of an acceleration of the Senior Notes, and even if we could obtain additional financing, it is unlikely that we could obtain an amount sufficient to repay the Senior Notes in full.

The holders of the Senior Notes have a first priority security interest in all of our assets other than our inventory and accounts receivable and, in the event of an acceleration of our obligations and our failure to pay the amount that would then become due, the holders of the Senior Notes could seek to foreclose on our assets, as a result of which we would likely need to seek protection under the provisions of the U.S. Bankruptcy Code.

In that event, we could seek to reorganize our business, or we or a trustee appointed by the court could be required to liquidate our assets, In either of these events, whether the stockholders receive any value for their shares is highly uncertain. If we needed to liquidate our assets, we might realize significantly less from them than the value that could be obtained in a transaction outside of a bankruptcy proceeding. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to secured and unsecured creditors, including the holders of the Senior Notes, before any funds would be available to pay our stockholders. If we are required to liquidate under the federal bankruptcy laws, it is unlikely that stockholders would receive any value for their shares.

While we believe that our current cash resources, together with anticipated revenues from product sales, would be sufficient to fund our operations, they are not sufficient to fund both our operations and any payment of interest or repayment of principal on the Senior Notes. In addition, we have based this estimate on assumptions that may prove to be wrong, including assumptions with respect to the level of revenues from sales of Xyrem and Luvox CR, and we could exhaust our available financial resources sooner than we currently expect. The sufficiency of

our current cash resources, and our need for additional capital and the timing thereof, will depend on many factors, including primarily the amount of revenues that we receive from sales of Xyrem and Luvox CR, as well as other factors set forth in Item 1A of this Annual Report on Form 10-K under the heading *We have a history of net losses, which may continue for the next few years and, if we are to grow our business in the future, we will need to commit substantial resources which could increase the extent of any future losses*.

Table of Contents

In light of the circumstances described above, including our default under our Senior Notes and discussions with the noteholders, we are seeking to raise funds as soon as possible. We may seek to raise additional funds through collaborations, partnering arrangements, development financings, or public or private debt or equity financings. It is likely that the consent of the holders of the Senior Notes would be required for some of these capital raising transactions. We cannot assure you that the Senior Note holders would consent to any transactions that we might propose. Because the holders of the Senior Notes currently have a first priority security interest in our assets, they may be unwilling to consent to any transaction that limits their rights or impacts the protection of their security interest. If we raise additional funds through the issuance of debt securities, these securities could have rights that are senior to holders of our common stock and could contain covenants that restrict our operations. Any additional equity financing would likely be substantially dilutive to our stockholders, particularly given the prices at which our common stock has been recently trading. In addition, if we raise additional 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 would otherwise seek 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, particularly in light of the current illiquidity and instability in the global financial markets.

If we are unable to raise sufficient additional funds when needed, we would be required to further reduce operating expenses by, among other things, curtailing significantly or delaying or eliminating part or all of our development programs, including JZP-6, and/or scaling back our commercial operations, or we may need to seek protection under the provisions of the U.S. Bankruptcy Code.

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

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Net cash used in operating activities	$ (130,232)	$ (81,091)	$ (57,350)
Net cash provided by (used in) investing activities	(11,942)	5,337	(1,507)
Net cash provided by financing activities	64,132	99,751	117,191
Net increase (decrease) in cash and cash equivalents	$ (78,042)	$ 23,997	$ 58,334

In each of 2008, 2007 and 2006, 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, plant and equipment, non-cash interest expense, stock-based compensation, and changes in working capital and the provision for the government liability. In 2008 and 2007, operating cash outflows included $2.0 million and $1.0 million, respectively, paid to the government as part of our settlement.

Net cash provided by or 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 cash restricted under our previous senior secured note agreement, 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 used in investing activities in 2006 primarily related to the purchase of property and equipment of $1.7 million.

Net cash provided by financing activities in 2008 related primarily to the sales of senior secured notes and warrants for net proceeds of $38.5 million and the issuance of common stock in a registered direct public offering of $24.5 million. 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. Net cash provided by financing activities in 2006 related primarily to issuances of preferred stock for net proceeds of $100.0 million and $15.0 million of funding under a development financing agreement.

Table of Contents

Solvay License Agreement and Amendments

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, which we expected would be met in April 2009 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 is payable 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 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the U.S. as of December 31, 2014.

Senior Secured Notes

On March 17, 2008, JPIC sold $40.0 million aggregate principal amount of our Senior Notes pursuant to a new debt arrangement. As part of the transaction, we issued to the purchasers of these notes warrants to purchase a total of 562,192 shares of our common stock exercisable at an exercise price of $14.23 per share at any time until March 17, 2013. We paid an arrangement fee of $800,000 to LB I Group Inc. and incurred other expenses of $634,000 in connection with the transaction. The notes generally bear interest at 15% per annum, payable quarterly in arrears, and are due on June 24, 2011. In addition, on March 17, 2008, a total of $80.0 million aggregate principal amount of senior secured notes of Orphan Medical were exchanged for the same principal amount of new senior secured notes issued by JPIC pursuant to the debt arrangement described above at the same interest rate. In these transactions, we guaranteed the repayment obligations of JPIC and granted the note holders a security interest in all of our assets and those of our wholly-owned subsidiaries. We also agreed to restrictions on working capital borrowings, dividends and certain other payments. Under the terms of the debt agreement, we may borrow from other sources up to $15.0 million secured by our accounts receivable and inventory. JPIC may be required to redeem up to $30.0 million of the outstanding principal amount of senior secured notes if our annualized net product sales are less than $100.0 million and a generic version of Xyrem has been approved in the U.S. To date, no generic version of Xyrem has been approved.

In August 2008, JPIC paid certain holders of the senior secured notes $504,000 aggregate principal amount plus accrued interest as their pro rata share of the proceeds from the JPIC s sale of its rights to Antizol and Antizol-Vet and the principal amount was reduced accordingly. Under the terms of the agreement with the senior secured note holders, JPIC is obligated to pay the holders of the senior secured notes the proceeds from any future sale of the JPIC s rights to Xyrem, Luvox CR and JZP-6, if the holders so elect.

JPIC may, at its option, prepay some or all of the notes subject to a prepayment premium. The prepayment premium on the first $40.0 million principal amount is 10% of the principal repaid. The prepayment premium on any additional principal prepayment was 16.6% of the principal prepayment at December 31, 2008, and reduces ratably to zero on June 24, 2011. As a result of the default under the terms of the notes, JPIC could be required to prepay some or all of the notes, including the prepayment premium and effective December 31, 2008, interest accrues on the principal amount of the notes at an annual rate of 17% instead of 15%. We are not currently required to maintain a restricted cash balance under this arrangement. However, under the terms of the loan agreement, we expect that JPIC will be required to maintain a restricted cash balance equal to 15% of the then outstanding principal amount of notes after the quarter ending March 31, 2009. JPIC is unlikely to be able to restrict this amount of cash, particularly if we are unable to obtain additional funding.

Line of Credit

In May 2008, we amended our existing line of credit so that we may borrow up to 75% of eligible accounts receivable, up to a maximum of $15.0 million in borrowings, subject to certain other limitations. As of December 31, 2008, we owed $3.9 million, the maximum amount available for borrowing at that time under the line of credit, all of which was repaid in January 2009 in the ordinary course of business. Under the credit agreement, a commitment fee of $75,000 will become payable in May 2009. In addition, a minimum monthly interest of $14,000 and a collateral monitoring fee up to 0.15% per month on the outstanding principal amount are payable under the line of credit. We are subject to certain financial and operating covenants under the credit agreement. Because of our default under the Senior Notes, the bank will currently not make advances to us. The line of credit is still outstanding and borrowings could re-commence upon agreement with the bank.

Committed Equity Financing Facility

On May 7, 2008, we entered into the CEFF with Kingsbridge pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to $75.0 million of our common stock over a three year period starting June 19, 2008, subject to early termination in certain circumstances. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase up to 220,000

63

Table of Contents

shares of our common stock with an exercise price of $11.20 per share. The warrant is exercisable for a period of five years beginning six months after the date of issuance. Under the CEFF, the maximum number of shares that we may sell to Kingsbridge is 4,922,064 shares (exclusive of the shares underlying the warrant issued to Kingsbridge). Subject to certain conditions and limitations, from time to time under the CEFF, we may require Kingsbridge to purchase shares of our common stock at a price that is between 90% and 94% of the volume weighted average price on each trading day during an eight day pricing period. The maximum number of shares we may require Kingsbridge to purchase in any pricing period is, the greater of (i) 1.5% of our market capitalization at the time of the commencement of the pricing period or (ii) the lesser of (A) 3.0% of our market capitalization at the time of the commencement of the pricing period or (B) a number of shares determined by a formula based in part on the average trading volume and trading price of our common stock prior to the date of the draw down notice issued by us with respect to that pricing period; provided, however, that the shares we can require Kingsbridge to purchase in any pricing period cannot exceed an aggregate purchase price of $25 million. If the average price of our common stock is lower than $4.50 or declines more than 10% from the closing price on the trading day immediately prior to the start of a pricing period, we cannot draw under the CEFF during that pricing period for so long as the price remains below either of these thresholds. We filed a registration statement which became effective as of June 19, 2008 with respect to the resale of shares issuable pursuant to the CEFF and underlying the warrant, and the registration rights agreement requires us to maintain the effectiveness of the registration statement for up to two years following the termination of the common stock purchase agreement. If we fail to maintain the effectiveness of the registration statement or if we suspend the use of the registration statement, under certain circumstances we may be required to pay certain amounts to Kingsbridge (or issue to Kingsbridge additional shares of common stock in lieu of cash payment) as liquidated damages. We are not obligated to sell any of the $75.0 million of common stock available under the CEFF and there are no minimum commitments or minimum use penalties. The CEFF does not contain any restrictions on our operating activities, automatic pricing resets or minimum market volume restrictions. We have not drawn down funds and have not issued shares of our common stock under the CEFF, and, for so long as the average price of our common stock remains lower than $4.50, which our common stock has recently been trading well below, we will not be able to sell shares under the CEFF. Accordingly, we do not expect to utilize this financing facility in the near term.

Registered Direct Public Offering

On July 21, 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 common stock at a public offering price of $6.75625 per unit for net proceeds of $24.5 million after deducting the placement agents fees and other estimated offering expenses payable by us. The warrants are exercisable for $7.37 per share of common stock at any time on or after January 21, 2009 and prior to July 21, 2014.

UCB Agreement Amendment

On July 23, 2008, we entered into an amendment to our license and distribution agreement with UCB. Under the terms of the original license and distribution agreement with UCB, UCB was required to pay $7.5 million to us within 30 days after the last patient completed or had withdrawn from our second Phase III trial of sodium oxybate for the treatment of fibromyalgia which is ongoing. Under the terms of the amendment, a $10.0 million payment was made to us in July 2008 in lieu of the $7.5 million payment. UCB was entitled to a credit of $2.5 million against future royalties otherwise due under our license and distribution agreement if we did not enroll at least 185 patients in the clinical trials within the European Union, a milestone we achieved in December 2008. In addition, under the terms of the amendment, the notice period for UCB s right to terminate the entire license and distribution agreement without cause was reduced from 18 months to 12 months, and a provision was added permitting UCB to terminate its rights to sodium oxybate for the fibromyalgia indication on six-months notice at any time prior to the receipt of marketing approval of sodium oxybate for fibromyalgia in the European Union.

Sale of Product Rights

In August 2008, we sold our rights to and interests in Antizol and Antizol-Vet for cash consideration of $5.5 million and we sold existing inventory, raw materials and work in process for cash consideration of $275,000. In connection with this transaction, we recognized a gain of $3.9 million.

Table of Contents

Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2008:

		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)	$ 123,977	$ 123,977	$	$	$
Liability under government settlement(3)	17,000	2,500	6,000	8,500	
Amounts due to Solvay (4)	14,000	14,000			
Line of credit	3,875	3,875			
Operating lease obligations (5)	3,366	1,820	1,545	1	
Purchase obligations (6)	6,339	6,339			
Total	$ 168,557	$ 152,511	$ 7,545	$ 8,501	$

(1) Milestone payments and royalty payments under our license and collaboration agreements that we cannot, as of December 31, 2008, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur are not included in the table above.

(2) We are currently in default under the terms of our notes. As a result, the commitments shown in the table above represent the full principal amount of $119.5 million, plus the interest payment of $4.5 million that was due on December 31, 2008, as currently payable. In addition to the amounts shown in the table above we may owe a prepayment penalty and, effective January 1, 2009, interest accrues on the notes at a default interest rate of 17% of the principal amount rather than the 15% regular interest rate

(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, $3.7 million plus interest payable under the civil settlement agreement described in Note 7 of the notes to our financial statements 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 have 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. These additional payments would be applied to the payment schedule under the civil settlement agreement in reverse chronological order so that the amounts otherwise payable in 2012 would be paid first, then the amounts otherwise payable in 2011 and continuing in reverse order. Payments due under the civil settlement agreement that could be accelerated under these provisions are as follows: $537,000 otherwise payable in October 2009, $645,000 otherwise payable in January 2010, $645,000 otherwise payable in January 2011, and $1.8 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, which we expected would be met in April 2009 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 is payable 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 million on or before December 31, 2014 and no AB-rated generic version of Luvox CR has been or is being sold in the U.S. as of December 31, 2014.

(5) Includes the minimum rental payments for our corporate office building and automobile lease payments for the sales force. In addition to the minimal rental payments on our office buildings 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. Does not include obligations under contracts with a contract research organization that are not cancellable without the payment of liquidated damages of $7.6 million.

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 initiation of a Phase II clinical program for JZP-4. Initiation of a Phase II program is subject to partnering or otherwise

Table of Contents

securing funding for this program. The agreement includes aggregate payments of $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 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.

Related Parties

Prior to the issuance of the new notes on March 17, 2008, as described in Liquidity and Capital Resources above, LB I Group, an entity affiliated with Lehman Brothers Holdings Inc., purchased certain senior notes and warrants then outstanding, including certain senior notes and warrants held by an affiliate of Kohlberg Kravis Roberts & Co. L.P., a significant stockholder. Subsequent to the issuance of the new notes, LB I Group held notes with an aggregate principal amount of $89.5 million, warrants to purchase 479,853 shares of common stock excisable at $20.36 per share and warrants to purchase 470,836 shares of common stock exercisable at $14.23 per share. We paid LB I Group an arrangement fee of $800,000 in connection with the issuance of the new notes.

In connection with the sale of our rights to Antizol and Antizol-Vet to an unrelated third party and pursuant to the terms of the senior secured notes, we paid $327,000 to an entity affiliated with Kohlberg Kravis Roberts & Co. L.P. as partial prepayment of the outstanding principal of the senior secured note held by it.

In the registered direct public offering we 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.

Recent Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations, or SFAS 141(R), and SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51, or SFAS 160. SFAS 141(R) requires an acquirer to measure the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at their fair values on the acquisition date, with goodwill being the excess value over the net identifiable assets acquired. SFAS 160 clarifies that a noncontrolling interest in a subsidiary should be reported as equity in the consolidated financial statements. The calculation of earnings per share will continue to be based on income amounts attributable to the parent. SFAS 141(R) and SFAS 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption is prohibited. The effect of the adoption of SFAS 141(R) will depend upon the nature of any future business combinations we undertake.

In December 2007, the FASB issued EITF 07-1, Accounting for Collaborative Agreements, or EITF 07-1. EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, which includes arrangements entered into regarding development and commercialization of products. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaborative relationship. EITF 07-1 is effective for us beginning January 1, 2009. We are currently evaluating the effect that the adoption of EITF 07-1 will have on our results of operations and financial position.

In February 2008, the FASB issued Staff Position, or FSP No. 157-2 which delays the effective date of SFAS 157 for one year for all nonfinancial assets and nonfinancial liabilities, except those recognized or disclosed at fair value in the financial statements on a recurring basis. FSP No. 157-2 is effective for us beginning January 1, 2009. We are currently evaluating the effect that the adoption of SFAS 157 for nonfinancial assets and nonfinancial liabilities will have on our results of operations and financial position.

In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-05, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock, or EITF 07-05. EITF 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity s own stock, which would qualify as a scope exception under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. EITF 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. We are currently evaluating the effect that the adoption of EITF 07-05 will have on our results of operations and 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.

Table of Contents

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 $26.7 million and $114.9 million as of December 31, 2008 and 2007, 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, 2008 and 2007 consisted primarily of obligations of U.S. government agencies, commercial paper and money market funds. The effect of a hypothetical change of ten percent in the average yield earned on our cash equivalents and short-term investments would have resulted in a change in our interest income of $183,000 for the year ended December 31, 2008. Since we typically invest in highly liquid, relatively low yield investments, we do not believe interest rate changes of greater than 10% would have a significant impact on us.

Our senior secured notes have fixed interest payments, and therefore our interest payments will not change if market interest rates change.

We have no operations outside the U.S., and almost all of our operating expenses and capital expenditures are denominated in U.S. dollars. Operating expense denominated in foreign currencies typically expose us to fluctuations in the 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 $230,000 for the year ended December 31, 2008.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and financial statement schedule as listed below are attached to this Annual Report on Form 10-K as pages F-1 through F-37.

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

Not applicable.

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 acting 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 acting principal financial officer concluded that, subject to the limitations described below, our disclosure controls and procedures were effective as of December 31, 2008.

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

Table of Contents

objectives of our disclosure control system are met and, as set forth above, our principal executive officer and acting 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 sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

No changes in our internal control over financial reporting occurred during our fiscal quarter ended December 31, 2008 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 Rules 13a-15(f)and 15d-15(f) under 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 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, 2008 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 the effectiveness of Jazz Pharmaceuticals internal controls over financial reporting pursuant to temporary rules of the Securities and Exchange Commission that permit Jazz Pharmaceuticals to provide only management s report in this annual report.

Item 9B. Other Information

By a unanimous written consent, effective March 25, 2009, the Board of Directors of Jazz Pharmaceuticals, Inc. (the Company) designated Joan Colligan as the Company s principal accounting officer and acting principal financial officer, effective immediately. Joan E. Colligan, age 58, has served as the Company s Controller since July 2004. 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.

Ms. Colligan s base salary in 2009 is $200,000. In January 2009, she was awarded 35,000 options with an exercise price of $1.25 which vest over the next three years. In 2008, Ms. Colligan s paid salary was $181,448 and she received a bonus in April 2008 related to her performance in 2007 of $20,631. In 2008, she was awarded 7,500 options with a fair value of $37,556. Ms. Colligan is also eligible to participate in the employee stock ownership plan.

Ms. Colligan s appointment as the Company s principal accounting officer and acting principal financial officer did not alter her existing compensatory arrangements with the Company, and no new plans, contracts or arrangements were entered into in connection with her appointment, nor were any grants or awards made to Ms. Colligan in connection with her appointment.

Table of Contents

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 2009 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 2009 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 2009 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 2009 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, acting 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 2009 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 2009 annual meeting of stockholders under the section entitled Security Ownership of Certain Beneficial Owners and Management and is incorporated herein by reference.

Table of Contents

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2008.

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	3,397,978	$ 16.32(1)	1,963,518(2)
2007 Employee Stock Purchase Plan			330,569(3)
2007 Non-Employee Directors Stock Option Plan	100,000	$ 10.30	121,052(4)
Equity compensation plans not approved by security holders:			
Directors Deferred Compensation Plan	42,688(5)		(6)
Total	3,540,666		2,415,139

(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 and rights under the 2007 Plan was $16.59 after excluding the grant of the restricted stock units.

(2) As of December 31, 2008, an aggregate of 5,515,731 shares of common stock were reserved for issuance under the 2007 Plan, of which 1,963,518 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, 2009, the number of shares reserved for issuance under the 2007 Plan increased by 1,301,630 shares pursuant to this automatic share increase provision.

(3) As of December 31, 2008, an aggregate of 700,000 shares of common stock were reserved for issuance under our 2007 Employee Stock Purchase Plan, or the 2007 ESPP, of which 330,569 remained available for future issuance under the 2007 ESPP with up to a maximum of 150,000 shares that could be purchased in the current purchase period. It is expected that the actual shares purchased in the current purchase period will be substantially less. 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, 2009, 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, 2008, an aggregate of 266,583 shares of common stock were reserved for issuance under our 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Plan, of which 121,052 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

Table of Contents

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, 2009, the number of shares reserved for issuance under the 2007 Directors Plan increased by 78,948 shares pursuant to this automatic share increase provision.

(5) Represents shares credited to individual non-employee director stock accounts as of December 31, 2008 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 2009 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 2009 annual meeting of stockholders under the section entitled Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm.

Table of Contents

PART IV

Item 15. Exhibits, 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. Index to Financial Statement Schedules:

See Index to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K. All other schedules are omitted because they are inapplicable or the requested information is shown in the consolidated financial statements of the registrant or related notes thereto.

3. 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.(6)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(3)
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.(4)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(12)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(13)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(5)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(12)
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.(12)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(12)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(12)
4.5D	Form of Common Stock Warrant of the Registrant.(12)
4.5E	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(12)

4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(13)
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
4.7	Form of Registered Direct Common Warrant.(15)
10.1+	Form of Indemnification Agreement between the Registrant and its officers and directors.(3)
10.2+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce C. Cozadd.(6)
10.3+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel R. Saks.(6)

Table of Contents

Exhibit Number	Description of Document
10.4+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert M. Myers.(6)
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew K. Fust.(6)
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol A. Gamble.(6)
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne L.T. Wissel.(6)
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.(6)
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert M. Myers.(6)
10.17+	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert M. Myers.(6)
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert M. Myers.(6)
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew K. Fust.(6)
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol A. Gamble.(6)
10.21+	2003 Equity Incentive Plan, as amended.(3)
10.22+	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.(3)
10.23+	2007 Equity Incentive Plan.(3)
10.24+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.(7)

Table of Contents

Exhibit Number	Description of Document
10.25+	2007 Non-Employee Directors Stock Option Plan.(3)
10.26+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.(3)
10.27+	2007 Employee Stock Purchase Plan.(3)
10.28+	Form of 2007 Employee Stock Purchase Plan Offering Document.(3)
10.29+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(6)
10.30	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.(8)
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(7)
10.32	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.(7)
10.33	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.(9)
10.34	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.35	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.36	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.41	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.(8)
10.42	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(8)
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.45	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc. and Elan Pharma International Limited.(9)
10.46	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(8)
10.47	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(9)
10.48	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(9)
10.49	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.(8)
10.50	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(8)

Table of Contents

Exhibit Number	Description of Document
10.51	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(9)
10.52	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.(9)
10.53	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.(9)
10.54	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.(7)
10.55+	Directors Deferred Compensation Plan.(3)
10.56+	Non-Employee Director Compensation Arrangements, as modified on August 14, 2008.(18)
10.57A	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.(10)
10.57B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and the Registrant.(10)
10.57C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.(10)
10.57D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and the Registrant.(10)
10.58+	Amended Executive Change in Control and Severance Benefit Plan.(1)
10.59+	Form of Amendment to Employment Agreement, by and between the Registrant and each of Bruce Cozadd, Samuel Saks, M.D., Robert Myers, Matthew Fust, Carol Gamble and Janne Wissel.(1)
10.60+	Form of Letter, amending outstanding options granted under the Registrant s 2003 Equity Incentive Plan.(1)
10.62+	Amendment No. 2 to Employment Agreement, effective on September 1, 2007, by and between the Registrant and Bruce C. Cozadd.(11)
10.63	Addendum No. 4 to Amended and Restated Master Services Agreement, dated as of July 6, 2007, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(11)
10.64+	Form of Restricted Stock Unit Award under the Registrant s 2007 Equity Incentive Plan.(11)
10.65+	Non-Employee Director Compensation Arrangements, as modified on December 18, 2007.(12)
10.66	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.(12)
10.67	Addendum No. 5 to Amended and Restated Master Services Agreement, dated as of October 5, 2007, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and Orphan Medical, Inc.(12)
10.68	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.(12)
10.69	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.(12)
10.70	Common Stock Purchase Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
10.71+	Amended Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(14)
10.72+	2008 Executive Officer Compensation Arrangements.(14)

Table of Contents

Exhibit Number	Description of Document
10.73+	Form of Stock Award Grant Notice and Stock Award Agreement under the Registrant s 2007 Equity Incentive Plan.(14)
10.74	Master Services Agreement dated May 6, 2008, by and between the Registrant and CuraScript, Inc.(14)
10.75	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.(16)
10.76	Antizol® Product Rights Acquisition Agreement, dated as of August 1, 2008, by and among the Registrant, JPI Commercial, LLC, Paladin Labs (Barbados) Inc., and Paladin Labs (USA) Inc.(17)
10.77	Amendment No. 2 to License Agreement, dated as of October 17, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(18)
10.78	Amendment No. 3 to License Agreement, dated as of December 19, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.
10.79	Amendment No. 4 to License Agreement, dated as of February 5, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.
10.80+	Directors Deferred Compensation Plan, as amended.
10.81+	Amended and Restated Executive Change in Control and Severance Benefit Plan.
10.82	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.
10.83	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.
10.84	Form of Registered Direct Subscription Agreement. (19)
12.1	Statement re: Computation of Ratio 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 in 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 Acting 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 Acting 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 requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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 the same numbered exhibit to 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 3.4 to the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(3) Incorporated herein by reference to the same numbered exhibit to 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 4.3 to 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.

Table of Contents

(5) 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.

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

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

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

(9) Incorporated herein by reference to the same numbered exhibit to the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.

(10) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K, filed with the SEC on July 18, 2007.

(11) Incorporated herein by reference to the same numbered exhibit to 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.

(12) Incorporated herein by reference to the same numbered exhibit to 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.

(13) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.

(14) Incorporated herein by reference to the same numbered exhibit to 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.

(15) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.

(16) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 24, 2008.

(17) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 6, 2008.

(18) Incorporated herein by reference to the same numbered exhibit to 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.

(19) Incorporated by reference to Exhibit 10.1 to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.

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

Table of Contents

SIGNATURES

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

Jazz Pharmaceuticals, Inc.
(Registrant)

Date: March 26, 2009

/s/ SAMUEL R. SAKS, M.D.
Samuel R. Saks, M.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Table of Contents

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Samuel R. Saks, M.D. and Carol A. Gamble, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his 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 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/ Samuel R. Saks, M.D. **Samuel R. Saks, M.D.**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 26, 2009
/s/ Joan E. Colligan **Joan E. Colligan**	Controller *(Principal Accounting Officer and Acting Principal Financial Officer)*	March 26, 2009
/s/ E. Alexander Albert **E. Alexander Albert**	Director	March 26, 2009
/s/ Samuel D. Colella **Samuel D. Colella**	Director	March 26, 2009
/s/ Bruce C. Cozadd **Bruce C. Cozadd**	Director	March 26, 2009
/s/ Bryan C. Cressey **Bryan C. Cressey**	Director	March 26, 2009
/s/ Michael W. Michelson **Michael W. Michelson**	Director	March 26, 2009
/s/ James C. Momtazee **James C. Momtazee**	Director	March 26, 2009
/s/ Kenneth W. O Keefe **Kenneth W. O Keefe**	Director	March 26, 2009

/s/ Alan M. Sebulsky **Alan M. Sebulsky**	Director	March 26, 2009
/s/ James B. Tananbaum, M.D. **James B. Tananbaum, M.D.**	Director	March 26, 2009
/s/ Nathaniel M. Zilkha **Nathaniel M. Zilkha**	Director	March 26, 2009

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Jazz Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals, Inc. as of December 31, 2008 and 2007, 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, 2008. Our audits also included the financial statement schedule listed in the Index at Item 8. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, 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.

As discussed in Note 2 to the consolidated financial statements, Jazz Pharmaceuticals Inc. s recurring losses from operations and net capital deficiency raise substantial doubt about its ability to continue as a going concern. Management s plans as to these matters also are described in Note 2. The 2008 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Palo Alto, California

March 26, 2009

Table of Contents

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,903	$ 102,945
Restricted cash	1,913	1,939
Marketable securities	1,004	
Accounts receivable, net of allowances of $176 and $218 at December 31, 2008 and 2007, respectively	6,643	5,389
Inventories	4,788	2,213
Prepaid expenses	2,366	3,224
Other current assets	2,382	381
Total current assets	43,999	116,091
Property and equipment, net	2,514	3,941
Intangible assets, net	32,526	36,040
Goodwill	38,213	38,213
Long-term restricted cash and investments		12,000
Other long-term assets	246	1,269
Total assets	$ 117,498	$ 207,554
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Line of credit	$ 3,875	$ 3,459
Senior secured notes (including $95,548 pertaining to related parties at December 31, 2008)	118,534	
Accounts payable	5,736	2,856
Accrued liabilities	19,024	29,047
Purchased product rights liability	14,000	
Deferred revenue	12,322	1,494
Total current liabilities	173,491	36,856
Non-current portion of deferred revenue	11,330	12,468
Liability under government settlement	13,063	14,881
Senior secured notes (including $52,581 pertaining to related parties at December 31, 2007)		75,116
Commitments and contingencies (Note 7)		
Common stock subject to repurchase	12,492	13,241
Stockholders equity (deficit):		
Preferred stock, $0.0001 par value; 20,000,000 shares authorized at December 31, 2008 and 2007; no shares issued and outstanding at December 31, 2008 and 2007, respectively		
Common stock, $0.0001 par value; 150,000,000 shares authorized at December 31, 2008 and 2007; 28,925,117 and 24,620,829 shares issued and outstanding at December 31, 2008 and 2007, respectively	3	2
Additional paid-in capital	407,923	371,440
Accumulated other comprehensive income	4	19
Accumulated deficit	(500,808)	(316,469)
Total stockholders equity (deficit)	(92,878)	54,992
Total liabilities and stockholders equity (deficit)	$ 117,498	$ 207,554

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

Table of Contents

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2008	2007	2006
Revenues:			
Product sales, net	$ 64,637	$ 53,536	$ 43,299
Royalties, net	1,739	1,156	594
Contract revenues	1,138	10,611	963
Total revenues	67,514	65,303	44,856
Operating expenses:			
Cost of product sales (excluding amortization and impairment of acquired developed technology)	13,924	8,903	6,968
Research and development	69,963	69,792	54,956
Selling, general and administrative	111,401	78,540	51,384
Intangible asset amortization	12,828	9,217	9,600
Intangible asset impairment	29,763	20,160	
Provision for government settlement		17,469	
Total operating expenses	237,879	204,081	122,908
Loss from operations	(170,365)	(138,778)	(78,052)
Interest income	1,834	5,942	2,307
Interest expense (including $15,082, $9,193 and $9,024 for the years ended December 31, 2008, 2007 and 2006, respectively, pertaining to related parties)	(19,742)	(13,647)	(14,129)
Other income (expense)	16	1,797	(1,109)
Gain on extinguishment of development financing obligation			31,592
Gain on sale of product rights	3,918	5,860	
Net loss	(184,339)	(138,826)	(59,391)
Beneficial conversion feature			(21,920)
Loss attributable to common stockholders	$ (184,339)	$ (138,826)	$ (81,311)
Loss per share attributable to common stockholders, basic and diluted	$ (7.19)	$ (10.04)	$ (6,254.69)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	25,646	13,829	13

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

Table of Contents

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF

STOCKHOLDERS EQUITY (DEFICIT)

(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Compre-hensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount				
Balance at January 1, 2006	617,974	$	$	$ 4	$ (118,252)	$ (118,248)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements			53			53
Vesting of common stock subject to repurchase			(2,226)			(2,226)
Issuance of Series B convertible preferred stock for cash						
Issuance of Series B Prime convertible preferred stock for cash						
Issuance of common stock for cash upon exercise of stock options	6,012		10			10
Stock-based compensation			3,498			3,498
Beneficial conversion feature - deemed dividend on issuance of Series B preferred stock			21,920			21,920
Beneficial conversion feature			(21,920)			(21,920)
Comprehensive loss:						
Net loss					(59,391)	(59,391)
Unrealized gain on available-for-sale securities				8		8
Comprehensive loss						(59,383)
Balance at December 31, 2006	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 upon initial public offering	17,921,551	2	259,646			259,648
Conversion of preferred stock warrant liability to equity upon initial public offering			6,675			6,675
Issuance of common stock for cash upon 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 upon 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

Table of Contents

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF

STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Compre - hensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount				
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 upon exercise of stock options for cash & 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 upon 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)

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

Table of Contents

JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2008	2007	2006
Operating activities			
Net loss	$ (184,339)	$ (138,826)	$ (59,391)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,198	1,309	710
Amortization of intangible assets	12,828	9,217	9,600
Intangible asset impairment	29,763	20,160	
Loss on disposal of property and equipment	968	6	481
Fair value adjustment to acquired finished goods		54	775
Non-cash interest expense	2,060	1,132	949
Revaluation of preferred stock warrant liability		(1,846)	1,092
Stock-based compensation expense	8,106	6,060	3,480
Interest on development financing			1,147
Gain on extinguishment of development financing			(31,592)
Gain on sale of product rights	(3,918)	(5,860)	
Changes in assets and liabilities:			
Accounts receivable	(1,254)	(250)	(1,783)
Inventories	(2,634)	459	(521)
Prepaid expenses and other current assets	691	329	(473)
Other assets	(80)	(14)	323
Accounts payable	2,880	(2,587)	657
Accrued liabilities	(5,373)	15,843	2,492
Deferred revenue	9,690	(955)	14,917
Deferred rent		(203)	(213)
Provision for government settlement	(1,818)	14,881	
Net cash used in operating activities	(130,232)	(81,091)	(57,350)
Investing activities			
Purchases of property and equipment	(1,739)	(3,149)	(1,682)
Proceeds from sale of property and equipment			150
Purchase of product rights	(27,000)		
Decrease (increase) in restricted cash and investments	12,026	(1,664)	25
Transfer of restricted cash to marketable securities	(4,440)		
Purchases of marketable securities		(10,848)	(1,705)
Proceeds from maturities of marketable securities	3,436	10,848	
Proceeds from maturites of long-term restricted cash equivalents			1,705
Proceeds from sale of product rights	5,775	10,150	
Net cash (used in) provided by investing activities	(11,942)	5,337	(1,507)
Financing activities			
Proceeds from issuances of convertible preferred stock, net of issuance costs			99,990
Proceeds from employee stock purchases and exercise of stock options	1,168	995	10
Proceeds from public offerings, net of issuance costs	24,514	97,488	
Proceeds from line of credit	416	1,268	2,191
Proceeds from sale of senior secured notes and warrants, net of issuance costs (including $32,146 from related parties)	38,538		
Repayment of senior secured notes (including $327 paid to related parties)	(504)		
Proceeds from development financing			15,000

Net cash provided by financing activities	64,132	99,751	117,191
Net (decrease) increase in cash and cash equivalents	(78,042)	23,997	58,334
Cash and cash equivalents, at beginning of period	102,945	78,948	20,614
Cash and cash equivalents, at end of period	$ 24,903	$ 102,945	$ 78,948
Supplemental disclosure of cash flow information:			
Cash paid for interest (including $9,804, $8,400 and $8,363 for the years ended December 31, 2008, 2007 and 2006, respectively, paid to related parties)	$ 12,802	$ 12,000	$ 12,000
Supplemental disclosure of non-cash investing and financing activities:			
Liability for purchase of product rights	$ 14,000	$	$
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	$	$
Warrants to purchase common stock issued in conjunction with equity financing facility	$ 850	$	$
Beneficial conversion feature - deemed dividend attributable to preferred stockholders	$	$	$ 21,920

The accompanying notes are an integral part of these financial statements

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

Jazz Pharmaceuticals, Inc. (the Company) was incorporated in California in March 2003 and reincorporated in Delaware in January 2004. The Company is a specialty pharmaceutical company focused on developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. The Company s goal is to build a broad portfolio of products through a combination of internal development, acquisition and in-licensing activities and utilization of its specialty sales force to promote its products in its target markets.

Since its inception in 2003, the Company has built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products, one product in late Phase III clinical trials 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.

Significant Risks and Uncertainties

The Company has incurred significant losses from operations since its inception and as of December 31, 2008, had cash, cash equivalents and marketable securities of $25.9 million.

In late 2007 and early 2008, the Company incurred significant expenses in preparation for the launch of Luvox CR®. Sales of Luvox CR in 2008 did not approach the levels that the Company had anticipated prior to its commercial launch. As a result, the Company s net cash inflows were not sufficient to support the operation of its business as the Company had planned. On December 31, 2008, the Company did not make the $4.5 million quarterly interest payment that was due to the holders of its $119.5 million principal amount of senior secured notes which constitutes an event of default under the Company s agreement with the senior secured noteholders and permits the holders of more than 50% of the principal amount outstanding to accelerate payment of the senior secured notes. As a result of the default, under the terms of the notes, the Company could be required to prepay some or all of the notes, including a prepayment premium. Accordingly, the notes and accrued but unpaid interest are now included in current liabilities. The Company is not currently required to maintain a restricted cash balance under the terms of the loan agreement. However, under the terms of the loan agreement, the Company expects that JPIC will be required to maintain a restricted cash balance equal to 15% of the then outstanding principal amount of notes after the quarter ending March 31, 2009. JPIC is unlikely to be able to restrict this amount of cash, particularly if it is unable to obtain additional funding. In addition, the Company is currently unable to borrow under its line of credit due to the default.

In an effort to reduce the net cash used in operations, the Company implemented three reductions in force during 2008, focused its development efforts on JZP-6 and slowed development work on most of its other projects. The Company is continuing to review its operations in order to identify additional measures to further reduce spending. The Company amended its agreement with Solvay Pharmaceuticals, Inc. (Solvay), from which it licensed Luvox CR, to eliminate its obligation to make royalty payments on net sales of Luvox CR and to extend the timeframe in which other obligations are due. The Company also entered into arrangements with various government entities to postpone until October 2009 criminal and civil payments (totaling $2.5 million) that otherwise would have been due in January 2009.

In light of the circumstances described above, the Company is currently seeking a number of financing and strategic alternatives with respect to all aspects of its business and is in discussions with the holders of the senior notes with respect to its December 31, 2008 payment default and the status of the senior notes.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

If the Company is unable to raise sufficient additional funds when needed, it would be required to further reduce operating expenses, by, among other things, curtailing significantly or delaying or eliminating part or all of its development programs including JZP-6 and/or scaling back its commercial operations, or the Company may need to seek protection under the provisions of the U.S. Bankruptcy Code. The Company may also be required to license to third parties products and product candidates that it would prefer to develop and commercialize itself or to sell the rights to one or more commercial products to third parties in either case on terms that may not be advantageous to the Company.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The 2008 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company s ability to continue as a going concern.

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 the Company to concentrations of credit risk consist of cash equivalents, restricted cash, marketable securities and accounts receivable. The Company s 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. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and marketable securities and issuers of investments to the extent recorded on the balance sheet.

The Company monitors its exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit to pharmaceutical companies, pharmaceutical wholesale distributors and a specialty pharmaceutical distribution company primarily in the U.S. in the normal course of business. Customer creditworthiness is monitored and collateral is not normally required. Historically, the Company has not experienced significant credit losses on its accounts receivable. The Company s five largest customers accounted for an aggregate of approximately 97%, 93% and 90% of gross accounts receivable as of December 31, 2008, 2007 and 2006, respectively.

Fair Value of Financial Instruments

Effective January 1, 2008, the Company adopted Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS 157), for financial assets and liabilities and any other assets and liabilities carried at fair value. SFAS 157 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.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Cash Equivalents, Restricted Cash and Marketable Securities

The Company considers 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 consists of cash equivalents, the use of which is restricted either by contract or agreement. At December 31, 2008, the Company held restricted cash consisting of a certificate of deposit in the amount of $1.1 million as a single entry import bond and a money market account in the amount of $775,000 as collateral securing a letter of credit.

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 classified as marketable 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 equity (deficit). The Company uses 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. The Company s 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 the Company s estimates of future demand for a particular product. If the estimate of future demand is too high, the Company may have to increase the reserve for excess inventory for that product and record a charge to cost of product sales. For products that have not been approved by the U.S. Food and Drug Administration (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, 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 the Company s operating lease or their economic useful lives. Maintenance and repairs are charged to operations as incurred.

Goodwill and Intangible and Long-Lived Assets

Goodwill

Goodwill represents the excess of the purchase price over the fair value of assets acquired and liabilities assumed. The Company has determined that it operates in a single segment and has 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.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. Once an intangible asset is fully amortized, the gross costs and accumulated amortization are removed from the consolidated balance sheet. The Company evaluates 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 impairment charges.

Preferred Stock Warrant Liability

Effective July 1, 2005, the Company adopted the provisions of Financial Accounting Standards Board (FASB) Staff Position (FSP) No. 150-5, Issuer s Accounting under Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares that are Redeemable (FSP No.150-5), an interpretation of FASB Statement No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. Pursuant to FSP No. 150-5, freestanding warrants for shares that are puttable, or warrants for shares that are redeemable are classified as liabilities on the consolidated balance sheet at fair value. At the end of each reporting period, changes in fair value during the period are recorded as other expense.

Upon adoption of FSP No.150-5, the Company reclassified the fair value of its warrants to purchase shares of convertible preferred stock from equity to a liability. There was no cumulative effect on adoption. The Company recorded a benefit of $1.8 million and a charge of $1.1 million in other income (expense), net, during the years ended December 31, 2007 and 2006, respectively, to reflect changes in the fair value of the warrants. On June 6, 2007, upon completion of the Company s initial public offering, the warrants became exercisable for common stock and the liability was reclassified to stockholders equity (deficit) at its then fair value.

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, the Company considers 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.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Product Sales, Net

Revenues from sales of Xyrem within the Unites States are recognized upon transfer of title, which occurs when the Company s specialty pharmaceutical distributor, Express Scripts Specialty Distribution Services, Inc., or Express Scripts, removes product from the Company s consigned inventory location at its facility for shipment to a patient. Prior to the Company s sale of the Company s rights to Antizol® (fomepizole), Antizol-Vet® in August 2008 and Cystadane® (betaine anhydrous) in March 2007, Antizol, Antizol-Vet and Cystadane were shipped to the Company s wholesaler customers in the U.S. with free on board destination shipping terms, and the Company recognized revenues when delivery occurred. The Company s international sales often have customer acceptance clauses and therefore the Company recognizes revenues when it is notified of acceptance or when the time to inspect and reject a shipment has lapsed. When sales to international customers do not have acceptance clauses, the Company recognizes revenues when title transfers, which is generally when the product leaves the Company s logistics provider s facilities.

Luvox CR was approved by the FDA for the treatment of obsessive compulsive disorder and social anxiety disorder and the Company shipped initial stocking orders to its wholesaler customers in the first quarter of 2008. Luvox CR is subject to rights of return six months prior to and up to twelve months after product expiration. During 2008, the Company could not reliably estimate expected returns of Luvox CR at the time of shipment and therefore recognized revenue when units were dispensed through prescriptions at which point the product is generally not subject to return. In order to estimate units dispensed, the Company purchased dispensing data from an independent prescription tracking service which the Company believed to be accurate and reliable and not subject to material adjustments. In 2008, the Company recorded revenue of $5.7 million related to Luvox CR, net of estimated wholesaler fees, discounts, chargebacks and rebates. As of December 31, 2008, the Company had recorded a deferred revenue liability related to shipments of Luvox CR of $944,000, which represents amounts paid by wholesaler customers in excess of revenue recognized, net of estimated wholesaler fees, discounts, chargebacks and certain rebates.

Revenues from sales of products within the Unites States are recorded net of estimated allowances for specialty distributor and wholesaler fees, prompt payment discounts, Medicaid rebates, government chargebacks and customer rebates. For Xyrem, due to the nature of the distribution system and the Company s agreement with Express Scripts, and for Luvox CR, due to the way the Company recognized revenue in 2008, returns have been minimal. Calculating these items involves estimates and judgments based on sales or invoice data and historical experience. The Company s allowances and adjustments to estimates for allowances have historically not been material.

Royalties, Net

The Company receives royalties from third parties based on sales of its products under licensing and distribution arrangements. For those arrangements where royalties are reasonably estimable, the Company recognizes 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 material.

Contract Revenues

Under the Company s contractual relationships, nonrefundable fees where the Company has no continuing performance obligations are recognized as revenues when collection is reasonably assured. In situations where the Company has continuing performance obligations, nonrefundable fees are deferred and are recognized ratably over the Company s projected performance period. The Company recognizes at-risk milestone payments, which are typically related to regulatory, commercial or other achievements by the Company or its 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 the Company s performance obligations are completed.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2008, the Company recorded charges to cost of product sales related to Luvox CR totaling $4.2 million, which was composed of a reserve for inventory it 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 developed technology of $11.5 million, $7.5 million and $7.9 million for the years ended December 31, 2008, 2007 and 2006, 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.

The Company relies on certain sole suppliers for drug substance and certain sole manufacturing partners for each of its marketed products and certain of its product candidates. The Company attempts 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 the Company s product candidates. These expenses consist primarily of fees paid to contract research organizations and other third parties to assist the Company in managing, monitoring and analyzing the Company s 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 the Company has licensed, allocated expenses, such as facilities and information technology that support the Company s research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under the Company s license agreements. For products 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

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses for the years ended December 31, 2008, 2007 and 2006 were $11.0 million, $7.3 million and $2.3 million, respectively.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Income Taxes

The Company utilizes 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 equity (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, 2008, 2007 and 2006, the difference between comprehensive loss and net loss represented net unrealized gains or losses on available-for-sale securities.

Loss Per Common Share

Basic and diluted 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 convertible preferred stock, stock options, common stock subject to repurchase and warrants were not included in the diluted loss per share attributable to common stockholders for all periods presented because the inclusion of such shares would have had an antidilutive effect.

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except per share data)		
Numerator:			
Loss attributable to common stockholders	$ (184,339)	$ (138,826)	$ (81,311)
Denominator:			
Weighted-average common shares outstanding	26,524	14,594	620
Less: weighted-average common shares outstanding subject to repurchase	(878)	(765)	(607)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	25,646	13,829	13
Loss per share attributable to common stockholders, basic and diluted	$ (7.19)	$ (10.04)	$ (6,254.69)

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Year Ended December 31,		
	2008	2007	2006
Series A convertible preferred stock (as if converted)			1,355
Series B convertible preferred stock (as if converted)			7,952
Series B Prime convertible preferred stock (as if converted)			8,614
Warrants to purchase Series BB convertible preferred stock (as if exercised and converted)			786
Warrants to purchase common stock (as if exercised)	2,144	489	
Options to purchase common stock	3,687	1,693	1,597
Common stock subject to repurchase	828	879	604
Common stock issuable under directors deferred compensation plan	43	17	
Restricted stock units	94		

Stock-Based Compensation

The Company accounts for compensation cost for all stock-based awards at fair value on date of grant and recognizes the cost over the service period for awards expected to vest. The fair value of restricted stock units is determined based on the number of shares granted and the quoted price of its common stock on the grant date. 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 the Company s 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. The Company primarily considers historical experience when estimating expected forfeitures.

Beneficial Conversion Feature Series B Preferred Stock and Series B Prime Preferred Stock

The Company accounts for potentially beneficial conversion features under Emerging Issue Task Force (EITF) Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios (EITF 98-5) and EITF Issue No. 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments. In January and December 2006, the Company issued 2,319,264 and 4,307,211 shares, respectively, of Series B preferred stock and Series B Prime preferred stock at a purchase price of $15.09 per share. At the time of each of these issuances, the value of the common stock into which the Series B preferred stock and Series B Prime preferred stock is convertible had a fair value greater than the proceeds for such issuances. Accordingly, the Company recorded a deemed dividend on the Series B preferred stock and Series B Prime preferred stock of $3.5 million in January 2006 and $18.4 million in December 2006, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series B preferred stock and Series B Prime preferred stock exceeded the proceeds from such issuances.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Recent Accounting Pronouncements

In December 2007, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 141(R), Business Combinations, (SFAS 141(R)) and SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51 (SFAS 160). SFAS 141(R) requires an acquirer to measure the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at their fair values on the acquisition date, with goodwill being the excess value over the net identifiable assets acquired. SFAS 160 clarifies that a noncontrolling interest in a subsidiary should be reported as equity in the consolidated financial statements. The calculation of earnings per share will continue to be based on income amounts attributable to the parent. SFAS 141(R) and SFAS 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption is prohibited. The effect of the adoption of SFAS 141(R) will depend upon the nature of any future business combinations that the Company undertakes.

In December 2007, the FASB issued EITF 07-1, Accounting for Collaborative Agreements (EITF 07-1). EITF 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, which includes arrangements entered into regarding development and commercialization of products. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaborative relationship. EITF 07-1 is effective for the Company beginning January 1, 2009. The Company is currently evaluating the effect that the adoption of EITF 07-1 will have on its results of operations and financial position.

In February 2008, the FASB FSP No. 157-2 which delays the effective date of SFAS No. 157, Fair Value Measurements, (SFAS 157) for one year for all nonfinancial assets and nonfinancial liabilities, except those recognized or disclosed at fair value in the financial statements on a recurring basis. FSP No. 157-2 is effective for the Company beginning January 1, 2009. The Company is currently evaluating the effect that the adoption of SFAS 157 for nonfinancial assets and nonfinancial liabilities will have on its results of operations and financial position.

In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-05, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock (EITF 07-05). EITF 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity s own stock, which would qualify as a scope exception under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. EITF 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The Company is currently evaluating the effect that the adoption of EITF 07-05 will have on its results of operations and financial position.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Cash, Cash Equivalents, Marketable Securities and Restricted Cash

Cash, cash equivalents, restricted cash and marketable securities, all of which are considered available-for-sale, consisted of the following as of December 31, 2008 and 2007 (in thousands):

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 1,161	$	$	$ 1,161
Obligations of U.S. government agencies	1,000	4		1,004
Other debt securities, primarily money market funds	25,655			25,655
Total	$ 27,816	$ 4	$	$ 27,820
Amounts classified as cash and cash equivalents				24,903
Amounts classified as marketable securities				1,004
Amounts classified as restricted cash				1,913
Total				$ 27,820

	December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 1,993	$	$	$ 1,993
Obligations of U.S. government agencies	81,419	21	(1)	81,439
Corporate debt securities	9,572		(1)	9,571
Other debt securities, primarily money market funds	23,881			23,881
Total	$ 116,865	$ 21	$ (2)	$ 116,884
Amounts classified as cash and cash equivalents				102,945
Amounts classified as restricted cash				1,939
Amounts classified as long-term restricted cash				12,000
Total				$ 116,884

All marketable securities held as of December 31, 2008 and 2007 had contractual maturities of less than one year.

Since inception, there have been no material realized gains or losses on cash equivalents or marketable securities. No marketable securities held as of December 31, 2008 or 2007 had been in a continuous unrealized loss position for more than 12 months. The cash equivalents and marketable securities held at December 31, 2008 had no unrealized losses. The aggregate fair value of cash equivalents and marketable securities held at December 31, 2007 which had unrealized losses was $10.4 million. The amount of the unrealized loss at December 31, 2007 was immaterial.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes, by major security type, the Company s cash, cash equivalents, restricted cash and marketable securities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	December 31, 2008			
	Cash	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Cash	$ 1,161	$	$	$ 1,161
Obligations of U.S. government agencies			1,004	1,004
Money market funds		25,655		25,655
Total	$ 1,161	$ 25,655	$ 1,004	$ 27,820

	December 31, 2007			
	Cash	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Cash	$ 1,993	$	$	$ 1,993
Obligations of U.S. government agencies			81,439	81,439
Corporate debt securities			9,571	9,571
Money market funds		23,881		23,881
Total	$ 1,993	$ 23,881	$ 91,010	$ 116,884

4. Certain Balance Sheet Items

Inventories consist of the following (in thousands):

	December 31,	
	2008	2007
Raw materials	$ 2,175	$ 500
Work in process	156	
Finished goods (1)	2,457	1,713
Total inventories	$ 4,788	$ 2,213

(1) Includes, at December 31, 2008, deferred cost of sales of $495,000 for which the related revenue has been deferred.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	December 31, 2008	2007
Leasehold improvements	$ 704	$ 977
Computer equipment	1,469	1,504
Computer software	3,607	2,517
Furniture and fixtures	586	208
Construction-in-progress	133	1,257
Total	6,499	6,463
Less accumulated depreciation and amortization	(3,985)	(2,522)
Property and equipment, net	$ 2,514	$ 3,941

Accrued liabilities consist of the following (in thousands):

	December 31, 2008	2007
Accrued research and development expense	$ 7,735	$ 12,663
Accrued personnel expense	4,445	6,480
Accrued selling, general and administrative expense	1,117	5,568
Liability under government settlement	2,533	1,969
Other	3,194	2,367
Total accrued liabilities	$ 19,024	$ 29,047

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Goodwill and Intangible Assets

The gross carrying amount of goodwill was $38.2 million as of December 31, 2008 and 2007. The gross carrying amounts and net book values of the intangible assets are as follows (in thousands):

	December 31, 2008			December 31, 2007		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology - Xyrem	$ 39,700	$ 14,670	$ 25,030	$ 39,700	$ 10,499	$ 29,201
Developed technology - Luvox CR	4,700		4,700			
Developed technology - Antizol				2,715		2,715
Agreements not to compete	3,900	2,743	1,157	5,600	3,389	2,211
Trademarks	2,600	961	1,639	2,600	687	1,913
Total	$ 50,900	$ 18,374	$ 32,526	$ 50,615	$ 14,575	$ 36,040

Future amortization costs per year for the Company s existing intangible assets other than goodwill as of December 31, 2008 are estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2009	$ 6,214
2010	5,812
2011	5,434
2012	5,434
2013	5,187

In December 2008, as a result of lower than anticipated sales of Luvox CR the Company 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 Luvox CR asset was expected revenues 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. The Company used a discount rate of 20% to estimate fair value.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December 2007, a generic product competitive to Antizol was introduced and, as a result, the Company 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 similar products. In August 2008, JPIC sold its rights to and interests in Antizol and Antizol-Vet, associated product registrations, commercial inventory and trademarks for cash consideration of $5.8 million and the Company recorded a gain of $3.9 million. As a result of the sale, the Company reduced the gross carrying amount and accumulated amortization of this intangible asset by $2.7 million and $792,000, respectively.

In March 2007, the Company sold its 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, the Company reduced the gross carrying amount and accumulated amortization of this intangible asset 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 senior secured notes. As part of the transaction, the Company issued to the purchasers of these notes warrants to purchase a total of 562,192 shares of its common stock exercisable at an exercise price of $14.23 per share at any time until March 17, 2013. 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 that bore interest at 15% per annum, due on June 24, 2011 were exchanged for the same principal amount of new senior secured notes issued by JPIC. The effective interest rate on JPIC senior secured notes newly issued and exchanged for Orphan Medical senior secured notes in March 2008 was 19.8% and 19.2%, respectively. In these transactions, the Company guaranteed the repayment obligations of JPIC and granted the noteholders a security interest in all of its assets and those of its wholly-owned subsidiaries. The Company also agreed to restrictions on working capital borrowings, dividends and certain other payments. Under the terms of the debt agreement, the Company may borrow from other sources up to $15.0 million secured by the Company s accounts receivable and inventory. JPIC may be required to redeem up to $30.0 million of the outstanding principal amount of senior secured notes if annualized net product sales are less than $100.0 million and a generic version of Xyrem has been approved in the U.S. To date, no generic version of Xyrem has been approved.

In August 2008, JPIC paid certain holders of the senior secured notes $504,000 aggregate principal amount plus accrued interest as their pro rata share of the proceeds from JPIC s sale of its rights to Antizol and Antizol-Vet. Under the terms of the agreement with the senior secured note holders, JPIC is obligated to pay the holders of the senior secured notes the proceeds from any future sale of JPIC s rights to Xyrem, Luvox CR and JZP-6, if the holders so elect.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On December 31, 2008, JPIC did not make the $4.5 million quarterly interest payment that was due to the holders of the $119.5 million principal amount of senior secured notes. The failure to make the interest payment constitutes an event of default under the loan agreement with the senior secured noteholders and permits LB I Group Inc., a related party, as the holders of more than 50% of the principal amount outstanding, to accelerate payment of the senior secured notes. On January 8, 2009, the Company received a notice of default from LB I Group Inc. but to date the Company has not received a notice of acceleration. As a result of the event of default, interest on the notes will accrue after December 31, 2008 on the outstanding principal amount at an annual rate of 17% instead of 15%. Interest will continue to accrue at this higher rate until the even of default is cured. If the Company were to receive a notice of acceleration, it would immediately owe the noteholders the $119.5 million principal amount on the notes, a prepayment premium and accrued but unpaid interest. The Company does not have sufficient cash to repay these amounts.

As of December 31, 2008, the carrying amount of the senior secured notes which includes accrued but unpaid interest of $4.5 million was reclassified to current liabilities and the related debt issuance costs of $1.8 million was reclassified from other assets to other current assets.

JPIC may, at its option, prepay some or all of the notes subject to a prepayment premium. The prepayment premium on the first $40.0 million principal amount is 10% of the principal repaid. The prepayment premium on any additional principal prepayment was 16.6% of the principal prepayment at December 31, 2008, and reduces ratably to zero on June 24, 2011. As a result of the default under the terms of the notes, JPIC could be required to prepay some or all of the notes, including the prepayment premium. JPIC is not currently required to maintain a restricted cash balance under this arrangement. However, under the terms of the loan agreement, the Company expects that JPIC will be required to maintain a restricted cash balance equal to 15% of the then outstanding principal amount of notes after the quarter ending March 31, 2009 unless the Company meets certain net sales targets. The Company does not expect to meet those sales targets.

In conjunction with the sale of the senior secured notes, the Company issued warrants and recorded at fair value as a discount to the notes. The fair value was estimated using the Black-Scholes option pricing model. The Company also incurred issuance costs, which were recorded in current assets as of December 31, 2008. The discount is scheduled to accrete to zero over the life of the notes and the issuance costs are being amortized over the life of the notes using the effective interest method. Information about the warrants and issuance costs associated with the $40.0 million aggregate principal amount notes issued in March 2008 is as follows:

Warrant information:		
Shares of common stock underlying warrant		562,192
Exercise price per share	$	14.23
Black-Scholes fair value (thousands)	$	2,000
Warrant expiration date		March 2013
Black-Scholes option pricing model valuation assumptions:		
Volatility		51%
Term		5.0 years
Risk-free rate		2.2%
Dividend yield		0.0%
Issuance costs allocated to notes (thousands)	$	562
Issuance costs allocated to warrants (thousands)	$	72
Arrangement fee paid to LB I Group Inc. (thousands)	$	800

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Line of Credit

In May 2008, the Company amended its existing line of credit so that the Company may borrow up to 75% of eligible accounts receivable up to a maximum of $15.0 million in borrowings subject to certain other limitations. Borrowings under the line of credit bear interest at a variable rate which varies with the bank s prime rate. As of December 31, 2008 and 2007, $3.9 million and $3.5 million, respectively, were outstanding under the line of credit. These amounts bore interest at 5.5% and 7.25% at December 31, 2008 and 2007, respectively. The amount outstanding as of December 31, 2008 was repaid in January 2009 in the ordinary course of business. Under the credit agreement, a commitment fee of $75,000 will become payable in May 2009. In addition, a minimum monthly interest of $14,000 and a collateral monitoring fee up to 0.15% per month on the outstanding principal amount are payable under the line of credit. The Company is subject to certain financial and operating covenants under the credit agreement. Because of the occurrence of a default under the senior secured notes, the bank currently will not make advances to the Company. The line is still outstanding and borrowings could re-commence upon agreement with the bank.

Development Financing Obligation

In July 2006, the Company recorded a gain of $31.6 million resulting from the extinguishment of liabilities that were repayable conditional upon the success of a product candidate in development. Prior to this extinguishment of liabilities, the Company had recorded interest of $1.1 million during the year ended December 31, 2006, using the effective interest method.

7. Commitments and Contingencies

Indemnification

In the normal course of business, the Company enters 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. The Company s exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against the Company. To date, the Company has 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.

The Company has agreed to indemnify its officers, directors, certain other employees and the officers and directors of Orphan Medical and JPIC 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 the Company could be required to make under this indemnification is unlimited; however, the Company maintains insurance policies that may limit its exposure and may enable it 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, the Company believes the fair value of these indemnification obligations is not material. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2008 and 2007. 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 the Company may incur substantial liabilities as a result of these indemnification obligations.

Lease and Other Commitments

In June 2004, the Company entered into a noncancelable operating lease for its corporate office building located in Palo Alto, California. In February 2008, the Company exercised its option to extend the lease for one year beginning August 31, 2008. The lease is renewable through 2017, at the Company s option. In addition to these lease payments, the Company is obligated to pay for operating expenses for the leased property. Effective January 31, 2009, the Company agreed to terminate its short-term sublease for space in another office building in Palo Alto, California. The Company is also obligated to make payments under noncancelable operating leases for automobiles used by its sales force. Rent expense under all operating leases was $5.2 million, $2.0 million and $1.3 million for the years ended December 31, 2008, 2007 and 2006, respectively.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Future minimum lease payments under the Company s noncancelable operating leases at December 31, 2008, were as follows (in thousands):

Year ending December 31,	Lease Payments
2009	$ 1,820
2010	1,139
2011	406
2012	1
Total	$ 3,366

The Company uses third party contract manufacturers to manufacture products. As of December 31, 2008 and 2007, the Company had $6.3 million and $7.0 million, respectively, of noncancelable purchase commitments under agreements with contract manufacturers due in 2009.

Legal Proceedings

In April 2006, the Company and Orphan Medical, received subpoenas from the U.S. Department of Justice, acting through the United States Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem (sodium oxybate). In July 2007, the Company and Orphan Medical entered into agreements with various parties to settle this matter. Pursuant to these agreements Orphan Medical agreed to make payments as follows: $1.0 million in 2007 (which was paid in July 2007); $2.0 million in 2008 (which was paid in January 2008); $2.5 million in 2009; $3.0 million in 2010; $3.0 million in 2011 and $8.5 million in 2012. See Note 18 for additional information regarding a modification of the timing of the amount due in 2009. The remaining amounts due under one of the agreements, which totaled $3.7 million as of December 31, 2008, could be accelerated if the Company is acquired, or in the event of an uncured default resulting from the failure to make payments when due. The amounts unpaid could also become due, in whole or in part, or accelerated if the Company has net income in any year. In the event of an uncured material breach or deliberate violation, as the case may be of the agreements the Company could be excluded from participation in Federal healthcare programs and/or subject to prosecution. The Company also entered into a five-year corporate integrity agreement.

The Company recorded a charge of $17.5 million during the year ended December 31, 2007, which represents the present value of the settlement payments discounted at an interest rate of 4.6%. As of December 31, 2008 and 2007, the non-current portion of this provision was $13.1 million and $14.9 million, respectively and the current portion, which is included in accrued liabilities, was $2.5 million and $2.0 million, respectively.

From time to time the Company is involved in legal proceedings arising in the ordinary course of business. The Company currently has no ongoing litigation and is not aware of any claims that could lead to litigation that could have, individually or in the aggregate, a material adverse effect on the Company s results of operations or financial condition.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. In-Licensing Agreements

In January 2007, the Company entered into a product license agreement with Solvay for the rights to market Luvox CR and Luvox in the U.S. The agreement was subsequently amended a number of times. Under the agreement, as amended, the Company made a payment of $2.0 million in January 2007 and agreed to make payments totaling $41.0 million upon approval by the FDA and commercial launch of Luvox CR of which $10.0 million was paid by the Company in each of March and April 2008 and $3.5 million was paid in each of October and November 2008. The remaining amount due of $14.0 million as of December 31, 2008 was recorded as a current liability. In addition, the Company was required to pay Solvay royalties on commercial sales at specified rates. See Note 18 for additional information regarding an amendment to the agreement with Solvay in February 2009.

In October 2004, the Company entered into an agreement with GlaxoSmithKline to purchase worldwide rights to the active pharmaceutical ingredient in JZP-4. The Company paid and recorded research and development expense of $2.0 million upon execution of the agreement and $3.0 million in July 2006 upon achievement of a development milestone. The Company also 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 is due to GlaxoSmithKline upon the enrollment of the first patient in a JZP-4 Phase II clinical trial.

In August 2007, $1.3 million was returned to the Company from a third party under a contract which had previously been terminated; this amount was recorded as an offset to research and development expense. In connection with its product development activities, the Company may enter into agreements with third party technology providers, patent holders and others. Patent licenses may require upfront payments, patent prosecution and maintenance fees and royalties on sales of products covered by the patents. Agreements with technology providers often provide for upfront payments and milestone payments based upon the achievement of specified development and commercial milestones and royalties based on sales of the products the Company develops with the technology provider.

9. Out-Licensing Agreements

In June 2006, the Company entered into an agreement with UCB Pharma Limited, (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 U.S. UCB made nonrefundable milestone payments to the Company of $500,000 in June 2006, $2.0 million in March 2007 and $7.5 million in September 2007. These payments were all recognized as revenue when the respective milestone was achieved. UCB also made an upfront payment of $5.0 million upon execution of the amended agreement in June 2006 and an additional payment of $10.0 million in August 2006 upon exercise of its rights to develop and commercialize JZP-6 for the treatment of fibromyalgia. The Company recognized contract revenues of $1.1 million, $1.1 million and $463,000 related to these upfront payments during the years ended December 31, 2008, 2007 and 2006, respectively. The remaining $12.5 million was recorded as deferred revenues as of December 31, 2008 and is being recognized ratably through 2019, the expected performance period under the agreement.

The Company and UCB amended their license and distribution agreement in July 2008. Under the terms of the amendment, UCB made a nonrefundable payment of $10.0 million to the Company in July 2008 in lieu of a $7.5 million milestone payment which would have otherwise been due after the last patient completed or withdrew from the second Phase III trial of sodium oxybate for the treatment of fibromyalgia. Under the terms of the amendment, the Company is obligated to use commercially reasonable efforts to enroll at least 185 patients in the clinical trial from countries within the European Union; enrollment of the required number of patients was achieved in December 2008. As of December 31, 2008, the Company had deferred recognition of revenue related to the nonrefundable $10.0 million payment until the performance obligations under the original license and distribution agreement are met.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Restructuring Expense

As part of a strategic decision to focus on the Company s commercial products and JZP-6 and lower operating expenses, the Company recorded restructuring charges of $3.5 million during 2008 of which $708,000 was recorded as part of research and development expense and the remainder included in selling, general and administrative expense.

The following table presents the restructuring activities during 2008 (in thousands):

	Charges Incurred	Payments/ Reductions	Balance at December 31, 2008
Accrued Restructuring			
Employee severance, health insurance premium and outplacement assistance	$ 2,126	$ (1,147)	$ 979
Auto lease termination	374		374
Excess facilities, property, plant and equipment	950	(830)	120
Total	$ 3,450	$ (1,977)	$ 1,473

11. Common Stock

Registered Direct Public Offering

On July 21, 2008, the Company 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 common stock at a public offering price of $6.75625 per unit. Net proceeds from this offering were $24.5 million after deducting the placement agents fees and other offering expenses payable by the Company. The warrants are exercisable for $7.37 per share of common stock at any time on or after January 21, 2009 and prior to July 21, 2014. The fair value of the warrants was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free rate of 3.62%, volatility of 58%, an expected term of 6.5 years and an expected dividend yield of 0%. The estimated fair value of the warrants of $6.4 million was recorded in stockholders equity (deficit).

Committed Equity Financing Facility

In May 2008, the Company entered into a committed equity financing facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), that entitles the Company to sell and obligates Kingsbridge to purchase up to the lesser of $75.0 million of the Company s common stock or 4,922,064 shares over a three-year period, subject to early termination in certain circumstances. The Company s ability to sell shares under the CEFF is subject to various limitations, one of which relates to the price of the Company s common stock. As a result, unless the price of the Company s common stock reaches and stays above $4.50 per share, the Company will not be able to utilize the CEFF. Since the Company s common stock has lately been trading at a price significantly lower than $4.50 per share, the Company does not expect to utilize this financing facility in the near term. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase up to 220,000 shares of the Company s common stock with an exercise price of $11.20 per share. The warrant, issued in May 2008, is exercisable for a period of five years from November 2008 through November 2013. The fair value of the warrant was estimated using the Black-Scholes option pricing model with the following assumptions: a risk free rate of 3.18%, volatility of 52%, an expected term of 5.5 years and an expected dividend yield of 0%. The estimated fair value of the warrant of $850,000 was recorded in stockholders equity (deficit).

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

During 2008, the Company issued 299,756 shares of its common stock for proceeds of $1.2 million under its employee stock purchase plan. The Company issued 27,868 shares of common stock as a result of stock option exercises for proceeds of $2,000 and the vesting of restricted stock units (RSUs) during the year ended December 31, 2008. In May 2008, the Company issued 125,532 shares of common stock with a fair value of $999,000 to employees under the Company s employee bonus plan.

Initial Public Offering

In June 2007, the Company completed its initial public offering of 6,000,000 shares of its common stock at a public offering price of $18.00 per share. Net cash proceeds from the initial public offering were $97.5 million, after deducting underwriting discounts and commissions and offering expenses. In connection with the closing of the initial public offering, all of the Company s shares of preferred stock outstanding at the time of the offering were converted into 17,921,551 shares of common stock, and all of the Company s warrants to purchase Series BB preferred stock outstanding at the time of the offering were converted into warrants to purchase 785,728 shares of common stock.

Common Stock Subject to Repurchase

In February 2004, each of the Company s then executive officers entered into an employment agreement with the Company which permitted the executive officer or the officer s estate to require the Company 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 the Company s 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 the Company s 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 the Company s initial public offering in 2007, 278,609 shares of preferred stock held by five of the Company s 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 common stock. As of December 31, 2008 and 2007, the Company had recorded $12.5 million and $13.2 million as common stock subject to repurchase, respectively, associated with 827,761 and 877,458 vested shares held by executive officers, respectively.

The Company has reserved the following shares of authorized but unissued common stock:

	As of December 31, 2008
2007 Equity Incentive Plan	5,361,731
2007 Employee Stock Purchase Plan	330,569
2007 Non-Employee Directors Stock Option Plan	263,740
Exercise of warrants	3,299,644
Total reserved shares of common stock	9,255,684

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Stock-Based Compensation

2007 Equity Incentive Plan

In May 2007, the Board of Directors adopted, and the Company s stockholders approved, the 2007 Equity Incentive Plan (2007 Plan), which provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of equity compensation to employees, including officers, non-employee directors and consultants. Most of the grants of restricted stock units, restricted stock awards and stock options under the 2007 Plan were granted to employees and vest ratably over service periods of four to five years and expire no more than ten years after the date of grant. The aggregate number of shares of the Company s common stock that may be issued pursuant to stock awards under the 2007 Plan as of December 31, 2008, is 5,515,731 shares. The number of shares of the Company s 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 the Company s common stock outstanding on December 31 of the preceding calendar year or (b) 3,000,000 shares. On January 1, 2009, shares reserved for issuance under the 2007 Plan increased by 1,301,630 shares pursuant to this automatic share increase provision.

2007 Employee Stock Purchase Plan

Effective upon the Company s initial public offering in June 2007, employees became eligible to participate in the 2007 Employee Stock Purchase Plan (ESPP). The ESPP allows eligible employee participants to purchase shares of the Company s 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. A total of 700,000 shares of the Company s common stock have been authorized for issuance under the ESPP. As of December 31, 2008, the aggregate number of shares of the Company s common stock available for issuance ESPP is 330,569 shares. 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 the Company s common stock outstanding on December 31 of the preceding calendar year or (b) 350,000 shares (or such lesser amount as may be approved by the Company s Board of Directors). On January 1, 2009, 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, the Company s board of directors adopted, and the Company s stockholders approved, the 2007 Non-Employee Directors Stock Option Plan (2007 Directors Option Plan). The 2007 Directors Option Plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to the Company s 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. As of December 31, 2008, the aggregate number of shares of the common stock that may be issued under the 2007 Directors Option Plan was 263,740 shares. The number of shares of common stock reserved for issuance automatically increases on January 1 of each year. On January 1, 2009, the number of shares reserved for issuance under the 2007 Directors Plan increased by 78,948 shares pursuant to this automatic share increase provision.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Directors Deferred Compensation Plan

In May 2007, the Company s board of directors adopted the Directors Deferred Compensation Plan (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. Any amounts deferred under the Directors Plan are credited to a phantom stock account. The number of phantom shares of the Company s common stock credited to each director s phantom stock account are based on the amount of the compensation deferred, divided by the market value of the Company s common stock on the date the retainer fees are deemed earned. Any distributions in shares of the Company s common stock will be paid with shares reserved under the 2007 Directors Option Plan. In August 2007, certain directors elected to defer receipt of their annual retainer fees to be paid in stock and the Company recorded phantom shares equivalent to 16,585 shares of the Company s common stock with a market value per share of $12.75. In March 2008, a director elected to defer receipt of his annual retainer fees to be paid in stock and the Company recorded phantom shares equivalent to 2,165 shares of the Company s common stock with a market value per share of $12.12. In August 2008, certain directors elected to defer receipt of their annual retainer fees to be paid in stock and the Company recorded phantom shares equivalent to 26,783 shares of the Company s common stock with a market value per share of $7.84. For the years ended December 31, 2008 and 2007, total compensation cost related to phantom shares of common stock granted under the Directors Plan was $236,000 and $211,000, respectively.

Stock Based Compensation

The Company has elected to use the Black-Scholes valuation model to calculate the fair value of stock options which were estimated at the grant date using the following assumptions:

	Year Ended December 31,		
	2008	2007	2006
Weighted-average volatility	60%	56%	61%
Weighted-average expected term (years)	6.1	6.1	6.0
Range of risk-free rates	2.7-3.4%	3.4-4.9%	4.6-5.1%
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, 2008, 2007 and 2006 was $4.82, $8.42 and $10.68, respectively.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for the Company s stock option grants. As a result, for stock option grants made during the year ended December 31, 2008, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 110, Share-Based Payment.

As there is limited trading history for the Company s common stock, the expected stock price volatility for the Company s common stock was estimated primarily by taking the median historic stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the specialty pharmaceutical industry similar in size, stage of life cycle and financial leverage. The Company placed some reliance on the volatility of the Company s stock based on its trading history since June 1, 2007. The Company did not rely on the implied volatilities of traded options in the Company s industry peers common stock, because either the term of those traded options was much shorter than the expected term of the Company s stock option grants, or the volume of activity was relatively low.

The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data becomes available. The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments whose term was consistent with the expected term of the Company s stock option grants. The expected dividend assumption was based on the Company s history and expectation of dividend payouts.

Prior to the Company s initial public offering in June 2007, the fair value of the Company s common stock, which is also an input to the Black-Scholes model, was determined by the Company s board of directors with assistance from management. At two points in the year prior to the Company s initial public offering the board of directors directed management to perform in-depth contemporaneous valuations of the Company s common stock. Determining the fair value of the common stock of a private company involves a high degree of judgment and a number of different estimates.

The fair value of awards under the ESPP was estimated at the grant date using the Black-Scholes valuation model with assumptions similar to those used for stock option grants, except that the expected term used ranged from 0.5 to 2.0 years, with a weighted-average expected term of 1.4 years and volatility is based on the implied volatility of the Company s peer companies. As of December 31, 2008, total compensation cost related to awards under the ESPP not yet recognized was $1.3 million, which is expected to be allocated to expense and production costs over a weighted-average period of 8 months.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years ended December 31,		
	2008	2007	2006
Selling, general and administrative	$ 5,712	$ 4,600	$ 2,811
Research and development	2,207	1,419	661
Cost of product sales	187	41	8
Total stock-based compensation expense	$ 8,106	$ 6,060	$ 3,480

No income tax benefit was recognized in the statement of operations for the years ended December 31, 2008, 2007 and 2006. Employee stock-based compensation costs of $31,000 and $43,000 as of December 31, 2008 and 2007, 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, 2008 was $9.6 million and the weighted-average period over which these grants are expected to vest is 2.8 years.

The following table summarizes activity under all of the Company s stock option plans as of December 31, 2008, and changes during the year then ended:

	Shares Subject to Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2008	3,379,940	$ 17.91		
Options granted	980,718	8.32		
Options exercised	(1,807)	1.11		
Options forfeited	(825,858)	13.06		
Options expired	(90,145)	15.79		
Outstanding at December 31, 2008	3,442,848	16.41	6.9	10
Vested and expected to vest at December 31, 2008	2,920,070	17.13	6.6	10
Exercisable at December 31, 2008	1,873,262	20.27	5.3	10

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 the Company s common stock for stock options that were in the money.

The aggregate intrinsic value of stock options exercised during 2008, 2007 and 2006 were $18,000, $16,000 and $90,000, respectively.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company has issued new shares of common stock upon all exercises of stock options to date and does not currently expect to repurchase shares of common stock in future years to reserve for issuance upon exercise of stock options.

Restricted Stock Units

In August 2007, under the 2007 Plan, the Company granted RSUs, equivalent to approximately 124,000 shares of common stock, to employees. The fair value of RSUs is determined on the date of grant based on the market price of the Company s common stock. The fair value of RSUs is recognized as expense ratably over the vesting period, generally four years. The weighted-average grant date fair value of RSUs granted during the years ended December 31, 2008 and 2007 was $6.75 and $13.25, respectively. No RSUs were granted prior to 2007.

As of December 31, 2008, the total remaining unrecognized compensation cost related to non-vested RSUs was $649,000 which is expected to be recognized over a weighted-average period of 2.6 years. The total fair value of shares vested during the year ended December 31, 2008 was $220,000. No RSUs vested prior to 2008.

A summary of RSU activity as of December 31, 2008, and changes during the year then ended are presented below:

	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, 2008	119,041	$ 13.25		
RSUs granted	1,874	6.75		
RSUs exercised	(26,296)	12.79		
RSUs forfeited	(39,489)	13.25		
RSUs expired				
Outstanding at December 31, 2008	55,130	13.25	1.6	106
Vested and expected to vest at December 31, 2008	34,158	13.25	1.5	66
Exercisable at December 31, 2008				

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Income Taxes

The Company has a history of losses and therefore has made no provision for income taxes. All of the Company s 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 the Company s deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2008	2007
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 132,990	$ 90,859
Federal and state tax credit carryforwards	14,182	11,299
Deferred contract revenues	8,958	5,405
Acquired capitalized research and development	2,700	3,409
Stock-based compensation	2,345	1,868
Inventory reserves	1,961	1,337
Luvox CR intangible asset	8,716	727
Other	4,137	4,728
Total deferred tax assets	175,989	119,632
Deferred tax liabilities:		
Acquired intangible assets	(11,242)	(13,953)
Valuation allowance	(164,747)	(105,679)
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 the Company s deferred tax assets are not recognizable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $59.1 million, $50.1 million and $19.9 million for the years ended December 31, 2008, 2007 and 2006, respectively.

At December 31, 2008, the Company had net operating loss carryforwards for federal income tax purposes of approximately $361.1 million which expire in the period from 2009 to 2028, and federal tax credits of approximately $14.8 million which expire in the period from 2009 to 2028. Approximately $3.7 million of federal net operating losses and $256,000 of federal tax credits expire in the next five years. The Company also has state net operating loss carryforwards of approximately $229.4 million which expire beginning in 2013 and state tax credits of approximately $4.5 million which have no expiration date. Utilization of the Company s net operating loss carryforwards and tax credit carryforwards are 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 the Company s acquisition of Orphan Medical triggered an ownership change, approximately $40.8 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 only available from 2019 to 2024.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company adopted Financial Accounting Standards Board Interpretation No. 48 *Accounting for Uncertainties in Income Taxes an interpretation of FASB Statement No. 109 (FIN 48)* effective January 1, 2007. FIN 48 requires that the Company 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. Upon adoption of FIN 48, the Company recognized a $1.5 million reduction in gross deferred tax assets, offset by an equal reduction in the deferred tax asset valuation allowance. As a result, no cumulative adjustment to the Company s accumulated deficit was required upon the Company s adoption of FIN 48. At December 31, 2008 and December 31, 2007, the Company had unrecognized tax benefis of approximately $4.0 million and $2.1 million, respectively. A reconciliation of the unrecognized tax benefits recorded for 2008 and 2007 follows (in thousands):

	2008	2007
Balance at the beginning of the year	$ 2,060	$ 1,500
Additions based on tax positions related to the current year	871	560
Additions (reductions) for tax positions of prior years	1,110	
Settlements		
Lapse of applicable statute of limitations	(31)	
Balance at the end of the year	$ 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 the Company s tax expense. The Company does 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 the Company s tax years remain open to federal and state tax examination. The Company files income tax returns in the U.S. and various states, which typically have three tax years open at any point in time.

14. Related Party Transactions

In June 2005, entities affiliated with Kohlberg Kravis Roberts & Co. L.P., (KKR), a significant stockholder, purchased $25.0 million aggregate principal amount of senior secured notes issued by Orphan Medical and warrants to purchase 245,540 shares of the Company s common stock exercisable at $20.36 per share through June 2012. In June 2005, LB I Group Inc., an entity affiliated with Lehman Brothers Holdings Inc., a significant stockholder, purchased $30.0 million aggregate principal amount of senior secured notes issued by Orphan Medical and warrants to purchase 294,648 shares of the Company s common stock exercisable at $20.36 per share through June 2012. In March 2008, LB I Group Inc. purchased $33.5 million aggregate principal amount of senior secured notes issued by JPIC and warrants to purchase 470,836 shares of the Company s common stock exercisable at $14.23 per share through March 2013. In March 2008, the Company paid LB I Group Inc. an arrangement fee of $800,000 in association with the sale of the notes and warrants.

In August 2008, in connection with the sale of the JPIC s rights to Antizol and Antizol-Vet pursuant to the terms of the JPIC senior secured notes, the Company paid $327,000 to an entity affiliated with KKR as partial prepayment of the outstanding principal of the senior secured note held by it.

In addition, during the three years ended December 31, 2008, LB I Group Inc. and entities affiliated with KKR purchased and sold the senior secured notes and warrants in agreements among themselves and other third parties to which the Company was not a party.

As of December 31, 2008, an entity affiliated with KKR held 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 and LB I Group Inc. held notes with an aggregate principal amount of $89.5 million, warrants to purchase 479,853 shares of common stock exercisable at $20.36 per share and warrants to purchase 470,836 shares of common stock exercisable at $14.23 per share.

As of December 31, 2007, an entity affiliated with KKR held notes with an aggregate principal amount of $25.0 million and warrants to purchase 245,540 shares of common stock exercisable at $20.36 per share and LB I Group Inc. held notes with an aggregate principal amount of $31.0 million, warrants to purchase 304,469 shares of common stock exercisable at $20.36 per share.

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Cash paid for interest with respect to notes held by entities affiliated with KKR during the years ended December 31, 2008, 2007 and 2006 was $796,000, $4.1 million and $4.0 million, respectively, and cash paid for interest with respect to notes held by LB I Group during the years ended December 31, 2008, 2007 and 2006 was $9.0 million, $5.1 million and $5.0 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 the Company s existing stockholders with which certain members of its 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.

15. 401(k) Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. While the Company may elect to match employee contributions, no such matching contributions have been made through December 31, 2008.

16. Segment and Other Information

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

The following is a summary of the Company s product sales, net for the last three fiscal years (in thousands):

	Year Ended December 31,		
	2008	2007	2006
Xyrem	$ 53,803	$ 39,018	$ 29,049
Luvox CR (1)	5,728		
Antizol (2)	5,106	14,153	12,813
Cystadane (3)		365	1,437
Total	$ 64,637	$ 53,536	$ 43,299

(1) Includes sales of the active pharmaceutical ingredient in Luvox CR of $364,000 in 2008.

(2) Includes sales of Antizol-Vet, which were $163,000, $251,000 and $313,000 in 2008, 2007 and 2006, respectively. JPIC sold its rights to and interests in Antizol and Antizol-Vet in August 2008.

(3) The Company sold its 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,		
	2008	2007	2006
United States	$ 62,894	$ 53,132	$ 42,326

Europe	2,860	11,856	1,757
All other	1,760	315	773
Total	$ 67,514	$ 65,303	$ 44,856

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table presents a summary of revenues from significant customers as a percentage of the Company s total revenues:

	Year Ended December 31,		
	2008	2007	2006
Express Scripts	79%	59%	65%
UCB	*	18%	*
Cardinal Health	*	*	12%

* Less than 10% of the Company s total revenues.

17. Quarterly Financial Data (Unaudited)

The following interim financial information presents the 2008 and 2007 results of operations on a quarterly basis (in thousands, except per share amounts):

	2008			
	March 31	June 30	September 30	December 31
Revenues	$ 14,634	$ 15,539	$ 17,746	$ 19,595
Operating loss	(43,808)	(47,094)	(27,744)	(51,719)
Net loss and loss attributable to common stockholders	(46,710)	(51,880)	(28,809)	(56,940)
Loss per share attributable to common stockholders, basic and diluted	(1.97)	(2.17)	(1.07)	(2.04)

	2007			
	March 31	June 30	September 30	December 31
Revenues	$ 14,088	$ 14,264	$ 21,474	$ 15,477
Operating loss	(19,483)	(42,753)	(17,798)	(58,744)
Net loss and loss attributable to common stockholders	(19,584)	(39,863)	(19,359)	(60,020)
Loss per share attributable to common stockholders, basic and diluted	(851.48)	(5.27)	(0.82)	(2.53)

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

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;

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;

A gain of $5.1 million on the sale of the rights to Cystadane recorded in the three months ended March 31, 2007;

A charge of $17.5 million related to future settlement payments under the agreements with various government entities referenced under Legal Proceedings in Note 7 recorded in the three months ended June 30, 2007;

Table of Contents

JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Contract revenues of $7.5 million related to the achievement of a development milestone recorded in the three months ended September 30, 2007, and

A charge of $20.2 million related to the impairment of the intangible asset associated with Antizol recorded in the three months ended December 31, 2007.

18. Subsequent Events

Agreement with Solvay

In February 2009, the Company amended its 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, which the Company expected would be met in April 2009 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 is payable 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 the Company pays these amounts when due, the payment due in 2012 will decrease to $4.5 million. In addition, the Company agreed to pay Solvay $5.0 million in 2015 if 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 U.S. as of December 31, 2014.

Government Liability

In the first quarter of 2009, the Company entered into arrangements with various government entities to postpone until October 2009 criminal and civil payments (totaling approximately $2.5 million) that otherwise would have been due in January 2009.

Table of Contents

Schedule II

Valuation and Qualifying Accounts

(In thousands)

		Balance at beginning of period	Additions	Additions charged to costs and expenses (3)	Deductions	Balance at end of period
For the year ended December 31, 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		43		4,040	(3,657)	426
Allowance for government rebates		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
For the year ended December 31, 2006						
Allowance for doubtful accounts	(1)	$ 25	$	$ 28	$ (3)	$ 50
Allowance for sales discounts	(1)	71		880	(857)	94
Allowance for chargebacks	(1)	26		212	(233)	5
Allowance for customer rebates	(1)			44	(26)	18
Allowance for wholesaler fees	(1)	153		203	(325)	31
Allowance for government rebates	(2)	88		229	(254)	63

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

Table of Contents

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.(6)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(3)
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.(4)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(12)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(13)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(5)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(12)
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.(12)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(12)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(12)
4.5D	Form of Common Stock Warrant of the Registrant.(12)
4.5E	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(12)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(13)
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
4.7	Form of Registered Direct Common Warrant.(15)
10.1+	Form of Indemnification Agreement between the Registrant and its officers and directors.(3)
10.2+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce C. Cozadd.(6)
10.3+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel R. Saks.(6)

Table of Contents

Exhibit Number	Description of Document
10.4+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert M. Myers.(6)
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew K. Fust.(6)
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol A. Gamble.(6)
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne L.T. Wissel.(6)
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.(6)
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert M. Myers.(6)
10.17+	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert M. Myers.(6)
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert M. Myers.(6)
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew K. Fust.(6)
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol A. Gamble.(6)
10.21+	2003 Equity Incentive Plan, as amended.(3)
10.22+	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.(3)
10.23+	2007 Equity Incentive Plan.(3)
10.24+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.(7)

Table of Contents

Exhibit Number	Description of Document
10.25+	2007 Non-Employee Directors Stock Option Plan.(3)
10.26+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.(3)
10.27+	2007 Employee Stock Purchase Plan.(3)
10.28+	Form of 2007 Employee Stock Purchase Plan Offering Document.(3)
10.29+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(6)
10.30	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.(8)
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(7)
10.32	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.(7)
10.33	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.(9)
10.34	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.35	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.36	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.41	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.(8)
10.42	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(8)
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.45	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc. and Elan Pharma International Limited.(9)
10.46	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(8)
10.47	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(9)
10.48	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(9)
10.49	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.(8)
10.50	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(8)

Table of Contents

Exhibit Number	Description of Document
10.51	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(9)
10.52	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.(9)
10.53	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.(9)
10.54	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.(7)
10.55+	Directors Deferred Compensation Plan.(3)
10.56+	Non-Employee Director Compensation Arrangements, as modified on August 14, 2008.(18)
10.57A	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.(10)
10.57B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and the Registrant.(10)
10.57C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.(10)
10.57D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and the Registrant.(10)
10.58+	Amended Executive Change in Control and Severance Benefit Plan.(1)
10.59+	Form of Amendment to Employment Agreement, by and between the Registrant and each of Bruce Cozadd, Samuel Saks, M.D., Robert Myers, Matthew Fust, Carol Gamble and Janne Wissel.(1)
10.60+	Form of Letter, amending outstanding options granted under the Registrant s 2003 Equity Incentive Plan.(1)
10.62+	Amendment No. 2 to Employment Agreement, effective on September 1, 2007, by and between the Registrant and Bruce C. Cozadd.(11)
10.63	Addendum No. 4 to Amended and Restated Master Services Agreement, dated as of July 6, 2007, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(11)
10.64+	Form of Restricted Stock Unit Award under the Registrant s 2007 Equity Incentive Plan.(11)
10.65+	Non-Employee Director Compensation Arrangements, as modified on December 18, 2007.(12)
10.66	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.(12)
10.67	Addendum No. 5 to Amended and Restated Master Services Agreement, dated as of October 5, 2007, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and Orphan Medical, Inc.(12)
10.68	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.(12)
10.69	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.(12)
10.70	Common Stock Purchase Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
10.71+	Amended Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(14)
10.72+	2008 Executive Officer Compensation Arrangements.(14)

Table of Contents

Exhibit Number	Description of Document
10.73+	Form of Stock Award Grant Notice and Stock Award Agreement under the Registrant s 2007 Equity Incentive Plan.(14)
10.74	Master Services Agreement dated May 6, 2008, by and between the Registrant and CuraScript, Inc.(14)
10.75	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.(16)
10.76	Antizol® Product Rights Acquisition Agreement, dated as of August 1, 2008, by and among the Registrant, JPI Commercial, LLC, Paladin Labs (Barbados) Inc., and Paladin Labs (USA) Inc.(17)
10.77	Amendment No. 2 to License Agreement, dated as of October 17, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(18)
10.78	Amendment No. 3 to License Agreement, dated as of December 19, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.
10.79	Amendment No. 4 to License Agreement, dated as of February 5, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.
10.80+	Directors Deferred Compensation Plan, as amended.
10.81+	Amended and Restated Executive Change in Control and Severance Benefit Plan.
10.82	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.
10.83	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.
10.84	Form of Registered Direct Subscription Agreement. (19)
12.1	Statement re: Computation of Ratio 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 in 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 Acting 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 Acting 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 requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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 the same numbered exhibit to 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 3.4 to the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 17, 2007.

(3) Incorporated herein by reference to the same numbered exhibit to 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 4.3 to 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.

Table of Contents

(5) 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.

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

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

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

(9) Incorporated herein by reference to the same numbered exhibit to the Registrant s registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.

(10) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K, filed with the SEC on July 18, 2007.

(11) Incorporated herein by reference to the same numbered exhibit to 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.

(12) Incorporated herein by reference to the same numbered exhibit to 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.

(13) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.

(14) Incorporated herein by reference to the same numbered exhibit to 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.

(15) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.

(16) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 24, 2008.

(17) Incorporated herein by reference to the same numbered exhibit to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 6, 2008.

(18) Incorporated herein by reference to the same numbered exhibit to 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.

(19) Incorporated by reference to Exhibit 10.1 to the Registrant s current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.

* 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.