JAZZ PHARMACEUTICALS INC
Form 10-K
March 31, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2007

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 29, 2007, based upon the last sale price reported for such date on the NASDAQ Global Market, was $148,221,856. The calculation of the aggregate market value of voting and non-voting stock excludes 15,286,688 shares of the registrant s common stock held by current executive officers, directors, and affiliated stockholders. For purposes of determining whether a stockholder was an affiliate of the registrant at June 29, 2007, the registrant has assumed that a stockholder was an affiliate of the registrant at June 29, 2007 if such stockholder (i) beneficially owned 10% or more of the registrant s common stock and/or (ii) was affiliated with an executive officer or director of the registrant at June 29, 2007. 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 25, 2008, a total of 24,622,636 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 2008 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

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JAZZ PHARMACEUTICALS, INC.

2007 ANNUAL REPORT ON FORM 10-K

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This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, potential and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Annual Report on Form 10-K in greater detail under the heading Risk Factors. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by 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 identifying, 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 and 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. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies, we also explore potential new indications for known drug compounds. 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 $53.2 million in 2007, one product approved by the U.S. Food and Drug Administration, or FDA, on February 28, 2008 which we are currently launching, and four product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our marketed and approved products are:

Xyrem® (sodium oxybate) oral solution. Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain s inability to regulate sleep-wake cycles. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our approximately 200 person specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB markets Xyrem in 14 countries. In 2007, Xyrem net sales were $39.0 million.

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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 recently shipped initial quantities of Luvox CR to wholesalers. We will promote the product through our recently expanded specialty sales force of approximately 200. Luvox CR is a once-daily extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor. Selective serotonin reuptake inhibitors 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 United States, respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. During 2007 we made, and during 2008 we expect to make, significant expenditures relating to the commercial launch of Luvox CR.

Antizol® (fomepizole). Antizol is an FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisonings in dogs. In 2007, Antizol and Antizol-Vet net sales were $14.2 million. In December 2007, a generic fomepizole was approved and is now available in the United States, and in early 2008, a second generic fomepizole product was approved by the FDA. As a result, we expect that sales of Antizol will decrease substantially during 2008.

Our clinical development pipeline consists of the following product candidates:

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. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia. We are currently conducting two Phase III pivotal clinical trials, and we expect preliminary data from the first Phase III pivotal clinical trial in the fourth quarter of 2008. In Phase II clinical trials, JZP-6 achieved a statistically significant improvement compared to placebo in pain based on the pain visual analog scale, which the FDA and the European Agency for the Evaluation of Medicinal Products have indicated is the appropriate primary endpoint for our Phase III pivotal clinical trials. Subject to successful completion of the Phase III clinical trials, 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 United States to specialists who treat fibromyalgia patients, through an expanded specialty sales force or in partnerships with third parties. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

JZP-4 (sodium channel antagonist). JZP-4, a controlled release formulation of an anticonvulsant that is believed to work both through a similar mechanism of action as Lamictal® (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy, and according to the National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder.

JZP-8 (intranasal clonazepam). JZP-8, an intranasal formulation of clonazepam, is being developed 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

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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.

JZP-7 (ropinirole gel). JZP-7, a transdermal gel formulation of ropinirole, is being developed for the treatment of restless legs syndrome. Dopamine is naturally produced by the human body, and in the brain, dopamine functions to help nerve cells communicate. A dopamine agonist is a drug compound that mimics the effects of dopamine. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome.

We have an ongoing program for generating, identifying and conducting feasibility studies for new product candidates. Our JZP-7 and JZP-8 product candidates resulted from this program. Several other product candidates identified through this program are in various stages of early development, including the use of sodium oxybate for the treatment of movement disorders. Other such early stage projects include a structural analog of valproic acid for the treatment of epilepsy and bipolar disorder licensed from Yissum, the technology transfer company of the Hebrew University of Jerusalem, and a triple reuptake inhibitor for the treatment of depression licensed from Faes Pharma S.A. We are working on ways to expand our Xyrem franchise by developing improvements to Xyrem, such as an oral tablet form, that could be more convenient for patients. These activities are in the early stages of development.

Products and Product Candidates in Clinical Development

Product/Product Candidate	Active Pharmaceutical Ingredient/Mechanism of Action	Primary Indication(s)	Status	Commercialization Rights
Xyrem	Sodium oxybate	Cataplexy and excessive daytime sleepiness in patients with narcolepsy	Marketed	U.S. and countries not licensed to UCB or Valeant
Luvox CR	Fluvoxamine maleate	Obsessive compulsive disorder Social anxiety disorder	Approved by FDA	U.S.
Antizol	Fomepizole	Ethylene glycol and methanol poisoning	Marketed	Worldwide
JZP-6	Sodium oxybate	Fibromyalgia	Phase III	U.S. and countries other than Canada and those licensed to UCB
JZP-4	Type IIa sodium channel antagonist	Epilepsy Bipolar disorder	Phase II	Worldwide
JZP-8	Benzodiazepine	Recurrent acute repetitive seizures	Phase II	Worldwide
JZP-7	Transdermal ropinirole	Restless legs syndrome	Phase I/II	Worldwide

Marketed and Approved Products

Xyrem (sodium oxybate) oral solution

Xyrem is a sodium oxybate oral solution approved in the United States for the treatment of cataplexy and excessive daytime sleepiness 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. Xyrem is currently the only FDA-approved treatment for both cataplexy and excessive daytime sleepiness in patients with narcolepsy. In 2007, our net product sales of Xyrem were $39.0 million.

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Market Opportunity

Narcolepsy is a chronic neurologic disorder caused by the brain s inability to regulate sleep-wake cycles normally. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. The primary symptoms of narcolepsy include excessive daytime sleepiness, cataplexy, sleep paralysis, 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 the individual becoming drowsy or falling asleep, often at inappropriate times and places.

Attributes of Xyrem

Xyrem is the only product approved by the FDA to treat both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Xyrem is administered at night 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 the only generally accepted patient-care strategy for the treatment of both cataplexy and excessive daytime sleepiness associated with narcolepsy.

Product Development

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. In November 2005, the FDA approved a supplemental NDA, or sNDA, for the treatment of excessive daytime sleepiness in patients with narcolepsy.

Commercialization

We promote Xyrem in the United States through our approximately 200 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. Pursuant to the original agreement, UCB and its predecessor made upfront and milestone payments totaling $9.5 million in 2007. UCB currently markets the product in 14 countries. We are entitled to additional commercial milestone payments of up to $6.0 million specifically associated with Xyrem 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 the product 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.

The term of our agreement with UCB, as it applies to Xyrem, 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 narcolepsy, subject to automatic extension unless and until UCB terminates the agreement upon not less than 12 months notice. UCB may

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terminate our agreement for any reason upon 18 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.

The FDA has granted Xyrem orphan drug exclusivity in the United States for both cataplexy and excessive daytime sleepiness in patients with narcolepsy. This provides marketing exclusivity in the United States 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 patent in the Orange Book may require potential competitors to certify as to non-infringement or invalidity of the patent prior to FDA approval of their product candidates. A patent application covering Xyrem s distribution system is currently pending, and the patent, 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 is subject to a risk management program required by the FDA in conjunction with Xyrem s approval by the FDA. Under the Xyrem risk management program, Xyrem must be distributed through a single central pharmacy, Express Scripts Specialty Distribution Services, or Express Scripts. 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 physician s office and 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 patients may not receive more than a three-month supply at any time.

Pursuant to our agreement with Express Scripts, Express Scripts provides distribution and other customer support services to us related to the sale and marketing of Xyrem in the United States. We are billed monthly for the services performed by Express Scripts. Our agreement with Express Scripts expires on July 31, 2008, 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 upon five days notice if Express Scripts is not in compliance with applicable regulatory requirements.

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. 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 none of these compounds 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

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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 risk management program requires that it be distributed in the United States through a single central pharmacy, and it takes longer for a patient to receive medicine under the Xyrem distribution system than it takes to fill a typical prescription at a pharmacy. Xyrem is administered at night and can be used in conjunction with Provigil, which is administered during the day. During the pivotal Phase III trials of Xyrem, 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 solely for the treatment of both obsessive compulsive disorder and social anxiety disorder. Luvox CR received FDA approval on February 28, 2008. We recently shipped initial quantities of Luvox CR to wholesalers. In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR in the United States. Solvay retains the rights to market and distribute Luvox CR outside of the United States. Luvox CR is a once-daily extended release formulation of fluvoxamine maleate developed by Solvay in collaboration with Elan. Luvox, an immediate release formulation of fluvoxamine maleate, was previously approved by the FDA and marketed by Solvay for the treatment of obsessive compulsive disorder, and generic fluvoxamine remains one of the leading treatments for the disorder. 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.

Market Opportunity

Obsessive Compulsive Disorder. Obsessive compulsive disorder is a chronic anxiety disorder characterized by persistent, unwanted thoughts, or obsessions, and repetitive behaviors or rituals, or compulsions. According to the National Institute of Mental Health, obsessive compulsive disorder affects approximately 2.2 million adults in the United States. According to an article published in the *International Journal of Clinical Practice*, it is estimated that 60% of patients with obsessive compulsive disorder worldwide receive no treatment for their disorder. Patients with obsessive compulsive disorder use rituals to help control anxiety related to their obsessive thoughts, and these rituals become disruptive to their daily life. 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 United States. 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

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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 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 significant market opportunity for Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder, and that Luvox CR offers a compelling 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 already a broadly prescribed therapy for the treatment of obsessive compulsive disorder. The market potential for Luvox CR is demonstrated in part by the significant ongoing prescription rates for the generic formulations of fluvoxamine despite the absence of active marketing and sales activity.

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 could significantly improve 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.

Product Development

In January 2007, we licensed from Solvay the exclusive rights to market and distribute Luvox CR in the United States. FDA approval for Luvox CR as a treatment for obsessive compulsive disorder and for social anxiety disorder was received on February 28, 2008. 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.

Commercialization Strategy

We recently shipped initial quantities of Luvox CR to wholesalers in the United States. To effectively market Luvox CR, we significantly expanded our specialty sales force during the fourth quarter of 2007. A substantial majority of prescriptions for the treatment of obsessive compulsive disorder and social anxiety disorder are written by psychiatrists. We believe that this concentration provides an attractive, focused market opportunity for us. Our comprehensive launch strategy includes sampling, journal advertisements, speaker programs and other activities.

Through our license agreement with Solvay, we have the exclusive rights to market and distribute Luvox CR in the United States, and Solvay retained the rights to market and distribute Luvox CR outside of the United States. Solvay assigned to us its rights and obligations under its license and supply agreement with Elan, and we have sublicensed back to Solvay the rights under that agreement outside of the United States. 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,

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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 United States in exchange for supply price payments to us. We paid Solvay $2.0 million upon signing of the license agreement. A total of $10.0 million is due on March 28, 2008 and an additional $10.0 million is due April 7, 2008. In addition, $10.5 million is due on September 30, 2008 and $10.5 million is due on December 31, 2008. We are obligated to pay Solvay up to $95.0 million in commercial milestone payments associated with Luvox CR, as well as royalties on net product sales. We are obligated to pay Elan royalties on net product sales and supply price payments for the supply of Luvox CR.

Our license and supply agreements with Solvay will remain in force until terminated by either us or Solvay as a result of an uncured breach by the other party. We may also terminate the agreements with Solvay upon 180 days notice to Solvay.

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. Elan may also terminate our license if we fail to meet specified commercialization milestones within specified time periods.

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 have begun planning these studies and expect to provide the FDA with our proposed protocols in mid-2008. Failure to promptly conduct these Phase IV clinical trials could result in the FDA s withdrawal of approval for Luvox CR.

Luvox CR has three years of marketing exclusivity beginning on February 28, 2008, the date Luvox CR was approved by the FDA. In addition, Elan has filed a patent application covering the orally administered formulation of extended-release fluvoxamine that requires the release of fluvoxamine over a period of not less than 12 hours. If this patent issues in the United States, it could provide patent protection for this formulation until 2020. The patent has issued in Europe, Australia and Russia and is pending in four 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 United States in 2007, accounting for approximately $17.6 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 and other conditions. Since the approval of Prozac® (fluoxetine) in the United States 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.

Five branded products, in addition to Luvox CR, are currently approved by the FDA for the treatment of obsessive compulsive disorder, including four SSRIs: Paxil® (paroxetine HCl), which is marketed by GlaxoSmithKline, Zoloft® (sertraline HCl), which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly, and

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Luvox® which is not currently marketed. The fifth branded product is Anafranil® (clomipramine hydrochloride), a tricyclic antidepressant marketed by Mallinckrodt in the United States. 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.

Based on data from the 2007 Physicians Drug and Diagnosis Audit, we estimate that total fluvoxamine use represented approximately 12% of total drug usage for the treatment of obsessive compulsive disorder in 2007. Prior to the introduction of generic fluvoxamine in 2000, Luvox was considered one of the preferred treatments of obsessive compulsive disorder. Based on data from the 2007 Physicians Drug and Diagnosis Audit, we estimate that Luvox accounted for 21% of total drug usage for the treatment of obsessive compulsive disorder in 1999.

The market for drugs to treat obsessive compulsive disorder is extremely fragmented. Based on data from the 2007 Physicians Drug and Diagnosis Audit, we estimate that Paxil, Zoloft, Prozac and Anafranil (and their generic equivalents) and fluvoxamine accounted for 53% of the total drug usage for the treatment of obsessive compulsive disorder in 2007. Although they are not FDA-approved for the treatment of obsessive compulsive disorder, based on data from the 2007 Physicians Drug and Diagnosis Audit, we estimate that the currently marketed branded products, Lexapro, Celexa, Effexor XR and Cymbalta, accounted for approximately an additional 21% of total drug usage for the treatment of obsessive compulsive disorder in 2007, with more than 40 other drugs making up the remaining 26%. Given the prevalence of generic products, in order to gain significant market acceptance, we will need to demonstrate that the benefits of Luvox CR to patients justify its price.

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® (venlafaxine HCl). Effexor XR, which was developed and is sold by Wyeth, does not have a generic equivalent, whereas Paxil, Paxil CR and Zoloft have generic equivalents. Effexor XR was approved for the treatment of social anxiety disorder in 2003 and generic equivalents may be launched as early as June 2008.

As is the case with obsessive compulsive disorder, the market for drugs to treat social anxiety disorder is extremely fragmented. Based on data from the 2007 Physicians Drug and Diagnosis Audit, we estimate that Zoloft, Paxil, Paxil CR and their generic equivalents, and Effexor XR, in the aggregate accounted for only approximately 29% of the total drug usage for the treatment of social anxiety disorder in 2007. Although they are not approved for the treatment of social anxiety disorder, based on data from the 2007 Physicians Drug and Diagnosis Audit, we estimate that the currently marketed products Lexapro, Celexa and Cymbalta accounted for 26% of total drug usage for the treatment of social anxiety disorder in 2007, with fourteen other drugs making up the remaining 45%. As with obsessive compulsive disorder, in order to gain significant market acceptance, we will need to demonstrate that the benefits of Luvox CR to patients justify its price.

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. These products therefore may be more likely to be prescribed than Luvox CR.

Although SSRIs have a favorable side-effect profile compared to other classes of agents, the current SSRI products used to treat obsessive compulsive disorder and social anxiety disorder, particularly those formulated for immediate release, all have significant adverse side effects. Adverse side effects associated with SSRIs include nausea, sleep abnormalities, sexual dysfunction, weight gain, adverse drug interactions, risk of hypertension and, in adolescents, increased suicidal tendencies. SSRIs are known to have little effect on patients disease condition during the initial six to eight weeks of therapy. As a result, multiple psychotropic drugs are

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often prescribed during this time period to provide patients with more immediate relief. Additional adverse effects associated with immediate release formulations of SSRIs include significant incidence of nausea and reduced compliance as a result of multiple daily dosing.

Antizol (fomepizole)

Antizol, an injectable formulation of fomepizole, is an FDA approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. According to the 2006 annual report of the American Association of Poison Control Centers, more than 6,000 exposures to ethylene glycol were reported in the United States in 2006, resulting in 34 fatalities. More than 2,000 exposures to methanol were reported in the United States in 2006, resulting in eight fatalities. If ingested, ethylene glycol, commonly found in antifreeze, and methanol, commonly found in windshield wiper fluid, can lead to death or permanent, serious physical damage. When administered promptly after ingestion of either of these poisons, Antizol inhibits the formation of toxic metabolites and helps prevent renal damage or death. Guidelines issued by the American Academy of Clinical Toxicologists have established Antizol as the standard of care for such poisonings.

In 2007, our net product sales of Antizol were $13.9 million. In December 2007, a generic fomepizole product was launched in the United States, and in early 2008, a second generic fomepizole product was approved by the FDA. As a result of the availability of generic competition, we expect Antizol sales to decline significantly during 2008. It is also possible that additional generic competitors will be introduced, which could lead to a more rapid decline in sales of Antizol. We obtained the rights to Antizol in connection with our acquisition of Orphan Medical. Orphan Medical had obtained the worldwide rights to develop and market Antizol through a sublicense agreement with Mericon Investment Group. The license expires in July 2013, subject to a five-year renewal option that may be exercised by either party. Under the agreement Mericon receives quarterly royalties on sales of Antizol through the duration of the sublicense.

Antizol is primarily used in a hospital setting, and we estimate that over one-third of all U.S. hospitals with emergency rooms currently stock the product. We market the product primarily to hospitals and emergency rooms. In addition to domestic sales, Antizol is marketed by our distributors in Canada and Israel.

We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisonings in dogs. In 2007, our net product sales of Antizol-Vet were $251,000.

Product Candidates

JZP-6 (sodium oxybate)

We are developing sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. We are currently conducting two Phase III pivotal clinical trials for JZP-6 in fibromyalgia. We have completed a Phase II clinical trial for JZP-6 in which fibromyalgia patients taking sodium oxybate achieved a statistically significant improvement compared to placebo in pain based on the pain visual analog scale, which the FDA and the European Agency for the Evaluation of Medicinal Products have indicated is the appropriate primary endpoint for our Phase III pivotal clinical trials.

Market Opportunity

Fibromyalgia is a chronic pain syndrome defined by widespread pain lasting at least three months. 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. In addition to pain, fibromyalgia patients often suffer from a combination of muscle stiffness, fatigue, disturbed sleep, restless legs syndrome and impaired memory and concentration. Although physicians do not understand the cause of fibromyalgia, it may be triggered by physical trauma, emotional stress or infection. The criteria established by

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the American College of Rheumatology for the classification of fibromyalgia require the application of pressure at 18 different points on the body and measurement of pain induced by such pressure. If at least 11 of the 18 points are painful and have been painful for three months, the patient is diagnosed with fibromyalgia.

Competition

Lyrica® (pregabalin) is the only product currently 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. Based on available market data, we estimate that more than 8.7 million total prescriptions were written to treat fibromyalgia symptoms in 2007. Of these, approximately 28% were for antidepressants, 16% for anti-epileptics (gabapentin and pregabalin), 19% for muscle relaxants, 10% for non-steroidal anti-inflammatory drugs, 12% for opioids and 6% 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 designed to comprehensively address the syndrome and many of its related symptoms.

Two products in addition to Lyrica have completed Phase III clinical development for the treatment of fibromyalgia. Eli Lilly submitted a sNDA for Cymbalta® (duloxetine) in August 2007 seeking FDA approval for the treatment of fibromyalgia. Forest Laboratories and Cypress Bioscience jointly filed an NDA for milnacipran in December 2007 seeking FDA approval for the treatment of fibromyalgia.

Attributes of JZP-6

We are developing JZP-6 to provide an effective treatment for fibromyalgia. While the primary symptom of fibromyalgia is widespread pain, fatigue and mood disturbances 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 physical functioning.

The primary endpoint for our pivotal trials measuring the efficacy of JZP-6 is the change from baseline in pain based on the pain visual analog scale. 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 communicated verbally that the pain visual analog scale is an acceptable primary endpoint to obtain an indication for the treatment of fibromyalgia. The European Agency for the Evaluation of Medicinal Products 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 II Clinical Trial Results. In August 2005, we completed a Phase II clinical trial of 195 patients with fibromyalgia in a randomized, double blind placebo-controlled safety and efficacy study. Patients received a fixed dose of 4.5 grams of sodium oxybate divided into two nightly doses, 6 grams of sodium oxybate divided into two nightly doses, or placebo twice nightly for an eight-week period. The primary endpoint for this trial was a composite of change from baseline in three co-primary measures of patients pain: the pain visual analog scale, the fibromyalgia impact questionnaire and patient global impression of change. Secondary endpoints included measurement of a tender point count, tender point index, Epworth sleepiness scale, Jenkins scale for sleep, global score on the functional outcome of sleep questionnaire, severity of fatigue and clinical global impression of change. The Phase II clinical trial demonstrated significant improvement in the composite endpoint results in both dosage strengths. In addition, the study demonstrated significant improvements in secondary measures of fatigue, sleepiness and sleep quality. There were no unexpected adverse events in the study.

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JZP-6 also demonstrated statistically significant improvement in each of the co-primary measures that comprise the composite endpoint in either one or both dosage strengths. The visual analog scale is a self-assessed measurement of pain in which zero is no pain at all and 100 is the worst pain experienced. The baseline pain for the fibromyalgia patients in the trial was roughly 65. Patients on both dosage strengths experienced a statistically significant improvement in pain at eight weeks. In addition, the study measured pain throughout the day. Patients experienced pain relief in the morning, at midday and in the evening, which represents an important clinical benefit for patients. 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. The total score is normalized to 100 points. The questionnaire also has a single inquiry about anxiety and depression. The Phase II clinical trial results demonstrated that patients on both dosage strengths experienced statistically significant improvement in the total score. The patient global impression of change is a seven point scale on which patients assess how much better or worse they feel throughout the trial. Our Phase II clinical trial demonstrated a statistically significant improvement for this measure for patients on the 4.5 gram per night dose.

Ongoing Phase III Clinical Trials. We are currently conducting two Phase III pivotal clinical trials, each in approximately 525 patients, to confirm the results or our Phase II clinical trial. 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 pivotal Phase III trials. Based on communications from the FDA after completion of our Phase II clinical trial, the primary endpoint in both of our ongoing Phase III pivotal clinical trials is the improvement on a pain visual analog scale. Each of our Phase III pivotal clinical trials is a randomized, double blind, placebo controlled study. The first of the trials commenced in September 2006 and as of March 13, 2008 was ongoing in approximately 66 sites located in the United States. As of March 13, 2008, more than 400 patients had been enrolled in the first trial. The second trial commenced in February 2007 and as of March 13, 2008 was ongoing in approximately 45 United States and European sites. As of March 13, 2008, more than 150 patients were enrolled in the second trial. Approximately 30% of the subjects for the second trial are expected to reside outside of the United States. The dosages being studied in the ongoing Phase III pivotal trials are consistent with those in our Phase II clinical trial.

We expect preliminary data from the first Phase III pivotal clinical trial in the fourth quarter of 2008. We currently anticipate submission of an NDA for this product candidate in the fourth quarter of 2009.

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 rheumatologists, neurologists, psychiatrists and sleep specialists. Because the number of rheumatologists in the United States is relatively small, we expect to be able to expand our specialty sales force or to develop partnerships with third parties to promote JZP-6 in the United States. We may also identify one or more pharmaceutical company partners or a contract sales organization to promote JZP-6 to other audiences, 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. Under the terms of the amended agreement, UCB has paid us $22.5 million. We are entitled to up to $32.5 million in additional development milestone payments associated with JZP-6, and additional commercial milestone payments of up to $100.0 million related primarily to JZP-6 for the treatment of fibromyalgia as well as Xyrem for the treatment of narcolepsy. 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 European Agency for the Evaluation of Medical Products 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 18 months notice. 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.

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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. 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 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 cover JZP-6. In addition, we hold a U.S. patent, which expires in 2017, and patents in 29 other countries which expire in 2018, that cover the use of sodium oxybate for the treatment of fibromyalgia.

JZP-4 (sodium channel antagonist)

We are developing JZP-4, a controlled release formulation of an anticonvulsant that is believed to work through a similar mechanism of action as Lamictal® (lamotrigine). We have completed a number of preclinical animal models related to antiepileptic activity that suggest that JZP-4 may be effective in treating epilepsy. We have successfully completed two proof of concept clinical trials, a long-term toxicology study and a formulation study. We began activities in connection with a Phase II clinical trial for the treatment of epilepsy in December 2007, and we plan to dose the first patient with JZP-4 in the third quarter of 2008.

Market Opportunity

Epilepsy. Epilepsy, a seizure disorder, is a serious neurological illness affecting people of all ages. A seizure is a sudden surge of electrical activity in the brain that affects how a person feels or acts for a short time. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy. In 2007, over $10 billion of seizure disorder drugs were sold in the United States as measured by the Pharmaceutical Audit Suite. Based on available market data, we estimate that approximately $3.3 billion of these drugs were prescribed for the treatment of epilepsy. Epileptic seizures are classified as either partial or generalized depending upon how the abnormal brain activity begins. Partial seizures begin with abnormal activity in part of the brain. Generalized seizures have abnormal activity in most or all of the brain. Seizure symptoms may be hardly noticeable, such as confusion and staring, or totally disabling, such as convulsions, shaking and falling down.

Bipolar disorder. Bipolar disorder is a serious, chronic psychiatric disorder that causes shifts in mood, energy and ability to function. According to National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder. Based on available market data, we estimate that approximately $2 billion of antiepileptic drugs were sold for the treatment of bipolar disorder in 2007. People suffering from the condition experience dramatic mood swings from an overly high mania state to an overly low or depressive state, often with periods of normal mood in between.

Competition

Epilepsy. Seizures in epileptic patients are typically controlled by treatment with one or more antiepileptic drugs. According to the Pharmaceutical Audit Suite, in 2007 there were approximately 7.4 million prescriptions written for Lamictal. While up to 70% of epilepsy patients respond to therapy and become seizure-free with chronic treatment with antiepileptic drugs, the remaining patients fail treatment either because the drugs do not stop their seizures or because they cannot tolerate the side effects. These patients usually take more than one

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antiepileptic drug at a time and are therefore more susceptible to adverse effects associated with drug interactions. Selection of the appropriate medication for an individual patient is typically based on the type of epilepsy from which a patient suffers, the genesis of the disease, and the patient s age and gender. Side effects and tolerability are significant concerns with currently available antiepileptic drugs. Side effects for most antiepileptic drugs include sleepiness, cognitive impairment, weight gain, mood changes, dizziness and potentially life-threatening immune system reactions. Physicians generally start their patients on a low dose of antiepileptic drugs, and titration may take up to 12 weeks. During this period, patients often continue to suffer from epileptic seizures of various severities.

Bipolar Disorder. Bipolar disorder is typically managed with drugs from a variety of different drug classes. While treatment duration varies for each patient, treatment of an acute phase of the disease generally lasts for up to two months, followed by a continuation phase of between one and six months, and a maintenance phase of up to 24 months. Generally, the treatment is chosen based on the mood episode a patient is experiencing at a particular time. Treatment for patients in the acute mania phase includes a mood stabilizer, such as lithium or an antiepileptic drug, in addition to an atypical antipsychotic. Patients in the acute depression phase are initially treated with Lamictal, Symbyax® (olanzapine and fluoxetine HCl capsules), a combination antidepressant and antipsychotic, or Seroquel® (quetiapine), an antipsychotic. For long-term maintenance, the same medications that were effective for the acute episodes are typically continued at the same or lower doses. Many of the drugs currently used in the treatment of bipolar disorder have adverse drug interactions affecting each drug s efficacy and safety as well as adverse tolerability and other negative side effects such as sedation, weight gain, involuntary movements, tremors, stiffness, orthostatic hypotension and potentially life-threatening immune system reactions. These side effects discourage compliance and may pose serious health risks.

Attributes of JZP-4

We are developing JZP-4 to address the unmet needs of patients with epilepsy and bipolar disorder for a more effective product with fewer side effects. JZP-4 is being developed as a controlled release product that can be taken once a day, with a shorter titration schedule and fewer interactions with other drugs than current therapies. The active pharmaceutical ingredient in JZP-4 is an antiepileptic drug in the same class of drugs, and with a similar chemical structure, as Lamictal, an antiepileptic drug approved for the treatment of epilepsy and bipolar disorder. We believe that JZP-4 has the potential to provide the demonstrated efficacy of antiepileptic drugs in treating these conditions while addressing many of the adverse side effects of current therapies. In particular, our pharmacokinetic studies indicate that the active pharmaceutical ingredient in JZP-4 may result in a favorable titration schedule. Preclinical studies also indicate that the active pharmaceutical ingredient in JZP-4 may have fewer adverse drug interactions than current therapies. In addition, we believe that JZP-4 has the potential to be effective in treating bipolar depression with minimal sedation, low incidence of weight gain and limited risk of causing mood switches, thereby addressing a significant unmet need for this patient population.

Product Development

We acquired the worldwide rights to the active pharmaceutical ingredient in JZP-4 from GlaxoSmithKline in 2004. Since acquiring these rights, we have completed our initial formulation development and human bioavailability studies to show that the drug can be formulated as a once-a-day product, and we have conducted preclinical animal model studies which we believe confirmed studies previously completed by GlaxoSmithKline showing that the drug has central nervous system activity comparable to Lamictal and other antiepileptic drugs.

Our preclinical development has involved a range of preclinical studies to determine how the active pharmaceutical ingredient in JZP-4 works and its potential to treat epilepsy. The results of these studies indicate that the active pharmaceutical ingredient in JZP-4 is a broad spectrum antiepileptic drug with sodium and calcium channel blockade as the primary mechanisms of action. From the results of these preclinical studies, we infer that the active pharmaceutical ingredient has a broad spectrum of activity, which indicates that it may be effective in treating many different types of epileptic seizures. We have also completed preliminary toxicology

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and clinical pharmacology tests that have provided early indications of safety and a low potential for certain adverse drug interactions. These tests involved exposure of more than 170 healthy individuals in eight single dose and multi-dose studies. We developed a prototype once-a-day formulation and tested it in the fourth quarter of 2007 in a pharmacokinetic study that showed the viability of once-a-day dosing.

We have conducted two proof-of-concept clinical trials that were designed to provide evidence of central nervous system activity for JZP-4. The first, a transcranial magnetic stimulation study in healthy human volunteers, used lamotrigine as a positive control. The results from these subjects indicate central nervous system activity of JZP-4. The second, a photic-induced paroxysmal electroencephalographic study in photosensitive epilepsy patients, used the active pharmaceutical ingredient in JZP-4 and a higher dose of baseline antiepileptic drug as a positive control. This study was completed in the fourth quarter of 2007, providing information on the effective dose range in epilepsy patients and possible adverse drug interactions with other antiepileptic drugs.

Our completed long-term toxicology studies support use of the active pharmaceutical ingredient in JZP-4 in humans for up to 13 weeks. Based on the results we received from these long-term toxicology studies, formulation studies, two proof-of-concept studies and certain drug-drug interaction studies, we began our Phase II activities in the fourth quarter of 2007, and we expect to dose the first patient in this Phase II clinical trial of JZP-4 for the treatment of epilepsy beginning in the third quarter of 2008. We expect preliminary information from this trial in late 2008.

Commercialization Strategy

Our strategy to market any approved formulation of JZP-4 will depend on the outcome of our clinical trials, the specific indications it is approved to treat and the specialties of the physicians most likely to prescribe the product based on the approved indications. Any such sales efforts may involve the utilization of our internal sales force, collaborations with partners, or a combination of both. Pursuant to our agreement with GlaxoSmithKline, we have paid upfront and development milestone payments of $5.0 million, and will pay $5.0 million upon first dosing of a patient in a Phase II clinical trial, which is currently expected in the third quarter of 2008. The agreement with GlaxoSmithKline provides for $108.5 million in additional development and commercial milestone payments, and royalties on commercial sales. Under the agreement, we are obligated to use diligent efforts to develop and commercialize JZP-4 in accordance with a specified timeline. If we fail to use such efforts, then GlaxoSmithKline may elect, following notice and opportunity to cure, to terminate the agreement and reclaim all product rights. In addition, if we elect to discontinue development of JZP-4, GlaxoSmithKline has a right to re-acquire the product upon payment of specified amounts. We have contracted for the supply of clinical trial materials for our clinical trials of JZP-4, and we will need to arrange for commercial supply.

The composition of matter for the active pharmaceutical ingredient in JZP-4 is covered by patents in 53 countries, including in the United States and countries in Europe. The United States patent expires in 2018. In addition, we hold a United States patent covering the use of the active pharmaceutical ingredient in JZP-4 for the treatment of bipolar disorder that expires in 2018, and a United States patent that covers the process used for preparing the active pharmaceutical ingredient in JZP-4 that expires in 2021. A patent application covering a sustained release composition for delivering the active pharmaceutical ingredient in JZP-4 is currently pending in the United States Patent and Trademark Office and would, if issued, expire in 2026.

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. Our initial development work suggests that JZP-8 has the potential to provide fast-acting efficacy associated with currently available therapies while addressing problems associated with administration that make such therapies largely impractical to employ. We have received orphan drug designation from the FDA for this product candidate for the treatment of recurrent acute repetitive seizures.

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Market Opportunity

Recurrent acute repetitive seizures are bouts of acute seizure activity within a 24-hour period in adults and a 12-hour period in children. According to the Epilepsy Foundation, approximately 2.7 million people in the United States have epilepsy. According to an article published in the *New England Journal of Medicine*, approximately 30% of epilepsy patients are 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. Recurrent acute repetitive seizures are an acute and repetitive reaction to the abnormal electrical activity that builds up and releases in the brain. Epilepsy patients and their caregivers are usually able to distinguish between a regular seizure and the first seizure in a series of recurrent acute repetitive seizures.

Competition

Quick identification and treatment of the first seizure in a series of recurrent acute repetitive seizures can often interrupt the ongoing seizure, reduce its severity, and prevent subsequent seizures. Interrupting a seizure cluster may also lessen the severity of post-seizure symptoms. In the United States, Diastat® (diazepam rectal gel), marketed by Valeant Pharmaceuticals, is the only FDA-approved, acute, outpatient treatment for patients on stable antiepileptic drugs who experience bouts of increased seizure activity. In 2007, sales of Diastat totaled approximately $80.0 million in the United States as measured by the Pharmaceutical Audit Suite. Although generally considered safe and effective for patients of all ages, because it is a rectally administered gel, Diastat is primarily prescribed for children under the age of ten and is administered to them by caregivers or parents. Diastat s rectal administration has made it impractical for most of the adolescent, adult and elderly population. Patients with seizure clusters who do not use Diastat have no other outpatient treatment option and thus, typically, are treated through the emergency medical system.

In paramedic and hospital settings, benzodiazepines such as diazepam, lorazepam and midazolam are the first line of emergency treatment for patients presenting with recurrent acute repetitive seizures. These medications, all available in intravenous formulations, provide rapid onset of action and known efficacy for patients. However, treatment in an emergency setting results in significantly increased costs to the individual and health care system as well as the potential increased harm and danger associated with the time delay in obtaining emergency treatment.

Attributes of JZP-8

JZP-8 is being developed as an intranasal formulation of clonazepam which has been shown to enter the bloodstream faster than a dose from a conventional tablet form. Clonazepam has been approved for chronic treatment of some forms of epilepsy. Like other benzodiazepines, JZP-8 will likely be regulated as a controlled substance by the DEA if approved for marketing by the FDA. We believe JZP-8 will provide a far easier means of administration while patients are actively seizing and a delivery form that will be accepted for use by adolescent and adult patients as well as caregivers. In addition, we believe that JZP-8 will have sufficient duration of action to prevent recurrence of subsequent seizures in the following 24 hours.

Product Development

We completed development activities to select clonazepam as the active pharmaceutical ingredient for this product candidate, and we have conducted further development activities related to formulation, safety and tolerance of the product candidate. We have completed a pharmacokinetics and pharmacodynamics study in healthy volunteers. Pharmacokinetics deals with the absorption, distribution, biotransformation and excretion of drugs, which, coupled with dosage, determines the concentration of a drug in the body and hence, the intensity of its effects as a function of time. Pharmacodynamics is the study of the biochemical and physiological effects of drugs and their mechanisms of action. These pharmacokinetic and pharmacodynamic results demonstrate that JZP-8 has an acceptable plasma profile. In December 2007, we dosed the first patient in a Phase II clinical trial of

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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 continue to have seizures while on stable anti-epileptic regimens. Subject to satisfactory results of the Phase II clinical trial, we plan to begin Phase III clinical trial activities for JZP-8 in the first half of 2009.

Commercialization Strategy

Our commercialization strategy for JZP-8 will depend on the outcome of our clinical trials, the nature of any indications JZP-8 is approved to treat and the specialties of the physicians most likely to prescribe the product. Any sales efforts may involve the utilization of our internal sales force, collaborations with sales partners or a combination of both.

We have entered into a license agreement with a technology provider for the development of JZP-8. Pursuant to that agreement we are obligated to make clinical and commercial milestone payments to this provider and to pay royalties on commercial sales of the product.

We have contracted for the supply of the active pharmaceutical ingredient in JZP-8 in sufficient quantities to complete clinical trials. We intend to begin to seek a contract manufacturer for commercial quantities of JZP-8 in late 2008.

In December 2007, we received orphan drug designation from the FDA for JZP-8. The FDA s orphan drug designation is intended to encourage research and development of new therapies for diseases that affect fewer than 200,000 persons in the United States. Because JZP-8 is a designated orphan drug, we will be eligible for tax credits based upon JZP-8 s clinical development costs, exemption from the Prescription Drug User Fee Act application fee and waiver of annual product and establishment fees. After receiving marketing approval from the FDA, designated orphan drug products are entitled to seven years of exclusive marketing rights in the United States.

JZP-7 (ropinirole gel)

We are developing JZP-7, a transdermal gel formulation of ropinirole, for the treatment of restless legs syndrome. Based on our development activities, we believe that JZP-7 offers the potential for effective treatment of restless legs syndrome while reducing adverse effects associated with existing treatments.

Market Opportunity

Restless legs syndrome is a common, underdiagnosed neurological disorder that frequently manifests itself as a sleep disorder. According to the Restless Legs Syndrome Foundation, up to ten percent of the U.S. population suffers from restless legs syndrome. An article reviewing the results of several studies which was published in the March 2004 issue of Sleep Medicine indicated that between five and ten percent of the general population experience restless legs syndrome symptoms. Patients who suffer from restless legs syndrome experience an irresistible urge to move their legs. This urge is usually accompanied by unpleasant sensations of burning, creeping, tugging or tingling inside the patients legs, ranging in severity from uncomfortable to painful. These restless legs syndrome-related symptoms typically begin or worsen during periods of rest or inactivity, particularly when lying down or sitting, and may be temporarily relieved by movement such as walking or massaging the legs. Symptoms often worsen at night and disturbed sleep is a common result of restless legs syndrome. Left untreated, restless legs syndrome may cause exhaustion, daytime fatigue, inability to concentrate and impaired memory.

Competition

Requip® (ropinirole), marketed by GlaxoSmithKline, was the first product approved by the FDA for the treatment of restless legs syndrome. In 2006, Mirapex® (pramipexole), marketed by Boehringer Ingelheim, was

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approved by the FDA for the treatment of moderate to severe restless legs syndrome. UCB is developing a rotigotine transdermal patch for restless legs syndrome under the trade name Neupro®, for which UCB filed a supplemental NDA, or sNDA, with the FDA in December 2007. The symptoms of restless legs syndrome are also currently treated by dopamine agonists, opioids, benzodiazepines and anticonvulsants. While Requip and Mirapex have been shown to be effective in treating restless legs syndrome, they have been associated with adverse side effects including nausea, vomiting, orthostatic hypotension and sudden onset of sleep. In a study of patients on dopamine agonist treatments reported in the *Archives of Neurology*, approximately 48% of patients who had continued treatment for longer than six months developed augmentation, with approximately 22% of these patients having severe augmentation. Augmentation refers to the earlier onset of symptoms, increase in symptoms, and spread of symptoms to involve other extremities. For these patients, physicians often add an additional, earlier dose of the existing treatment, increase dosage, or switch to an alternative therapy.

Attributes of JZP-7

We are developing JZP-7 as a transdermal gel formulation of ropinirole to provide the effective treatment of restless legs syndrome while addressing adverse events associated with current therapies. We are seeking to develop JZP-7 as a once-daily formulation. We believe this formulation has the potential to significantly reduce the titration schedule associated with Requip and adverse events associated with products that are often used to treat restless legs syndrome, including nausea, vomiting, orthostatic hypotension and sudden onset of sleep. JZP-7 may also have the potential to provide extended relief of restless legs syndrome for those patients needing longer symptom relief than may be provided by existing oral therapies.

Product Development

We have conducted two pharmacokinetic studies in healthy volunteers. The results demonstrated that our JZP-7 product has a pharmacokinetic profile consistent with our development target. We are planning to initiate Phase III clinical trials for the treatment of restless legs syndrome in the fourth quarter of 2008.

Commercialization Strategy

Our marketing strategy for JZP-7 will depend on the outcome of our clinical trials, the nature of any indications JZP-7 is approved to treat, and the specialties of the physicians most likely to prescribe the product. Any sales efforts may involve the utilization of our internal sales force, collaborations with partners, or a combination of both.

We have an agreement with a technology provider to conduct feasibility studies associated with the formulation and method of delivery of JZP-7. Based on the successful outcome of these studies, we entered into a license agreement that will provide for clinical milestone payments to this technology provider and royalties on commercial sales of the product.

We have contracted for the supply of the active pharmaceutical ingredient in JZP-7 in sufficient quantities to complete clinical trials. We intend to begin to seek a contract manufacturer for commercial quantities of JZP-7 following initiation of a Phase III trial.

New Product Candidate Identification and Development

Our program for identifying and developing new product candidates involves many disciplines across our company. We identify unmet patient needs and opportunities to improve upon existing therapies through market research, new product planning activities, interactions with thought leaders in neurology and psychiatry, and research and development. Once a potential product candidate is identified, we conduct feasibility activities to help us determine whether we can develop a product that may improve patients lives. In developing new product candidates, we access a broad range of available technologies and services from third party providers to help ensure our products will have the characteristics we desire.

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Through our feasibility activities and proof of concept studies, we attempt to determine if a product candidate has the requisite pharmacological activity, would be valuable to patients and healthcare providers, and could be developed within the timeframe and budget we find acceptable. We focus our early-stage activities on obtaining proof of concept for each product candidate at a relatively low cost, in order to eliminate some risks before we incur significant development expenses for the product candidate. We then execute a development program with a defined set of goals for the product candidate, and a series of development milestones by which we measure progress. The activities at each stage of development are designed to reduce risk, so that as a product candidate moves through the stages of development we can more confidently allocate additional resources to it.

Our program is designed to shorten the development cycle for our product candidates as compared with most new chemical entities. Because we generally work with known drug compounds, and compounds with the same mechanism of action or similar chemical structure as marketed products, we can often move from a proof of concept study directly into pivotal clinical trials. In certain cases where we develop new formulations of existing marketed compounds, we may only be required to complete one Phase III clinical trial, rather than the two Phase III clinical trials generally required for new chemical entities. If we are able to complete product development with fewer clinical trials than are required for a new chemical entity, we may have lower costs of development and shorter development timelines.

Our JZP-7 and JZP-8 product candidates resulted from this program. We currently have several other product candidates identified through this program in various stages of early development, including the use of sodium oxybate for the treatment of movement disorders. Other such early stage projects include a structural analog of valproic acid for the treatment of epilepsy and bipolar disorder licensed from Yissum, the technology transfer company of the Hebrew University of Jerusalem, and a triple reuptake inhibitor for the treatment of depression licensed from Faes Pharma S.A. We are also developing an oral tablet form of sodium oxybate.

We expect to begin more early-stage projects than will progress into later-stage development. If a product candidate does not successfully meet our requirements at any stage of development, we terminate the project. We also review our portfolio periodically to ensure that we have a balanced mix of product candidates moving into later stages of development across our therapeutic areas on a regular basis.

Sales and Marketing

As of March 21, 2008, we had a specialty sales force consisting of approximately 200 full-time sales professionals which include our Specialty Sales Consultants, Regional Sales Managers, and Area Business Directors, who currently promote Xyrem and will promote Luvox CR beginning in April 2008. Our Specialty Sales Consultants are experienced, with an average of eight years of specialty pharmaceutical selling experience. Our Regional Sales Management team has an average of eight years of specialty sales management experience and 16 years of industry experience. Our sales force calls primarily on psychiatrists, neurologists, pulmonologists and sleep specialists. If JZP-6 is approved by the FDA, we may further expand our specialty sales force to include additional sales professionals who would focus on specialists treating fibromyalgia. As other product candidates are approved by the FDA, we will assess the specific market needs and adjust our sales force deployment and size as appropriate.

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 significantly expanded our commercial operations in 2007 to accommodate promotional and marketing activities necessary to prepare for the commercial launch of Luvox CR. 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.

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Medical Affairs Department

We have a Medical Affairs Department consisting of approximately 18 professionals as of March 21, 2008 that provides medical information regarding our products to health care providers and handles related medical issues. Our Medical Affairs Department answers medical questions from health care professionals and provides them with publications on request. The medical education activities of our Medical Affairs Department focus on grants for continuing medical education activities and the creation of enduring educational materials. Our ten Medical Affairs scientists, who are based around the U.S, foster relationships with thought leaders and work with investigators who are interested in exploring novel uses of our products.

Customers and Financial Information about Geographic Areas

In the United States, Xyrem is sold to a specialty pharmacy which ships Xyrem directly to patients. Our other products in the United States are sold primarily to distributors who distribute our product to pharmacies. During the year ended December 31, 2007, the specialty pharmacy for Xyrem was Express Scripts, and the principal distributors for our other products were Cardinal Health and AmerisourceBergen, and outside the U.S., UCB Pharma.

Information on total revenues attributed to domestic and foreign sources is included in Note 18 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, Xyrem, Antizol and Antizol-Vet.

Pursuant to an agreement with Lonza which was originally executed in November 1996 and subsequently amended, we must 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, 2008 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. The quotas issued by the DEA for 2008 were greater than initially issued for 2007; however, we believe that the quota for 2008 may not be sufficient to satisfy all of our commercial and clinical needs. 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 both.

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Pursuant to a supply agreement with Solvay, we are responsible for purchasing, and Solvay is responsible for providing us with, 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 will be responsible for satisfying Solvay s commercial requirements of Luvox CR outside of the United States 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. We are also seeking or have identified qualified suppliers and contract manufacturers for JZP-4, JZP-8 and JZP-7.

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

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

Government Regulation

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

Drug Approval Process

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

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

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

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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 either an approval letter or an approvable 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 an approvable 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.

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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.

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.

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To the extent that the Section 505(b)(2) applicant is relying on the FDA s findings for an already-approved 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 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 the submission of 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

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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 an approved drug, that represents the first commercial marketing of that active pharmaceutical ingredient, 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.

Orphan Drug Designation and Exclusivity

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

The FDA designated and approved Xyrem as an orphan drug for each of cataplexy and excessive daytime sleepiness 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 of 2007, we received orphan drug designation from the FDA for JZP-8.

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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 authorizes the FDA to require pediatric studies for drugs to ensure the drugs safety and efficacy in children. The Pediatric Research Equity Act of 2003 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 Pediatric Research Equity Act of 2003. Unless otherwise required by regulation, the Pediatric Research Equity Act of 2003 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 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

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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 United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above. A World Health Organization (WHO) subcommittee 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. 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 United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include:

- controls on government funded reimbursement for drugs;
- 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.

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

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

Patents and Proprietary Rights

We actively seek to patent, or to obtain licenses to or to acquire third party patents, to protect our products, inventions and improvements that we consider important to the development of our business. We own eight issued U.S. patents and have rights to three 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 18 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 application filed 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. If a patent issues for this application, it would expire on May 10, 2020. We obtained a license to this patent application and any resulting patent that issues 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.

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

JZP-4. 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 52 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

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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.

JZP-8. 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-7. 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.

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

We have also applied for a number of trademarks and service marks to further protect the proprietary position of our products. We own 46 registered trademarks and service marks in the United States and 29 registered trademarks and service marks in other countries. We also have 30 pending trademark and service mark applications in the United States 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. 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.

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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 is Lyrica, an anticonvulsant marketed by Pfizer. In addition, Eli Lilly filed a sNDA for Cymbalta® (duloxetine) in August 2007, seeking FDA approval for the treatment of fibromyalgia, and Forest Laboratories and Cypress Bioscience jointly filed an NDA for milnacipran in December 2007, seeking FDA approval for the treatment of fibromyalgia.

For a more detailed description of current products that compete with Xyrem, please see Marketed and Approved Products Xyrem (sodium oxybate) oral solution Competition. For a more detailed description of current products that compete with Luvox CR, please see Marketed and Approved Products Luvox CR (fluvoxamine maleate) Extended Release Capsules Competition. For a more detailed description of current products that may be competitive with our product candidates, please see the descriptions under the headings Competition for each our product candidates described under Product Candidates.

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

efficacy, safety and reliability of our product candidates;

the timing and scope of regulatory approvals;

product acceptance by physicians and other health care providers;

our ability to expand and grow our specialty sales force;

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

the speed with which we develop product candidates;

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

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

obtaining reimbursement for product use in approved indications;

our ability to recruit and retain skilled employees; and

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

Employees

As of March 21, 2008, we had 409 full-time employees. Of the full-time employees, 228 were engaged in sales and marketing, 98 were engaged in manufacturing, product development and clinical activities, and 83 were engaged in general and administrative activities. We plan to continue to expand our product development programs and product commercialization activities. To support this growth, we will need to expand managerial, operations, development, manufacturing, regulatory, sales, marketing, financial and other functions. In particular,

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our potential future commercial products, including JZP-6, may require an expanded sales force and sales support organization. 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., 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 28, 2008:

Name	Age	Position
Bruce C. Cozadd	44	Executive Chairman and Director
Samuel R. Saks, M.D.	53	Chief Executive Officer and Director
Robert M. Myers	44	President
Matthew K. Fust	43	Executive Vice President and Chief Financial Officer
Carol A. Gamble	55	Senior Vice President, General Counsel and Corporate Secretary
Janne L.T. Wissel	52	Senior Vice President, Chief Regulatory 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 serves on the board of Cogentus Pharmaceuticals, a private company. He received B.S. and M.S. degrees from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

Matthew K. Fust was appointed as Executive Vice President in March of 2008 and has served as our Chief Financial Officer since 2003. From 2002 to 2003, he served as Chief Financial Officer at Perlegen Sciences, a biopharmaceutical company. He previously held various positions with ALZA Corporation from 1996 to 2002, most recently as its Chief Financial Officer. He serves on the board of Sunesis Pharmaceuticals, a biopharmaceutical company. He received a B.A. from the University of Minnesota and an M.B.A. from the Stanford Graduate School of Business.

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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.

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.

Recent Financings

On March 17, 2008, we expanded our secured indebtedness from $80 million to $120 million at face value. For a more detailed description of the expansion of our debt, please see Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources.

About Jazz Pharmaceuticals

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

Available Information

We file electronically with the U.S. Securities and Exchange Commission our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at *www.jazzpharmaceuticals.com*, free of charge, copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to the SEC. Further copies of these reports are located at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at www.sec.gov.

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Item 1A. Risk Factors

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

Risks Related to Our Business

We may not be able to successfully market or supply Luvox CR in the United States, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

On February 28, 2008, the FDA approved Luvox CR for the treatment of obsessive compulsive disorder and social anxiety disorder. Under the terms of our license agreement with Solvay, we made an initial payment of $2.0 million and will pay Solvay $10.0 million on March 28, 2008, $10.0 million on April 7, 2008, $10.5 million on September 30, 2008 and $10.5 million on December 31, 2008. Elan is manufacturing commercial launch quantities of Luvox CR for us. In anticipation of the commercial launch of Luvox CR, we significantly expanded our sales force, marketing and commercial operations departments and administrative staff in the fourth quarter of 2007. In addition, we have engaged numerous third party vendors, such as advertising agencies, market research firms and other service providers, to assist in the launch of Luvox CR. These expenses are significant and have been incurred prior to the commercial launch of Luvox CR in order for us to be prepared to launch the product as soon as possible following approval. Most of the costs cannot be recouped or applied to other products. If our efforts to market Luvox CR are not as successful as we currently anticipate, the time at which we could potentially become profitable would be postponed, or we might never become profitable, and our ability to raise additional funds could be impaired.

For quantities of Luvox CR that may be used for commercial launch, and for product that was used in clinical studies, Solvay manufactured the active pharmaceutical ingredient, fluvoxamine maleate. Solvay no longer manufactures the active pharmaceutical ingredient, and manufacturing has been transferred to Lonza which we expect will, in the future, be our sole source of fluvoxamine maleate. We cannot assure you that Lonza can or will supply, in the time we need, sufficient quantities of active pharmaceutical ingredient to enable Elan to manufacture the quantities of Luvox CR 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 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.

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 may not otherwise 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 conducting two Phase III pivotal clinical trials for the use of JZP-6 to treat fibromyalgia, 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. Our Phase III clinical program for JZP-6 is costly, and we do not expect to have preliminary results from our first Phase III study until the fourth quarter of 2008. We do not know if our ongoing Phase III pivotal clinical trials 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. Favorable results from our prior Phase II clinical trials with JZP-6 for the treatment of fibromyalgia may not be indicative of the clinical results from our Phase III pivotal clinical trials. Further,

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although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of cataplexy and excessive daytime sleepiness 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. Unsuccessful Phase III pivotal clinical trials 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, and our ability to raise funds could be impaired.

Lyrica (pregabalin), a product marketed by Pfizer, was approved by the FDA in June 2007 for the treatment of fibromyalgia. In addition to Lyrica, Eli Lilly submitted a sNDA for Cymbalta (duloxetine) in August 2007, and Forest Laboratories and Cypress Bioscience jointly filed an NDA for milnacipran in December 2007 seeking FDA approval for the treatment of fibromyalgia. With a treatment for fibromyalgia already approved and others that may be approved before JZP-6 and which the FDA may believe have a less risky profile to the general public if marketed, the FDA may be less willing to approve JZP-6 for the treatment of fibromyalgia.

Even if the FDA approves JZP-6 for the treatment of fibromyalgia, the FDA is likely to require us to have a risk management program similar to the one we use for Xyrem. Under the Xyrem risk management program, 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 physician s office and 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 patients may not receive more than a three month supply at any time.

The Xyrem risk management program is labor intensive, complex and expensive to operate. Since Xyrem is currently prescribed for a relatively small number of patients, the risk management program 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 risk management program is required for JZP-6, scale-up of the risk management program 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.

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

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despite having progressed successfully through initial clinical testing. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials. The completion of clinical trials for our product candidates may be delayed or halted for many reasons, including:

- delays in patient enrollment, and variability in the number and types of patients available for clinical trials;
- regulators or institutional review boards may not authorize us to commence or continue a clinical trial;
- our inability, or the inability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials;
- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective;
- difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data;
- poor effectiveness of product candidates during clinical trials;
- safety issues, including adverse events associated with product candidates;
- the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons;
- governmental or regulatory delays or changes in regulatory requirements, policy and guidelines; and
- varying interpretation of data by the FDA or foreign regulatory agencies.

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. Some of these companies have more significant financial and human resources than we do.

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

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

We design the clinical trials for our product candidates, but rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as their highest priority, or in the manner in which we would prefer, which could result in delays.

Although we rely on third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. The FDA enforces good clinical

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practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our contract research organizations or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA s current Good Manufacturing Practices, or 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.

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.

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

We have exclusively licensed to UCB the rights to market and promote Xyrem in 54 countries outside of the United States. If UCB does not obtain regulatory approvals for and launch Xyrem in its licensed countries in the time frames we expect, or at all, our revenues would be adversely affected. 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 and will continue to rely in part on milestone payments from UCB to

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offset our development costs of JZP-6. UCB has the right to terminate our collaboration on 18 months notice (or less in certain circumstances). If UCB terminates our collaboration, 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.

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

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the United States must be shipped directly to patients through a central pharmacy. The process under which patients receive Xyrem under our risk management program is cumbersome. While we have entered into an agreement with the central pharmacy for Xyrem, Express Scripts Specialty Distribution Services, 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 distributor 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 risk management program approved by the FDA. If we change distributors, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new distributor could result in product shortages, which would adversely affect sales of Xyrem in the United States.

Our supplier of the active pharmaceutical ingredient and our product manufacturer 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 United States in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem and JZP-6, sodium oxybate, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient and our product manufacturers must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our supplier s and contract manufacturer s DEA quotas, our supplier and contract manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. 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 quotas issued by the DEA for 2008 were greater than initially issued for 2007; however, we believe that the quota for 2008 may not be sufficient to satisfy all of our commercial and clinical 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 for the marketplace or JZP-6 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

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commercialized products and product candidates. 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, DEA quotas relating to Xyrem and JZP-6, and the limited market size for our approved products, 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.

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.

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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 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 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.

Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale. Luvox CR has only recently been manufactured on a commercial scale and the NDA for Luvox CR was previously withdrawn as a result of difficulties encountered during the scale-up of manufacturing.

Our product candidates have never been manufactured on a commercial scale and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. If our manufacturers are unable to produce sufficient quantities of our products for commercialization or at a cost that we expect, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Luvox CR, for which we have obtained the exclusive rights to market and distribute in the United States from Solvay and which was recently approved for commercial sale, is being manufactured for us by Elan in exchange for royalty and milestone payments and supply price payments. Luvox CR has never previously been produced on a commercial scale, and the NDA for Luvox CR was withdrawn in June 2001 by Solvay and Elan as a result of difficulties encountered during the scale-up of manufacturing of Luvox CR. Although the FDA has approved Luvox CR, there is no assurance that Elan will be able to manufacture Luvox CR without a higher batch failure rate than we expect or in sufficient quantities to meet potential future demand.

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

From time to time, there is negative publicity about 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 GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally. Xyrem s label includes information about adverse events from GHB, and we anticipate that if JZP-6 is approved, its label will include similar information. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Because of our dependence upon patient and physician perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products or any similar products distributed by other companies could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

In April 2006, we and our subsidiary Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. In April 2006, a physician who was a speaker for Orphan Medical, and for a short time for us, was indicted by a federal grand jury in the U.S. District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for us, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce.

We and Orphan Medical have settled this matter with the United States, acting through the Department of Justice, the U.S. Attorney s Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately $20.0 million in civil and criminal payments will be paid in connection with this matter. Of which $1.0 million was paid in July 2007 and $2.0 million was paid in January 2008; the remaining will be paid over the next four years. We agreed to guarantee payment of amounts payable by Orphan Medical.

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.

Even though we have executed definitive settlement agreements, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states attorneys general with respect to the activities covered by the settlement. We cannot predict whether this additional action will occur, nor can we reasonably estimate the amount of any fines or penalties that might result from an adverse outcome.

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 directly to consumers, 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 directly to consumers. Provigil, the only other product approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy,

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does not have a box warning and can be advertised directly to consumers. 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 recently approved a product for the treatment of fibromyalgia. This product 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 cataplexy and excessive daytime sleepiness 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 intend to market Luvox CR in the United States 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. Five branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including four selective serotonin reuptake inhibitors: Paxil, which is marketed by GlaxoSmithKline, Zoloft, which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly and Luvox which is not currently marketed. Anafranil, the other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the United States. Each of these products currently has generic equivalents. Generic products are generally sold at significantly lower prices than branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Four 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. Effexor XR, developed and sold by Wyeth, does not have generic competitors, whereas Paxil, Paxil CR and Zoloft 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. 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. Eli Lilly submitted a sNDA for Cymbalta in August, 2007 seeking FDA approval for the treatment of fibromyalgia, and Forest Laboratories and Cypress Bioscience jointly filed an NDA for milnacipran in December, 2007 seeking FDA approval for the treatment of fibromyalgia. These are large pharmaceutical companies with far greater resources than we have.

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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.

Our competitors may obtain FDA or other regulatory approvals for their product candidates more rapidly than we may. For example, other major pharmaceutical companies are conducting, or have completed, Phase III clinical trials of product candidates for the treatment of fibromyalgia. These product candidates may reach the market before JZP-6, or may be better accepted by physicians and patients. Thus, even if we successfully complete our Phase III 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, 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.

Orphan exclusivity for Antizol for ethylene glycol poisoning expired in 2004 and the orphan exclusivity for Antizol for methanol poisoning expired in December 2007. A generic form of fomepizole was introduced into the market in December 2007 and a second generic form of fomepizole was approved by the FDA in January 2008. We expect sales of Antizol to decline significantly in 2008 and thereafter as a result of this competition. We have filed a patent application covering Antizol, but no patent has yet issued and we cannot know when, or if, a patent will issue or if issued, if it would prevent or inhibit generic competition. 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 with claims covering the formula and process for manufacturing our commercial formulation of Xyrem, it is possible that other companies could manufacture generic equivalents of Xyrem 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 risk management program for its distribution, and therefore generic competition may be more difficult and expensive than it might be for other products not requiring a risk management program 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.

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Luvox CR is covered by a patent application filed by Elan with claims covering the orally administered extended release formulation of fluvoxamine. This patent may not issue, and even if this patent issues, 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 commercializing 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 United States 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 enter into acceptable agreements to commercialize our products in international markets.

If appropriate regulatory approvals are obtained, we generally intend to commercialize our products in most markets outside of the United States through arrangements with third parties. If we decide to sell our products in markets outside of the United States, we may not be able to enter into any arrangements on acceptable terms, or at all. In addition, these arrangements could result in lower levels of income to us than if we promoted our products directly in international markets. If we choose to market our products directly in markets outside of the United States, we may not be able to develop an effective international sales force. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenues outside of the United States would be limited. In either case, our marketing efforts (and those of our partners) outside of the United States may be subject to regulatory requirements and politico-economic climates that are dissimilar to those in the United States and which could impose unforeseen costs or restrictions on us or our partners.

We may not be able to successfully acquire or in-license additional products or product candidates as part of growing our business.

In order to grow our business, we intend to acquire or in-license additional products and product candidates that we believe have significant commercial potential. Any growth through acquisitions or in-licensing will be dependent upon the 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. 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 we are unable to appropriately expand our specialty sales force and sales organization in the United States to adequately promote our current and potential future products, the commercial opportunity for our products may be diminished.

We recently expanded our sales force significantly in anticipation of the launch of Luvox CR. We cannot be sure that we will retain these new sales representatives, or that they will be effective at promoting our commercial products. Our potential future commercial products, including JZP-6, may require further 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

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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 will also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel. If we elect to rely on third parties to sell our products in the United States, we may receive less revenue or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately expand 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 attract and 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 attract, retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team. 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.

Competition for qualified personnel in the life sciences industry is intense. We will need to hire additional personnel as we expand our development, clinical and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms. We do not carry key person insurance. Although the members of our executive management team have employment contracts with us through February 2009, each member of our executive management team and each of our other key employees may terminate his or her employment at any time without notice and without cause or good reason.

We will need to maintain and increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company, with 409 regular full-time employees as of March 21, 2008, approximately 55% of whom joined us in the previous 12 months. To continue our commercialization and development activities, we will need to retain our existing employees and expand our employee base for managerial, operations, development, regulatory, sales, marketing, financial and other functions. It is particularly difficult to recruit new employees to the San Francisco Bay Area, where our offices are located, in large part due to high housing costs. If we cannot recruit qualified employees when we need them, our key activities could be delayed. Growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, particularly with respect to our expanded sales and marketing organization and related functions for the commercialization of Luvox CR and potential commercialization of our product candidates. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any growth 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.

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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 United States and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. 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

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is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents or in or our licensed patents or those of our partners, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party s activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Patent infringement lawsuits are costly and could affect our results of operations and divert the attention of management and development personnel. There is a risk that a court could decide that we or our partners are infringing third party patent rights. In the event that we or our partners are found to infringe any valid claim of a patent held by a third party, we may, among other things, be required to:

- pay damages, including up to treble damages and the other party s attorneys fees, which may be substantial;
- cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;
- expend significant resources to redesign our products so they do not infringe others patent rights, which may not be possible;

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discontinue manufacturing or other processes incorporating infringing technology; or

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

The pharmaceutical and life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the United States.

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

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

Risks Related to Our Industry

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

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

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 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.

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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 United States or overseas or at our contract manufacturers facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers facilities, or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products 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. 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

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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. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company s products from reimbursement under government programs, criminal fines and imprisonment. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and 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

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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 United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because Luvox CR will compete in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts 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. Since Luvox CR has only recently been approved, we do not yet know what the reimbursement levels and other requirements will be for that product.

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 presidential primary campaign, various candidates have been discussing 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.

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Sales of our products in the United States 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 Antizol, which accounted for $13.9 million and $12.5 million in net product sales in 2007 and in 2006, respectively, and the market participants to whom we expect to sell most of our future products, including Luvox CR, 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 United States of personal use quantities of FDA-regulated products in personal baggage and mail when the product does not present an unreasonable risk to the user. Thus, individuals may import prescription drugs that are unavailable in the United States from Canada and other countries for their personal use under specified circumstances. Other imports, although illegal under U.S. law, also enter the country as a result of the resource constraints and enforcement priorities of the FDA and the U.S. Customs Services. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 will permit pharmacists and wholesalers to import prescription drugs into the United States from Canada under specified circumstances. These additional import provisions will not take effect until the Secretary of Health and Human Services makes a required certification regarding the safety and cost savings of imported drugs and the FDA has promulgated regulations setting forth parameters for importation. These conditions have not been met to date and the law has therefore not taken effect. However, legislative proposals have been introduced to remove these conditions and implement changes to the current import laws, or to create other changes that would allow foreign versions of our products priced at lower levels than in the United States to be imported or reimported to the United States from Canada, Europe and other countries. If these provisions 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 United States. Due to the risk management program for Xyrem and our agreement with Valeant, we believe that it is unlikely that Xyrem will be imported from Canada to the United States.

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

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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 Our Financial Condition

We have a history of net losses, which we expect to continue for at least several years and, as a result, we are unable to predict the extent of any future losses or when, if ever, we will become profitable.

We have a limited operating history and have incurred significant net losses since our inception in 2003, and we expect to continue to incur net losses for the next several years. Our net loss for the year ended December 31, 2007 was $138.8 million and we had an accumulated deficit of $316.5 million at December 31, 2007. We expect our operating expenses to increase over the next several years as we launch Luvox CR, develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We will need to expand our commercial organization to launch additional products. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

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.

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Our operations have generated negative cash flows, and if we are unable to secure additional funding when we need it, we may be required to reduce operations.

As of December 31, 2007, we had approximately $102.9 million in cash and cash equivalents. Our net cash used in operations for the year ended December 31, 2007 was approximately $81.1 million. Substantially all of our $53.5 million in net product sales during the year ended December 31, 2007 resulted from sales of Xyrem and Antizol. Sales of Antizol are likely to decrease substantially in 2008 due to generic competition, and sales of Xyrem could decrease due to adverse market conditions, negative publicity or other events outside our control. We must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials of our product candidates and significant funds to our commercial operations. We believe that our current cash and cash equivalents and interest earned thereon, together with future financings and anticipated revenues from product sales and royalties will be sufficient to satisfy our current operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect. 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 Luvox CR and Xyrem in the United States, including the cost and timing of expanding our marketing and sales capabilities;
- revenues from current and potential future development and/or commercial collaboration partners;
- the scope, rate of progress, results and costs of our preclinical studies, clinical trials 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.

Although we generate product revenues, since our inception in 2003 we have financed our operations primarily through the sale of preferred stock, the issuance of senior secured notes and warrants, a line of credit, development financing related to one of our previous product candidates, our collaboration with UCB related to Xyrem and JZP-6 and the sale of common stock in our initial public offering.

We will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and commercial operations. We may also be required to license to third parties products and product candidates that we would prefer to develop and commercialize ourselves or to sell the rights to one or more commercial products to third parties. We may seek to raise additional funds through development financings, collaborations, or public or private debt or equity financings. If we raise funds through

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collaborations, 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. 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 may be dilutive to our stockholders. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development or commercialization or our products. Our failure to raise capital when needed may harm our business and operating results.

We are launching Luvox CR and, as is the case with new product launches, we cannot predict with certainty the timing or level of Luvox CR sales. If sales of Luvox CR do not reach the levels we expect and if we do not generate additional cash resources from financings or partnering activities, we may be unable to meet our cash requirements under our current operating plan. If product sales do not meet our expectations and we do not raise additional funds, we will need to reduce our planned expenditures, perhaps significantly, to preserve our cash. If necessary, we would implement, beginning as early as the third quarter of 2008, appropriate plans and measures to quickly reduce discretionary spending and capital expenditures, terminate or slow one or more of our product development programs, reduce headcount, license or sell some of our product candidates or products, or implement a combination of these and other cost cutting measures.

We have a substantial amount of debt, which may adversely affect our cash flows and our ability to operate our business.

On March 17, 2008, we incurred $40 million of additional secured indebtedness in connection with the expansion of our senior debt to $120 million at face value, of which $80 million had been incurred previously. Our substantial debt combined with our other financial obligations and contractual commitments could have other important consequences. For example, it could:

- make us more vulnerable to adverse changes in general 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, capital expenditures, acquisitions and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- place us at a competitive disadvantage compared to our competitors who have less debt; and
- limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

Any of these factors could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, under specified circumstances, our lenders could demand repayment of all or a portion of our debt, including if annualized net sales of our products fall below certain specified levels, which would have a material adverse effect on our business, financial condition and results of operations. If we do not have sufficient earnings to service our debt, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner or at all.

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

Our senior secured debt contains, 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;
- repay a portion of the debt early under certain circumstances; and
- maintain restricted cash balances under certain circumstances.

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.

Investors who purchase our common stock may not be able to sell their shares at or above the purchase price. Security prices for companies similar to us experience significant price and volume fluctuations. The following factors, in addition to other risks described herein, may have a significant effect on our common stock market price:

- the success of Luvox CR in the United States;
- the success of our development efforts and clinical trials;
- 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;
- 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;

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

our ability or inability to raise additional capital and the terms on which we raise it;

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;

conditions or trends in the pharmaceutical industry, the financial markets or the economy in general;

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.

In addition, the stock market in general and the market for life sciences companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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, 2007, we had 24,620,829 shares of common stock outstanding. The 6,000,000 shares of common stock sold in our initial public offering are freely tradable without restrictions or further registration under the Securities Act of 1933, as amended. The remaining 18,620,829 shares of common stock outstanding as of December 31, 2007, 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), are now 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 December 31, 2007, 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 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, on or before June 6, 2008, 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, and the shares underlying the warrants we may issue in a further expansion of that debt. In addition, we have filed a registration statement on Form S-8 under the Securities Act of 1933, as amended, to register up to 4,957,794 shares of our common stock 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.

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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 25, 2008, our executive officers and directors, together with their respective affiliates, beneficially owned 58.3% of our capital stock, of which 7.9% is beneficially owned by our executive officers. Accordingly, our executive officers and directors 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, 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. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning with our annual report on Form 10-K for the fiscal year ending December 31, 2008. 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.

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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

Not applicable.

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 $798,000. In February 2008, we exercised our option to extend the lease on the building for one year beginning August 31, 2008. We may extend the term for up to an additional nine years to August 2017. We lease a second facility of approximately 13,000 square feet of office space in Palo Alto, California. The annual lease payments for this space are approximately $317,000. The fixed lease term expires in August 2008 and cannot be extended. In August 2007, we signed a 24 month lease for approximately 11,000 square feet of space in Palo Alto, California with annual lease payments of approximately $419,000 per year.

We may need to lease additional space in or near our current facilities to accommodate future growth.

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Item 3. Legal Proceedings

In April 2006, we and our wholly owned subsidiary, 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 April 2006, a physician who was a speaker for Orphan Medical, and for a short time for us, was indicted by a federal grand jury in the United States District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the United States Food and Drug Administration, or FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for us, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce. This investigation has resulted in adverse publicity for Xyrem and for us.

On July 13, 2007, we entered into (i) a civil settlement agreement (the Civil Settlement Agreement) with the United States of America, acting through the United States Department of Justice, the United States Attorney s Office for the Eastern District of New York, the Office of Inspector General of the Department of Health and Human Services (HHS-OIG), the United States Office of Personnel Management and the United States Department of Defense TRICARE Management Activity to resolve the governmental investigation related to the promotion of Xyrem and (ii) a non-prosecution agreement with the United States Attorney s Office for the Eastern District of New York (the Non-prosecution Agreement) under which the United States Attorney s Office agreed we would not be prosecuted for the matters that were the subject of the investigation. Orphan Medical, which we acquired in June 2005, entered into (i) a plea agreement with the United States Attorney s Office for the Eastern District of New York (the Plea Agreement), under which Orphan Medical pled guilty, on July 13, 2007, to one felony count of introducing a misbranded drug into interstate commerce and (ii) the Civil Settlement Agreement. We expect that both Jazz Pharmaceuticals and Orphan Medical will also enter into agreements with Medicaid participating states, although to date the states have not provided us with any drafts of such agreements.

Pursuant to the Civil Settlement Agreement and the Plea Agreement, payments totaling approximately $20.0 million are required to be made over the period from July 20, 2007 through January 15, 2012. The total includes payments to Federal healthcare programs and Medicaid participating states, as well as restitution and fines. In addition, under the Non-prosecution Agreement, we agreed to guarantee payment by Orphan Medical of the amounts due under the Plea Agreement. The total payments due under the Civil Settlement Agreement and the Plea Agreement are payable 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. All remaining amounts due under the Civil Settlement Agreement could be accelerated if we are acquired, or in the event of an uncured default resulting from the failure to make payments when due. In addition, all or a portion of the remaining amounts due under the Civil Settlement Agreement could be accelerated if we have net income in any year. Orphan Medical, which no longer directly markets products, may be excluded from participation in Federal healthcare programs as a result of the settlement.

We also entered into a five-year corporate integrity agreement with HHS-OIG (the Corporate Integrity Agreement) pursuant to which we agreed, among other things, to keep in place and continue our current compliance program which includes a compliance committee, a compliance officer, a code of conduct, comprehensive compliance policies, training and monitoring, a compliance hotline, an open door policy and a disciplinary process for compliance violations. We have agreed to provide periodic reports to HHS-OIG and our compliance program will be reviewed by an independent review organization.

The settlement is neither an admission of liability by us nor a concession by the United States that its claims are not well founded. Participation in Federal healthcare programs by Jazz Pharmaceuticals, which was not prosecuted, will not be affected by the settlement. In the event of an uncured material breach or deliberate

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violation, as the case may be, of the Civil Settlement Agreement, the Corporate Integrity Agreement or the Non-prosecution Agreement, we could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

The Plea Agreement was approved by the United States District Court for the Eastern District of New York on July 13, 2007.

While we have reached a settlement agreement with the United States Attorney s Office, and the other government agencies described above, we might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states attorneys general with respect to activities covered by the settlement. We cannot predict whether these actions are likely to occur, nor can we reasonably estimate the amount of any fines or penalties that might result from an adverse outcome.

On April 10, 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against Orphan Medical and former officers of Orphan Medical in the Untied States District Court for the District of Minnesota. The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by Orphan Medical in connection with the solicitation of proxies to be voted at the special meeting of Orphan Medical stockholders held on June 22, 2005. The purpose of the special meeting was to consider and vote upon a proposal to adopt the definitive merger agreement pursuant to which we acquired Orphan Medical. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the United States District Court for the District of Minnesota. On February 16, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint, with leave to amend. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. Oral argument on the motion was heard on June 8, 2007. On September 13, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint with prejudice. On September 28, 2007, the plaintiff filed a Notice of Appeal to the United States Court of Appeals for the Eighth Circuit. On November 21, 2007 the plaintiff filed its brief with the United States Court of Appeals for the Eighth Circuit. On December 21, 2007 the defendants filed their brief with the United States Court of Appeals for the Eighth Circuit. On January 8, 2008 the plaintiff filed a reply brief. Oral arguments have not yet been scheduled. We cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome.

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

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

None

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PART II

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

Market Information

The following table sets forth the high and low sales prices of our common stock, par value $.0001, on the Nasdaq Global Market under the symbol JAZZ from June 1, 2007 through December 31, 2007 for the periods indicated.

	High	Low
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 25, 2008, the last reported sales price per share of our common stock was $10.03 per share.

Holders of Common Stock

As of March 25, 2008, there were 57 holders of record of our common stock.

Recent Sales of Unregistered Securities

From January 1, 2007 to December 31, 2007, we issued and sold the following unregistered securities (as adjusted to give effect to the 1-for-11.06701 reverse split of our common stock and preferred stock effected on May 15, 2007):

(1) From January 1, 2007 to March 6, 2007, we sold an aggregate of 5,017 shares of our common stock for cash consideration in the aggregate amount of $75,975.31 upon the exercise of stock options granted under our 2003 Equity Incentive Plan.

(2) On February 13, 2007, we granted stock options under our 2003 Equity Incentive Plan covering an aggregate of 100,259 shares of common stock, at an exercise price of $19.37 per share.

(3) On February 27, 2007, we granted stock options under our 2003 Equity Incentive Plan covering an aggregate of 180,719 shares of common stock, at an exercise price of $19.37 per share.

(4) On May 31, 2007, we granted stock options under our 2007 Equity Incentive Plan covering an aggregate of 84,096 shares of common stock, at an exercise price of $18.00 per share.

The offers, sales and issuances of the securities described in paragraphs (1), (2) and (3) were deemed exempt from registration under the Securities Act under in reliance on either (1) Rule 701 promulgated under the Securities Act as offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701 or (2) Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were our employees or directors and received the securities under our 2003 Equity Incentive Plan or 2007 Equity Incentive Plan, as applicable. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment or business relationships, to information about us.

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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 approximately $97.5 million after underwriters discounts of approximately $7.6 million and other expenses of $2.9 million.

As of December 31, 2007, we had used approximately $36.8 million 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 continued development of and feasibility activities for our portfolio of clinical and early-stage product candidates. We intend to use the remaining net proceeds to fund the planned U.S. launch and commercialization of Luvox CR, including for milestone payments to Solvay in connection with the acquisition of our U.S. rights to Luvox CR, to fund our Phase III pivotal clinical trials of JZP-6 and to fund continued development of and feasibility activities for our portfolio of clinical and early-stage 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. We continually assess the specific uses and allocations for these funds. Pending use of the remaining net proceeds of this offering, we have invested the funds in short-term, interest bearing, investment grade securities.

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.

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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, 2007. 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.

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

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Item 6. Selected Financial Data

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

The selected consolidated statements of operations data for the period from March 20, 2003 (date of inception) through December 31, 2003 and the selected consolidated balance sheet data as of December 31, 2003, 2004 and 2005 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. We derived the consolidated statements of operations data for the years ended December 31, 2007, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2007 and 2006 from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				Period from March 20, 2003 (Inception) to
	2007	2006(1)	2005(2)	2004	December 31, 2003
	(In thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net	$ 53,536	$ 43,299	$ 18,796	$	$
Royalties, net	1,156	594	146		
Contract revenues	10,611	963	2,500		
Total revenues	65,303	44,856	21,442		
Operating expenses:					
Cost of product sales (excluding amortization and impairment of acquired developed technology)	8,903	6,968	4,292		
Research and development	69,792	54,956	45,783	17,988	
Selling, general and administrative	78,540	51,384	23,551	7,459	2,538
Intangible asset amortization	9,217	9,600	4,960		
Intangible asset impairment	20,160				
Provision for government settlement	17,469				
Purchased in-process research and development			21,300		
Total operating expenses	204,081	122,908	99,886	25,447	2,538
Loss from operations	(138,778)	(78,052)	(78,444)	(25,447)	(2,538)
Interest income	5,942	2,307	1,318	643	10
Interest expense (including $9,193, $9,024 and $4,595 for the years ended December 31, 2007, 2006 and 2005, respectively, pertaining to related parties)	(13,647)	(14,129)	(7,129)		
Other income (expense)	1,797	(1,109)	(901)		
Gain on extinguishment of development financing obligation		31,592			
Gain on sale of product rights	5,860				
Net loss	(138,826)	(59,391)	(85,156)	(24,804)	(2,528)
Beneficial conversion feature		(21,920)			
Loss attributable to common stockholders	$ (138,826)	$ (81,311)	$ (85,156)	$ (24,804)	$ (2,528)
Loss per share attributable to common stockholders, basic and diluted	$ (10.04)	$ (6,254.69)	$ (14,192.67)	$ (1,550.25)	$ (81.55)

Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	13,829	13	6	16	31

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(1) In the year we adopted SFAS No. 123(R), Share-Based Payment, operating expenses included stock-based compensation expense of $3.5 million of which $8,000, $661,000 and $2.8 million were charged to cost of product sales, research and development and selling, general and administrative expense, respectively.

(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,				
	2007	2006	2005	2004	2003
			(In thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 102,945	$ 78,948	$ 20,614	$ 33,678	$ 4,460
Working capital	79,235	61,043	8,048	36,663	4,488
Total assets	207,554	214,571	164,781	42,850	4,900
Liability under government settlement	14,881				
Senior secured notes (including $52,581, $51,998 and $50,620 as of December 31, 2007, 2006 and 2005, respectively, held by related parties)	75,116	74,283	73,629		
Convertible preferred stock		263,852	163,862	64,009	7,076
Common stock subject to repurchase	13,241	8,183	5,924	3,665	
Accumulated deficit	(316,469)	(177,643)	(118,252)	(27,332)	(2,528)
Total stockholders equity (deficit)	54,992	(176,296)	(118,248)	(30,923)	(2,512)

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

The following discussion of our financial condition and 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. 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 identifying, 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 and 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. By working with these drug compounds, we believe that we can substantially mitigate the risks and reduce the costs and time associated with product development and commercialization of new therapies with significant market opportunities. Through the application of novel formulations and drug delivery technologies, we also explore potential new indications for known drug compounds. 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 $53.2 million in 2007, one product approved by the U.S. Food and Drug Administration, or FDA, on February 28, 2008 which we are currently launching, and four product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our marketed and approved products are:

Xyrem® (sodium oxybate) oral solution. Xyrem is the only product approved by the FDA for the treatment of both cataplexy and excessive daytime sleepiness in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain s inability to regulate sleep-wake cycles. According to the National Institutes of Health, 150,000 or more individuals in the United States are affected by narcolepsy. We promote Xyrem in the United States to neurologists, psychiatrists, pulmonologists and sleep specialists through our approximately 200 person specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the United States to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB markets Xyrem in 14 countries. In 2007, Xyrem net sales were $39.0 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 recently shipped initial quantities of Luvox CR to wholesalers. We will promote the product through our recently expanded specialty sales force of approximately 200. Luvox CR is a once-daily extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor. Selective serotonin reuptake inhibitors 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 United States, respectively. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We

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obtained the exclusive rights to market and distribute Luvox CR in the United States from Solvay in January 2007. Solvay retains the rights to market and distribute Luvox CR outside of the United States. During 2007 we made, and during 2008 we expect to make, significant expenditures relating to the commercial launch of Luvox CR.

Antizol® (fomepizole). Antizol is an FDA-approved antidote for suspected or confirmed ethylene glycol or methanol poisonings in humans. We market Antizol primarily to hospitals and emergency rooms. Antizol is distributed to wholesalers in the United States, and we retain the services of a third party to promote the product. Antizol is marketed by our distributors in Canada and Israel. We also market Antizol-Vet, an injectable formulation of fomepizole approved as an antidote for suspected or confirmed ethylene glycol poisonings in dogs. In 2007, Antizol and Antizol-Vet net sales were $14.2 million. In December 2007, a generic fomepizole was approved and is now available in the United States, and in early 2008, a second generic fomepizole product was approved by the FDA. As a result, we expect that sales of Antizol will decrease substantially during 2008.

Our clinical development pipeline consists of the following product candidates:

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. We have successfully completed a Phase II clinical trial of this product candidate for the treatment of fibromyalgia. We are currently conducting two Phase III pivotal clinical trials, and we expect preliminary data from the first Phase III pivotal clinical trial in the fourth quarter of 2008. In Phase II clinical trials, JZP-6 achieved a statistically significant improvement compared to placebo in pain based on the pain visual analog scale, which the FDA and the European Agency for the Evaluation of Medicinal Products have indicated is the appropriate primary endpoint for our Phase III pivotal clinical trials. Subject to successful completion of the Phase III clinical trials, 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 United States to specialists who treat fibromyalgia patients, through an expanded specialty sales force or in partnerships with third parties. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the United States.

JZP-4 (sodium channel antagonist). JZP-4, a controlled release formulation of an anticonvulsant that is believed to work both through a similar mechanism of action as Lamictal® (lamotrigine), an antiepileptic drug marketed by GlaxoSmithKline for the treatment of epilepsy and bipolar disorder. According to the Epilepsy Foundation, approximately 2.7 million people in the United States suffer from epilepsy, and according to the National Institute of Mental Health, approximately 5.7 million people in the United States are affected by bipolar disorder.

JZP-8 (intranasal clonazepam). JZP-8, an intranasal formulation of clonazepam, is being developed 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.

JZP-7 (ropinirole gel). JZP-7, a transdermal gel formulation of ropinirole, is being developed for the treatment of restless legs syndrome. Dopamine is naturally produced by the human body, and in the brain, dopamine functions to help nerve cells communicate. A dopamine agonist is a drug compound that mimics the effects of dopamine. According to the Restless Legs Syndrome Foundation, up to 10% of the U.S. population suffers from restless legs syndrome.

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We have an ongoing program for generating, identifying and conducting feasibility studies for new product candidates. Our JZP-7 and JZP-8 product candidates resulted from this program. Several other product candidates identified through this program are in various stages of early development, including the use of sodium oxybate for the treatment of movement disorders. Other such early stage projects include a structural analog of valproic acid for the treatment of epilepsy and bipolar disorder licensed from Yissum, the technology transfer company of the Hebrew University of Jerusalem, and a triple reuptake inhibitor for the treatment of depression licensed from Faes Pharma S.A. We are working on ways to expand our Xyrem franchise by developing improvements to Xyrem, such as an oral tablet form, that could be more convenient for patients. These activities are in the early stages of development.

On June 6, 2007, we completed our initial public offering of 6,000,000 shares of our common stock at a public offering price of $18.00 per share. Net cash proceeds from the initial public offering were approximately $97.5 million, after deducting underwriting discounts and commissions and offering expenses.

In July 2007, we and our wholly-owned subsidiary, Orphan Medical, Inc., settled a matter relating to an investigation by the United States, acting through the Department of Justice, the United States Attorney s Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General of the United States Department of Health and Human Services or HHS-OIG. 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 over the next several years in connection with this matter, of which $1.0 million and $2.0 million were paid in July 2007 and January 2008, respectively. We have agreed to guarantee payment of amounts payable by Orphan Medical. We were not prosecuted; however, as part of the settlement we entered into a corporate integrity agreement with the HHS-OIG. That agreement requires us to maintain a comprehensive compliance program, which we have in place, and we will have additional ongoing compliance-related operating costs related to our compliance program and the corporate integrity agreement. See Note 8 to our consolidated financial statements for additional details regarding this settlement.

In December 2007, after orphan drug exclusivity for Antizol (fomepizole) for methanol poisoning expired, a generic fomepizole product was introduced. Prior to this, we had believed that Antizol would not be of interest to generic drug manufacturers due to the small market size, the long expiry dating of our product and other factors. As a result of this competition, we performed an impairment test on the intangible asset associated with Antizol using revised, lower sales forecasts, and we recorded an impairment charge of $20.2 million. Prior to the impairment, the remaining useful life of this intangible asset was approximately 7 years. As a result of the impairment, the remaining useful life was reduced to two years and the net book value of this intangible asset associated with Antizol was $2.7 million as of December 31, 2007. In addition we wrote down the value of Antizol inventory held in excess of our estimated requirements and recorded a charge of $485,000. We expect revenues from sales of Antizol to decrease significantly in 2008 and in subsequent years.

Since our inception, we have incurred significant net losses, and we expect to continue to incur net losses for the next several years as we develop, acquire or in-license additional products or product candidates, expand clinical trials for our product candidates currently in clinical development, expand our research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We have expanded our commercial organization significantly in anticipation of the launch of Luvox CR. It is very expensive to launch a product, and many expenses are incurred before revenues are received. We are unable to predict the extent of any future losses or when we will become profitable, if at all. In addition, we will need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations.

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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,		
	2007	2006	2005(3)
Xyrem	$ 39,018	$ 29,049	$ 11,200
Antizol(1)	14,153	12,813	6,782
Cystadane(2)	365	1,437	814
Total	$ 53,536	$ 43,299	$ 18,796

(1) Includes sales of Antizol-Vet, which were $251,000, $313,000 and $99,000 in 2007, 2006 and 2005, respectively.
(2) We sold our rights to Cystadane to a third party in March 2007.
(3) Includes only approximately six months of product sales, subsequent to our acquisition of Orphan Medical in June 2005.

Xyrem (sodium oxybate) oral solution. Revenues from sales of Xyrem represented primarily sales in the United States to Express Scripts. Revenues from sales of Xyrem under our agreements with UCB and Valeant have not been material. Orphan drug exclusivity for Xyrem in the United States expires in 2009 for the treatment of cataplexy in patients with narcolepsy, and in 2012 for the treatment of excessive daytime sleepiness in patients with narcolepsy.

Antizol (fomepizole). Revenues from sales of Antizol in the United States represented primarily sales to pharmaceutical wholesalers. Antizol is stocked by hospitals for use in emergency rooms and sales are typically uneven from quarter to quarter. Our sales of Antizol to distributors outside of the United States have not been material. As a result of generic competition, we believe that revenues from sales of Antizol will decrease significantly in 2008 and in subsequent years.

Cystadane (betaine anhydrous). We sold our rights to Cystadane in March 2007 for $9.0 million and recorded a gain of $5.1 million. Accordingly, we will not receive future revenues from the sale of this product.

Royalties, Net

We receive royalties primarily from international distributors of our products, typically based on their net sales of our products. Royalty income was $1.2 million, $594,000 and $146,000 in the years ended December 31, 2007, 2006 and 2005, 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 which will offset a decrease in income due to a license we sold in 2007.

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 $2.5 million in November 2005, $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 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. This amortization resulted in $1.1 million and $463,000 of contract revenues during the years ended December 31, 2007 and 2006, respectively.

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Significant Customers

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

	Year Ended December 31,		
	2007	2006	2005
Express Scripts	59%	65%	51%
UCB Pharma Limited	18%	*	12%
Cardinal Health	*	12%	*
AmerisourceBergen	*	*	15%

* Less than 10% of our total revenues.

Research and Development Expenses

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 salaries, costs of non-clinical studies, including toxicity studies in animals, costs of contract manufacturing services, costs of materials used in clinical trials and non-clinical studies, fees paid to third parties for development candidates or drug delivery or formulation technologies that we have licensed, allocated expenses, such as facilities and information technology that support our research and development activities, and related personnel expenses, including stock-based compensation. Research and development costs are expensed as incurred, including payments made under our license agreements for product candidates in development.

Conducting a significant amount of research and development is central to our business model. During 2007, we incurred approximately $69.8 million in research and development expenses, and we plan to continue to make significant investments in research and development for the foreseeable future in order to realize the potential of our portfolio of product candidates and earlier-stage research and development projects. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and length of the clinical trials.

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 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 Other projects. We do not allocate salaries, benefits or other indirect costs to our development candidates or Other projects, but include these costs in R&D support in the following table. The following table summarizes our research and development expenses for JZP and other projects currently under development for the years ended December 31, 2007, 2006 and 2005, and, for ongoing JZP projects, from project inception through December 31, 2007 (in thousands):

	Year Ended December 31,			Project Inception to December 31,
	2007	2006	2005	2007
JZP-6	$ 24,457	$ 14,209	$	$ 38,666
JZP-4	9,040	6,699	2,141	17,880
Luvox CR	8,434			8,434
JZP-7	1,955	1,328	150	3,433
JZP-8	1,399	1,403	313	3,115
Terminated projects	(217)(1)	15,728(2)	34,753(2)	
Other projects	2,566	1,834	97	
R&D support	22,158	13,755	8,329	
Total	$ 69,792	$ 54,956	$ 45,783	

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(1) Benefit resulted from a $1.3 million partial refund of a milestone payment we made to a third party related to a project terminated in 2005.
(2) Primarily includes costs associated with a product candidate in development which was cancelled in 2006.

During the year ended December 31, 2007, our research and development expenses for Luvox CR consisted primarily of a $2.0 million payment upon execution of a product license agreement and $6.4 million of expenses in connection with the scale-up for commercial manufacturing of Luvox CR, which includes $3.0 million for pre-launch inventory manufactured for, but in advance of, launch.

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 our program for identifying and developing new product candidates is designed 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.

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 are recorded as deferred revenues and recognized when earned.

Product Sales, Net

Revenues from sales of Xyrem within the United States 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. Antizol is, and prior to the sale of our rights Cystadane was, shipped to our wholesaler customers in the United States with free on board destination shipping terms, and we recognize revenues when delivery occurs. Our international sales often have customer acceptance clauses and therefore we recognize revenues when we are notified of acceptance or when the time to inspect and reject the shipment has lapsed. When sales to international customers do not have acceptance clauses, we recognize revenues when title transfers, which is generally when the product leaves our logistics providers facilities.

Revenues from sales of products within the United States are recorded net of estimated allowances for specialty distributor and wholesaler fees, prompt payment discounts, Medicaid rebates, government chargebacks and customer rebates. Calculating these items involves estimates and judgments based primarily on sales or

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invoice data and historical experience. Due to the nature of our current products, product returns have been infrequent and immaterial. Our allowances and adjustments to estimates for allowances have not historically been material.

There are a significant number of uncertainties involved in estimating net product sales for recently launched products. As a result it may be difficult for us to obtain sufficient data upon launch to estimate provisions for chargebacks, rebates, sales incentives and allowances, royalties, distribution service fees, returns and losses. As a result it is possible that we may not record any revenues from sales of Luvox CR for a significant period after the product is launched. When we do recognize revenue from sales of Luvox CR, it may be subject to greater period to period fluctuations than products with a long established history.

Specialty Distributor and Wholesaler Fees. Express Scripts, our sole Xyrem distributor in the United States, provides services such as collecting patient registry information, providing reimbursement support, providing nursing assistance, distributing educational materials and administering a patient co-payment rebate program. The fees we pay to Express Scripts for these services and the cost of the patient rebate program, for which we reimburse Express Scripts, are recorded as a reduction of Xyrem product sales and are based on actual invoices for services and rebates earned rather than estimates. Since most of the fee is based primarily on product shipments, our allowance related to these fees would generally increase in proportion to increases in sales. We paid fees to Express Scripts of $1.5 million, $1.4 million and $546,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

Our service agreements with certain U.S. wholesaler customers require us to pay them fees. Wholesaler fees totaled $147,000, $203,000 and $64,000 for the years ended December 31, 2007, 2006 and 2005, respectively. These fees are likely to increase substantially as a result of the sales of Luvox CR, and they may also increase if we modify our existing 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 the first 30 days after the date of our invoice. In addition, we have 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, based on the gross amount of each invoice, at the time of our original sale to them, and we apply earned discounts at the time of payment. We adjust the allowance to reflect actual experience as necessary and, as a result, the actual amount recognized in any period may be slightly different from our allowance amount. Adjustments have not been material and we do not anticipate that changes to estimates will have a material impact on product sales, net for Xyrem and Antizol. Until we have accumulated sufficient sales data, we are not able to determine what changes, if any, in estimates we will experience related to Luvox CR. We recorded prompt payment discounts of $1.1 million, $880,000 and $381,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

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 throughout each period 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 Antizol will have a material impact on their product sales, net. Until we have accumulated sufficient sales data, we are not able to determine what changes, if any, in estimates we will experience related to Luvox CR. We recorded Medicaid rebates of $263,000, $229,000 and $135,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

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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 Antizol 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 Antizol product sales, net. Until we have accumulated sufficient sales data, we are not able to determine what changes, if any, in estimates we will make related to Luvox CR. Chargebacks from U.S. wholesalers were $285,000, $212,000 and $57,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

Customer Rebate. Under our agreement with our Antizol distributor in Canada, we pay a rebate, either in cash or as a credit against future purchases, based upon year-over-year unit sales increases. We account for the rebate by establishing an accrual equal to our estimate of the rebate amount. We determine our estimate of the rebate primarily based on historical experience regarding rebate payments and our Antizol distributor s current year sales forecast. The rebate was $14,000 and $44,000 for the years ended December 31, 2007 and 2006. There was no rebate for the year ended December 31, 2005.

Royalties, Net

We receive royalties from third parties based on sales of our products under out-licensing and distributor 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. For those arrangements where royalties are not reasonably estimable, we recognize revenues upon receipt of royalty statements from our licensee or distributor.

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 amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia in 54 countries outside of the United States. UCB made nonrefundable milestone payments to us of $2.5 million in November 2005, $500,000 in June 2006, $2.0 million in March 2007 and $7.5 million in September 2007. 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.

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We recognized contract revenues of $1.1 million and $463,000 related to these upfront payments during the years ended December 31, 2007 and 2006, respectively. The remaining $13.4 million was recorded as deferred revenues as of December 31, 2007 and is being recognized ratably through 2019, the expected performance period under the agreement. There has been no change in the expected performance period since its establishment in 2006 at the time of the initial upfront payment. The amended agreement requires UCB to make additional milestone payments of up to $138.5 million, of which up to $6.0 million relate specifically to Xyrem for the treatment of narcolepsy, up to $32.5 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 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 concluded that no impairment existed as of October 1, 2007. We will also test for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable.

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. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its fair value.

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 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 reflects our expectations of future cash flows related to Antizol and an appropriate risk premium.

Since a generic competitor entered the market immediately after orphan drug exclusivity for the second indication for Antizol expired, we determined that we should review our assumptions regarding the recoverability of the intangible assets associated with Xyrem. Orphan drug exclusivity in the United States for Xyrem for the treatment of cataplexy and Xyrem for the treatment of excessive daytime sleepiness, in patients with narcolepsy, expires in July 2009 and November 2012, respectively. The value of the intangible assets associated with Xyrem for cataplexy as recorded on our consolidated balance sheet at December 31, 2007 was $29.2 million and the remaining estimated useful life was 7.0 years. Based on the Xyrem risk management system, additional patent protection and the DEA quota system, we believe the intangible assets associated with Xyrem are recoverable and the remaining estimated useful life is appropriate. The estimates and assumptions used in these analyses are very subjective. Changes in our estimates and assumptions could have a material adverse effect on our results of operations.

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As of December 31, 2007 we had recorded goodwill of $38.2 million and intangible assets as follows:

	Gross Carrying Amount	Accumulated Amortization (In thousands)	Net Book Value	Weighted Average Remaining Useful Life (In years)
Developed technology Xyrem	$ 39,700	$ 10,499	$ 29,201	7.0
Developed technology Antizol	2,715		2,715	2.0
Agreements not to compete	5,600	3,389	2,211	2.2
Trademarks	2,600	687	1,913	7.0
Amortizable intangible assets	$ 50,615	$ 14,575	$ 36,040	

Stock-Based Compensation

Stock-Based Compensation Under SFAS 123

Prior to January 1, 2006, we accounted for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and related interpretations. Prior to January 1, 2006, we complied with the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* , (SFAS 123) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123*. Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of our common stock over the exercise price of the option on the date of grant. Prior to January 1, 2006, no stock-based compensation expense was recorded under APB 25.

Change in Accounting Principle Stock-Based Compensation Under SFAS 123R

Effective January 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment* (SFAS 123R), which requires compensation expense related to share-based transactions, including employee stock options, to be measured and recognized in the financial statements based on fair value. SFAS 123R revises SFAS 123, as amended, and supersedes APB 25. We adopted SFAS 123R using the modified prospective approach. Under the modified prospective approach, SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date are recognized as the requisite service is rendered on or after the required effective date. The compensation expense for that portion of awards is based on the grant date fair value of those awards. The compensation expense for awards with grant dates prior to January 1, 2006, are attributed to periods beginning on or after the effective date using the attribution method that was used under SFAS 123, except that the method of recognizing forfeitures only as they occur is not continued. The following table shows unrecognized stock-based compensation costs and expected weighted-average amortization periods for each type of award as of December 31, 2007:

	Unrecognized Stock-Based Compensation Cost (In thousands)	Expected Weighted-Average Amortization Period (In years)
Options	$ 13,710	3.3
Employee stock purchase plan	2,281	1.3
Restricted stock units	1,229	3.6
Total	$ 17,220	

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Under both SFAS 123 and SFAS 123R we elected to use the Black-Scholes valuation model to calculate the fair value of stock options and we are using the straight-line method to allocate compensation cost to reporting periods. During the years ended December 31, 2007, 2006 and 2005, the fair value of stock options granted was estimated using the Black-Scholes valuation model with the following assumptions:

	Year Ended December 31,		
	2007	2006	2005
Weighted-average volatility	56%	61%	60%
Weighted-average expected term (years)	6.1	6.0	5.0
Range of risk-free rates	3.4-4.9%	4.6-5.1%	3.9-4.4%
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 for our stock option grants. As a result, for stock option grants made during the year ended December 31, 2007, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107 Share-Based Payment.

As we have 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.

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 for stock options grants.

Beneficial Conversion Feature

We account for potentially beneficial conversion features under Emerging Issues Task Force No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF Issue No. 00-27, *Application of Issue 98-5 to Certain Convertible Instruments*. In January and December 2006, we 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, we 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.

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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 marketing and promotional materials, professional service fees, such as fees to lawyers and accountants, and 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. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under- or overestimate 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.

In-Process Research and Development

In connection with the acquisition of Orphan Medical, we recorded a charge of $21.3 million in 2005 for acquired in-process research and development. This amount represented the estimated fair value related to three incomplete product candidate development projects for which technological feasibility had not been established and that had no alternative future use at the time of the acquisition.

The fair value of the in-process research and development was determined using the income approach. This method requires a forecast of all the expected future net cash flows associated with the in-process technology discounted to present value by applying an appropriate discount rate. The discount rate used reflects the weighted-average cost of capital for companies in our industry, as well as specific risks associated with the cash flows being discounted.

In January 2005, Orphan Medical submitted a supplemental New Drug Application, or sNDA, to the FDA seeking an expanded label indication for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy. At the time of the acquisition, the FDA had not yet approved the sNDA. We used a discount rate of 26% to calculate the fair value of the expanded label indication for Xyrem and accounted for $15.2 million associated with the expanded label indication as in-process research and development expense. The sNDA was approved by the FDA in November 2005. At the time of acquisition, Orphan Medical was also conducting a Phase II clinical trial to evaluate the use of sodium oxybate, the active pharmaceutical ingredient in Xyrem, to treat fibromyalgia. We used a 50% discount rate to calculate the fair value associated with this development project and accounted for $5.9 million associated with the project as in-process research and development. In August 2006, we initiated a Phase III clinical trial of sodium oxybate for the treatment of fibromyalgia which is currently ongoing. In addition, at the time of acquisition, Orphan Medical was conducting initial research into new dosage forms of Xyrem which is currently ongoing. We used a 50% discount rate to calculate the fair value of these research efforts and accounted for $200,000 associated with this research to in-process research and development expense.

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Results of Operations

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. We believe the underlying reasons for the increase in product sales, net were:

- investments in Xyrem marketing programs;
- increases in the price we charged our central pharmacy for Xyrem of 9.0% and 7.4% in May 2007 and August 2006, respectively; and
- increases in the price we charged our wholesale customers for Antizol of 9.0% and 5.0% in August 2007 and November 2006, respectively.

These increases were partly offset by the sale of our rights to Cystadane in March 2007. As a result of generic competition, we believe that revenues from sales of Antizol will decrease significantly in 2008 and in subsequent years.

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 revenue in 2007 compared to 2006 was primarily due to a $7.5 million milestone payment from UCB triggered by achievement of a development milestone in the clinical trials of JZP-6 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.

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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 to Solvay in January 2007 for the exclusive right to market and distribute Luvox CR and Luvox in the United States 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. 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. We do not expect significant changes in our research and development spending in 2008 compared to our research and development expenses in 2007.

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 from 55 to 195;
- 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 trials.

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.

We expect selling, general and administrative expenses to increase during 2008 primarily due to a full year of marketing and selling expenses related to the launch of Luvox CR, including a full year of costs related to our expanded sales force, and an increase in expenses associated with being a public company.

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. We expect amortization expense to increase in 2008 due to amortization of Luvox CR intangible assets. The remaining value of the Antizol intangible asset will be amortized over the next two years.

Intangible Asset Impairment

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

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Provision for Government Settlement

In April 2006, we and Orphan Medical received subpoenas from the United States Department of Justice in connection with the sale and marketing of Xyrem. In July 2007, we reached a comprehensive settlement with the United States government in connection with this matter and agreed to make payments totaling approximately $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 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 2007 and 2006 primarily related to interest on our $80.0 million principal amount of senior secured notes issued in June 2005. Interest on the notes is comprised of the accretion of a discount related to warrants that were issued in conjunction with the notes, amortization of debt issuance costs and quarterly cash payments for interest and was calculated using the effective interest method. In 2006, interest expense also included $1.1 million related to the financing of a product candidate in development. 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)

In connection with the issuance of senior secured notes in June 2005, we issued warrants to purchase 785,728 shares of Series BB preferred stock at an exercise price of $20.36 per share. The warrants are exercisable, at the option of the holders, at any time until June 24, 2012, and were recorded as preferred stock warrant liability. Prior to our initial public offering the preferred stock warrant liability was revalued at the end of each reporting period to fair value using the Black-Scholes option pricing model. On June 6, 2007, upon completion of our initial public offering, the warrants became exercisable for common stock and the liability was reclassified to stockholders equity at its then fair value.

We recorded a benefit of $1.8 million in 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.

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 United States. In addition, we agreed to pay royalties at specified rates based on sales of the product within the United States. 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 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.

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Gain on Sale of Product Rights

In March 2007, we entered into an agreement under which an unrelated third party purchased our rights to Cystadane, along with the associated product registrations, commercial inventory and trademarks, for $9.0 million in cash. In connection with this transaction, we recorded a gain of $5.1 million in 2007. In December 2007, we sold our rights our rights to receive royalties on another product for $1.2 million in cash and recorded a gain of $715,000.

Comparison of Years Ended December 31, 2006 and 2005

	2006	2005	Increase/ (Decrease)	Increase/ (Decrease)
		(In thousands)		
Product sales, net	$ 43,299	$ 18,796	$ 24,503	130%
Royalties, net	594	146	448	307%
Contract revenues	963	2,500	(1,537)	(61)%
Cost of product sales	6,968	4,292	2,676	62%
Research and development	54,956	45,783	9,173	20%
Selling, general and administrative	51,384	23,551	27,833	118%
Intangible asset amortization	9,600	4,960	4,640	94%
Purchased in-process research and development		21,300	(21,300)	N/A(1)
Interest income	2,307	1,318	989	75%
Interest expense	(14,129)	(7,129)	(7,000)	98%
Other expense	(1,109)	(901)	(208)	23%
Gain on extinguishment of development financing obligation	31,592		31,592	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 2006 compared to 2005 was primarily due to the inclusion of only approximately six months of product sales in 2005, subsequent to our acquisition of Orphan Medical in June 2005, compared to a full year in 2006. Other factors affecting this increase included:

- expansion of the Xyrem sales force from 36 to 55 employees in the fourth quarter of 2005;
- receipt from the FDA in November 2005 of expanded marketing approval for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy and a corresponding launch of the new indication in early 2006;
- increases in the price that we charge our central pharmacy for Xyrem of 6.4% and 7.4% in December 2005 and August 2006, respectively; and
- increases in the price that we charge our wholesale customers for Antizol of 4.2% and 5.0% in December 2005 and November 2006, respectively.

Royalties, Net

The increase in royalties, net in 2006 compared to 2005 was principally due to an increase in royalties on sales of Xyrem by UCB from $9,000 in 2005 to $305,000 in 2006. Royalties we received from other products accounted for the remainder of the increase.

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Contract Revenues

Contract revenues in 2006 primarily consisted of a $500,000 milestone payment from UCB in June 2006, triggered by pricing approval in France for Xyrem, and amortization of deferred revenues on payments totaling $15.0 million from UCB in 2006 related to JZP-6. Contract revenues in 2005 consisted of a $2.5 million milestone payment from UCB received in November 2005, triggered by the approval by the European Agency for the Evaluation of Medical Products of Xyrem for the treatment of cataplexy associated with narcolepsy.

Cost of Product Sales

The increase in the cost of product sales in 2006 compared to 2005 was primarily due to the inclusion of a full year of product sales in 2006 compared to approximately six months of product sales in 2005, subsequent to our acquisition of Orphan Medical in June 2005. Our gross margin increased from 77% in 2005 to 84% in 2006. The primary reason for this increase was a lower fair value adjustment to inventory acquired as part of the acquisition of Orphan Medical in 2006 compared to 2005. Our cost of product sales reflected a fair value adjustment of $1.6 million and $775,000 during 2005 and 2006, respectively.

Research and Development Expenses

Higher research and development expenses in 2006 as compared to 2005 resulted primarily from higher spending in 2006 on early phase development and preclinical studies, along with higher salaries and benefits expenses related to a growth in research and development headcount during 2006. Research and development expenses did not increase substantially as a result of the Orphan Medical acquisition. Although total spending on late-stage programs did not change substantially from 2005 to 2006, the components of spending on late-stage programs changed. During 2005, a substantial portion of our research and development expenses related to a product candidate program that was terminated, and, during 2006, a substantial portion of our research and development expenses were attributable to the terminated program and JZP-6.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were higher in 2006 than in 2005 as a result of a number of factors, including:

- inclusion of only six months of Xyrem sales and marketing activities in 2005, compared to a full year of activities in 2006;
- costs associated with the launch of a new indication for Xyrem in early 2006;
- an increase in the Xyrem sales force from 36 at the time of the Orphan Medical acquisition to 55 in the fourth quarter of 2005;
- outside legal costs of $5.4 million incurred during 2006 in connection with an investigation by the U.S. Attorney s Office of activities related to the promotion of Xyrem;
- building a medical affairs department; and
- an increase in headcount and related salaries and benefits.

Intangible Asset Amortization

Amortization expense was higher in 2006 as compared to 2005 primarily due to the inclusion of only six months of amortization in 2005 as compared to a full year of amortization in 2006.

Purchased In-process Research and Development

In connection with our June 2005 acquisition of Orphan Medical, we recorded a charge of $21.3 million for acquired in-process research and development, representing the estimated fair value related to three incomplete projects for which, at the time of the acquisition, technological feasibility had not been established and that had no alternative future use.

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Interest Income

Interest income was higher in 2006 as compared to 2005 primarily due to higher average balances of investable assets coupled with higher interest rates.

Interest Expense

Interest expense primarily related to interest on our $80.0 million principal amount of senior secured notes and interest on the development financing of a product candidate program that was terminated, both of which were recorded using the effective interest method. $5.6 million of the increase in interest expense in 2006 as compared to 2005 was attributable to the fact the notes were outstanding for the full year in 2006. Interest expense related to the development financing was $445,000 in 2005, compared with $1.1 million 2006.

Other Expense

We recorded $901,000 and $1.1 million of expense as a result of an increase in the fair value of our preferred stock warranty liability in 2005 and 2006, respectively.

Gain on Extinguishment of Development Financing Obligation

As discussed more fully in the comparison of the years ended December 31, 2007 and 2006, we recorded a gain of $31.6 million resulting from the extinguishment of liabilities related to a development financing during 2006.

Liquidity and Capital Resources

Since our inception, we have incurred significant net losses and, as of December 31, 2007, we had an accumulated deficit of $316.5 million. We have not achieved profitability, and we anticipate that we will continue to incur net losses for the next several years.

From inception through December 31, 2007, in order to fund our operations, we have raised a total of $469.4 million, net of issuance costs, to fund our operations, including $263.9 million from the sale of convertible preferred stock prior to our initial public offering, $97.5 million from the sale of common stock in our initial public offering, $78.0 million from the sale of senior secured notes and warrants in 2005 and $30.0 million in project development financing. This funding does not include short-term borrowings under a line of credit or milestone payments received from our collaboration with UCB.

As of December 31, 2007, we had $102.9 million in cash and cash equivalents, held primarily in obligations of United States government agencies, money market funds and corporate debt securities. In December 2007, we extended our line of credit through November 2008, under which we could borrow up to 80% of eligible accounts receivable up to a maximum of $5.0 million in borrowings. In connection with a debt expansion on March 17, 2008, we terminated the $5.0 million line of credit. On March 28, 2008, the $5.0 million line of credit was reinstated. In addition, $12.0 million of cash, which had been previously restricted under the terms of our senior secured notes, became available to us as a result of our debt expansion on March 17, 2008.

On March 17, 2008, JPI Commercial, LLC, or JPIC, our wholly-owned subsidiary, sold $40.0 million aggregate principal amount of senior secured notes. 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 $0.8 million arrangement fee and incurred other expenses in connection with the transaction. We will use the net proceeds to fund milestone payments due under our license agreement with Solvay Pharmaceuticals, Inc., to fund Luvox CR launch expenses and for general corporate purposes. The notes 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

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secured notes of Orphan Medical were exchanged for the same principal amount of new senior secured notes issued by JPIC. 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. JPIC is not required to maintain a restricted cash balance under the new arrangement; however, if at any time after the quarter ending on March 31, 2009, our product sales do not reach certain specified levels, JPIC would be required to maintain a minimum cash balance equal to 15% of the then outstanding principal amount of notes. We have also agreed to restrictions on working capital borrowings, dividends and certain other payments. Under the agreement, we may borrow up to $15.0 million secured by our accounts receivable and inventory. JPIC may be required, upon the occurrence of certain events and if our annualized net product sales fall below a certain specified level, to redeem a portion of the notes, and may be required to repurchase or redeem a portion or all of the notes upon the occurrence of certain customary events.

Subject to satisfying conditions related to our net product sales and certain closing conditions, prior to January 31, 2009, we have the option to sell to certain of the note holders up to an additional $30.0 million aggregate principal amount of senior secured notes and warrants to purchase shares of our common stock at an exercise price based upon the closing stock price prior to the sale of the notes and warrants.

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

	Year Ended December 31,		
	2007	2006	2005
		(In thousands)	
Net cash used in operating activities	$ (81,091)	$ (57,350)	$ (52,162)
Net cash provided by (used in) investing activities	5,337	(1,507)	(153,754)
Net cash provided by financing activities	99,751	117,191	192,852
Net increase (decrease) in cash and cash equivalents	$ 23,997	$ 58,334	$ (13,064)

Net cash used in operating activities in 2007 primarily reflected our net loss, offset in part by changes in working capital, the impairment loss related to the intangible asset associated with Antizol, depreciation and amortization, the liability for future payments under the government settlement, the change in the preferred stock warrant liability and the gain on sale of product rights. Net cash used in operating activities in 2006 primarily reflected our net loss, less the gain on extinguishment of development financing, offset in part by depreciation and amortization and changes in working capital. Net cash used in operating activities in 2005 primarily reflected the net loss offset in part by depreciation and amortization, in-process research and development and changes in working capital.

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 related primarily to purchases of property and equipment. Net cash used in investing activities in 2005 related primarily to the acquisition of Orphan Medical, net of cash acquired, for $146.1 million and a net increase in the purchase, sale and maturity of investments.

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. Net cash provided by financing activities in 2005 related primarily to issuances of preferred stock for net proceeds of $99.9 million, net proceeds from the sale of senior secured notes and warrants of $78.0 million and $15.0 million of funding under a development financing agreement.

We believe that our current cash and cash equivalents and interest earned thereon, together with future financings and anticipated revenues from product sales and royalties will be sufficient to satisfy our current

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operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect. We are launching Luvox CR and, as is the case with new product launches, we cannot predict with certainty the timing or level of Luvox CR sales. If sales of Luvox CR do not reach the levels we expect and if we do not generate additional cash resources from financings or partnering activities, we may be unable to meet our cash requirements under our current operating plan. If product sales do not meet our expectations and we do not raise additional funds, we will need to reduce our planned expenditures, perhaps significantly, to preserve our cash. If necessary, we would implement, beginning as early as the third quarter of 2008, appropriate plans and measures to quickly reduce discretionary spending and capital expenditures, terminate or slow one or more of our product development programs, reduce headcount, license or sell some of our product candidates or products, or implement a combination of these and other cost cutting measures. See Part I Item 1A Risk Factors Our operations have generated negative cash flows, and if we are unable to secure additional funding when we need it, we may be required to reduce operations and other risk factors included in Part I Item 1A for a discussion of the factors that will influence our future capital requirements.

We will need to raise additional funds to finance our business and support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may not be able to continue development of our product candidates or we could be required to delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through development financings, collaborations, or public or private debt or equity financings. If we raise funds through collaborations, we may be required to relinquish, on terms that are not favorable to us, rights to some of our product candidates that we would otherwise seek to develop or commercialize ourselves or to sell the rights to one or more commercial products to third parties. 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 may be dilutive to our stockholders. In addition, if we raise additional funds through the sale of equity securities, new investors could have rights superior to our existing stockholders. The terms of future financings may restrict our ability to raise additional capital, which could delay or prevent the further development of our product candidates or commercialization of our products. Our failure to raise capital when needed may harm our business and operating results.

Contractual Obligations

The following table reflects a summary of our contractual obligations as of December 31, 2007:

		Payments due by period		
Contractual Obligations(1)	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**
		(In thousands)		
Senior secured notes(2)	$ 121,800	$ 12,000	$ 24,000	$ 85,800
Liability under government settlement(3)	19,000	2,000	8,500	8,500
Line of credit	3,459	3,459		
Operating lease obligations(4)	3,500	2,082	1,347	71
Purchase obligations(5)	7,022	7,022		
Total	$ 154,781	$ 26,563	$ 33,847	$ 94,371

(1) Milestone payments and royalty payments under our license and collaboration agreements that we cannot, as of December 31, 2007, 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.

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(2) On June 24, 2005, to partially finance the acquisition of Orphan Medical, we issued $80.0 million of senior secured notes. The notes bear interest at a rate of 15% per annum, payable quarterly in arrears. The amounts in the table above include interest and principal repayments on these notes. See Note 7 to our consolidated financial statements appearing elsewhere in this prospectus for additional information. The table above does not include our obligations to make quarterly interest payments at a rate of 15% on $40.0 million aggregate principal amount of new notes issued on March 17, 2008 which are due in full on June 24, 2011.

(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, $3.6 million plus interest payable under the civil settlement agreement described in Part I Item 3 Legal Proceedings , 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: $430,000 paid in January 2008, $537,000 otherwise payable in January 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) Includes the minimum rental payments for our corporate office building and two other office spaces in Palo Alto, California and automobile lease payments for the sales force. In February 2008, we exercised our option to extend the lease on our corporate office building for one year beginning August 2008. The obligation related to this one year extension is approximately $816,000, which is not included in the table above. In addition to these lease payments we are obligated to pay for operating expenses for the lease property.

(5) Consists of commitments to third party manufacturers of Antizol, 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 $6.6 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 January 2007, we entered into a product license agreement with Solvay for the right to market and distribute Luvox and Luvox CR in the United States. Under the terms of the agreement, we made a $2.0 million payment upon execution of the agreement and we are required to make additional payments based on the achievement of certain milestones. No milestones were achieved as of December 31, 2007 therefore no amounts are included in the table above. In March 2008, the license agreement was amended to provide that the milestone payments that were due as a result of approval and launch of Luvox CR will be paid as follows: $10.0 million on March 28, 2008; $10.0 million on April 7, 2008; $10.5 million on September 30, 2008; and $10.5 million on December 31, 2008. Additional payments of up to $95.0 million are due upon the achievement of certain commercial milestones. We are required to pay royalties on commercial sales at specified rates.

In October 2004, we entered into an agreement with GlaxoSmithKline to acquire worldwide rights to the active pharmaceutical ingredient in JZP-4. We paid $2.0 million upon execution of the agreement and $3.0 million in July 2006 upon achievement of a development milestone. We 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 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, which we expect to occur in the third quarter of 2008.

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The FDA 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. We have not yet developed the protocols or cost estimates for 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 $0.8 million in connection with the issuance of the new notes. Subject to certain conditions, LB I Group is obligated to purchase from JPIC additional notes with an aggregate principal amount of up to $27.0 million. Subsequent to the issuance of the new notes, entities affiliated with Kohlberg Kravis Roberts & Co. L.P. held notes with an aggregate principal amount of $7.1 million and warrants to purchase 70,156 shares of common stock exercisable at $20.36 per share.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and was adopted by us effective January 1, 2008. We are currently evaluating the effect that the adoption of SFAS 157 will have on our results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Most of the provisions in SFAS 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. We are currently evaluating the effect that the adoption of SFAS 159 will have on our results of operations and financial position.

In June 2007, the FASB ratified Emerging Issues Task Force, or EITF, 07-3, Accounting for NonRefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007 and was adopted by us effective January 1, 2008. We are currently evaluating the effect that the adoption of EITF 07-3 will have on our consolidated results of operations and financial position.

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

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SFAS 160. SFAS No. 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 No. 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 No. 141(R) and SFAS No. 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We will evaluate the effect on our consolidated financial statements, if any, upon adoption of SFAS No. 141(R) or SFAS No. 160.

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.

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 and investments, 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 $114.9 million and $91.0 million as of December 31, 2007 and 2006, 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 United States government agencies, corporate bonds, commercial paper and money market funds. Our cash equivalents, marketable securities and restricted cash as of December 31, 2007 and 2006 consisted primarily of obligations of United States 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 approximately $594,000 for the year ended December 31, 2007, largely driven by the excess cash invested from our initial public offering in June 2007. 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 United States, and almost all of our operating expenses and capital expenditures are denominated in United States 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 ten percent change in the U.S. dollar exchange rate against all other currencies would have resulted in a change in our operating expenses of approximately $225,000 for the year ended December 31, 2007.

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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-38.

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 principal financial officer, of our disclosure controls and procedures (as defined in Exchange Act Rule 13a 15(e)) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report on Form 10 K. Based on their evaluation, our principal executive officer and principal financial officer concluded that, subject to the limitations described below, our disclosure controls and procedures were effective as of December 31, 2007.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were 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, 2007 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

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

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Item 9B. Other Information

On February 26, 2008 we exercised our option to extend the lease on our corporate office building located in Palo Alto California for one year beginning August 31, 2008. In connection with this extension, we will pay an additional approximately $816,000 in lease payments during the one year extension. In addition to these lease payments, we are obligated to pay for operating expenses for the leased property.

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. As a result of the impairment, the remaining useful life was reduced to two years and the net book value of the intangible asset associated with Antizol was $2.7 million as of December 31, 2007. The fair value of 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 reflects our expectations of future cash flows related to Antizol and an appropriate risk premium.

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PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2008 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 appearing in the proxy statement for our 2008 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 2008 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 2008 annual meeting of stockholders. Such information is incorporated herein by reference.

We adopted the Jazz Pharmaceuticals Code of Conduct that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Conduct is available on our website at *www.jazzpharmaceuticals.com* under the section entitled Investors at Corporate Governance . 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 2008 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 ownership and management is include in our proxy statement for our 2008 annual meeting of stockholders under the section entitled Security Ownership of Certain Beneficial Owners and Management and is incorporated herein by reference.

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The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2007.

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	3,448,981	$ 17.36(1)	958,213(2)
2007 Employee Stock Purchase Plan			280,325(3)
2007 Non-Employee Directors Stock Option Plan	50,000	$ 12.75	133,417(4)
Equity compensation plans not approved by security holders:			
Directors Deferred Compensation Plan	16,583(5)		(6)
Total	3,515,564		1,371,955

(1) The weighted average exercise price of outstanding options, warrants 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, warrants and rights under the 2007 Plan was $17.99 after excluding the grant of the restricted stock units.

(2) As of December 31, 2007, an aggregate of 4,407,194 shares of common stock were reserved for issuance under the 2007 Plan, of which 958,213 remained available for future issuance. The number of shares reserved for issuance under the 2007 Plan includes shares subject to options originally granted 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 proceeding year or (b) 3,000,000 shares (or such lesser amount as may be approved by our Board of Directors). On January 1, 2008, the number of shares reserved for issuance under the 2007 Plan increased by 1,107,937 shares pursuant to this automatic share increase provision.

(3) As of December 31, 2007, an aggregate of 350,000 shares of common stock were reserved for issuance under our 2007 Employee Stock Purchase Plan, or the 2007 ESPP, of which 280,325 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, 2008, 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, 2007, an aggregate of 200,000 shares of common stock were reserved for issuance under our 2007 Non-Employee Directors Stock Option Plan, or the 2007 Directors Plan, of which 133,417 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

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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, 2008, the number of shares reserved for issuance under the 2007 Directors Plan increased by 66,583 shares pursuant to this automatic share increase provision.

(5) Represents shares credited to individual non-employee director stock accounts as of December 31, 2007 under the Directors Deferred Plan. Amounts creditable to individual non-employee director stock accounts under the Directors Deferred Plan are dependent on elections made by plan participants thereunder. 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 1 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 2008 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 2008 annual meeting of stockholders under the section entitled Proposal 2 Ratification of Selection of Independent Registered Public Accounting Firm.

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PART IV

Item 15. Exhibits, 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.(8)
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.
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(7)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.
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.
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.
4.5D	Form of Common Stock Warrant of the Registrant.
4.5E#	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.
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.(8)

10.3+ Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel R Saks.(8)

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Exhibit Number	Description of Document
10.4+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert M Myers.(8)
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew K Fust.(8)
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol A Gamble.(8)
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne L T Wissel.(8)
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.(8)
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce C Cozadd.(8)
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce C Cozadd.(8)
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C Cozadd.(8)
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C Cozadd.(8)
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel R Saks.(8)
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel R Saks.(8)
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel R Saks.(8)
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert M Myers.(8)
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.(8)
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert M Myers.(8)
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew K Fust.(8)
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol A Gamble.(8)
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.(9)

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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.(8)
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.(10)
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(9)
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.(9)
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.(11)
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.(11)
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.(11)
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.(11)
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.(10)
10.42	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(10)
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(9)
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(9)
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.(11)
10.46	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(10)
10.47	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(11)
10.48	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(11)
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.(10)
10.50	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(10)

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Exhibit Number	Description of Document
10.51	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc. (11)
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. (11)
10.53	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant. (11)
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. (9)
10.55+	Directors Deferred Compensation Plan. (3)
10.56+	Non-Employee Director Compensation Arrangements. (3)
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. (12)
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. (12)
10.57C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc. (12)
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. (12)
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)
10.61+	Non-Employee Director Compensation Arrangements, as modified on July 18, 2007. (1)
10.62+	Amendment No. 2 to Employment Agreement, effective on September 1, 2007, by and between the Registrant and Bruce C. Cozadd. (13)
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. (13)
10.64+	Form of Restricted Stock Unit Award under the Registrant s 2007 Equity Incentive Plan. (13)
10.65+	Non-Employee Director Compensation Arrangements, as modified on December 18, 2007.
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.
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.
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.
10.69#	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.

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Exhibit

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

+ 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. 333-33500) 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. 333-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.

(5) Incorporated by reference to Exhibit 4.4 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 Exhibit 4.5 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 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.

(8) 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.

(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 May 24, 2007.

(10) 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.

(11) 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.

(12) 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.

(13) Incorporated herein by reference to the same numbered exhibit to the Registrant s quarterly report on Form 10-Q (File No. 000-33500) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.

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

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SIGNATURES

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

Jazz Pharmaceuticals, Inc.
(Registrant)

Date: March 28, 2008

/s/ MATTHEW K. FUST
Matthew K. Fust

(Duly Authorized and Principal Accounting and Financial Officer)

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Samuel R. Saks, M.D., Matthew K. Fust 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 28, 2008
/s/ Matthew K. Fust **Matthew K. Fust**	Executive Vice President and Chief Financial Officer (*Principal Accounting and Financial Officer*)	March 28, 2008
/s/ Samuel D. Colella **Samuel D. Colella**	Director	March 28, 2008
/s/ Bruce C. Cozadd **Bruce C. Cozadd**	Director	March 28, 2008
/s/ Bryan C. Cressey **Bryan C. Cressey**	Director	March 28, 2008
/s/ Michael W. Michelson **Michael W. Michelson**	Director	March 28, 2008
/s/ James C. Momtazee **James C. Momtazee**	Director	March 28, 2008
/s/ Kenneth W. O Keefe **Kenneth W. O Keefe**	Director	March 28, 2008
/s/ Jaimin R. Patel **Jaimin R. Patel**	Director	March 28, 2008
/s/ Alan M. Sebulsky **Alan M. Sebulsky**	Director	March 28, 2008
/s/ James B. Tananbaum, M.D. **James B. Tananbaum, M.D.**	Director	March 28, 2008

/s/ Nathaniel M. Zilkha		Director	March 28, 2008

Nathaniel M. Zilkha

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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, 2007 and 2006, and the related consolidated statements of operations, convertible preferred stock and stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, 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. changed its method of accounting for stock-based compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), Share-Based Payment , on January 1, 2006.

/s/ Ernst & Young LLP

Palo Alto, California
March 28, 2008

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2007	2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,945	$ 78,948
Restricted cash	1,939	275
Accounts receivable, net of allowances of $218 and $198 at December 31, 2007 and 2006, respectively	5,389	5,380
Inventories	2,213	3,026
Prepaid expenses	3,224	3,447
Other current assets	381	487
Total current assets	116,091	91,563
Property and equipment, net	3,941	2,107
Intangible assets, net	36,040	69,140
Goodwill	38,213	38,213
Long-term restricted cash and investments	12,000	12,000
Other long-term assets	1,269	1,548
Total assets	$ 207,554	$ 214,571
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Line of credit	$ 3,459	$ 2,191
Accounts payable	2,856	5,443
Accrued liabilities	29,047	12,943
Deferred revenue	1,494	1,422
Preferred stock warrant liability (including $5,965 held by related parties as of December 31, 2006)		8,521
Total current liabilities	36,856	30,520
Liability for early exercise of options and unvested restricted common stock		98
Deferred rent		436
Non-current portion of deferred revenue	12,468	13,495
Liability under government settlement	14,881	
Senior secured notes (including $52,581 and $51,998 as of December 31, 2007 and December 31, 2006, respectively, held by related parties)	75,116	74,283
Commitments and contingencies (Note 8)		
Convertible preferred stock, $0.0001 par value; none and 27,851,839 shares authorized at December 31, 2007 and 2006, respectively; none and 17,921,551 shares issued and outstanding at December 31, 2007 and 2006, respectively; aggregate liquidation preference of $0 and $265,000 at December 31, 2007 and 2006, respectively		263,852
Common stock subject to repurchase	13,241	8,183
Stockholders equity (deficit):		
Preferred stock, $0.0001 par value; 20,000,000 and no shares authorized at December 31, 2007 and 2006, respectively; no shares issued and outstanding at December 31, 2007 and 2006, respectively		
Common stock, $0.0001 par value; 150,000,000 and 22,835,080 shares authorized at December 31, 2007 and 2006, respectively; 24,620,829 and 623,986 shares issued and outstanding at December 31, 2007 and 2006, respectively	2	

Additional paid-in capital	371,440	1,335
Accumulated other comprehensive income	19	12
Accumulated deficit	(316,469)	(177,643)
Total stockholders equity (deficit)	54,992	(176,296)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 207,554	$ 214,571

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

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2007	2006	2005
Revenues:			
Product sales, net	$ 53,536	$ 43,299	$ 18,796
Royalties, net	1,156	594	146
Contract revenues	10,611	963	2,500
Total revenues	65,303	44,856	21,442
Operating expenses:			
Cost of product sales (excluding amortization and impairment of acquired developed technology)	8,903	6,968	4,292
Research and development	69,792	54,956	45,783
Selling, general and administrative	78,540	51,384	23,551
Intangible asset amortization	9,217	9,600	4,960
Intangible asset impairment	20,160		
Provision for government settlement	17,469		
Purchased in-process research and development			21,300
Total operating expenses	204,081	122,908	99,886
Loss from operations	(138,778)	(78,052)	(78,444)
Interest income	5,942	2,307	1,318
Interest expense (including $9,193, $9,024 and $4,595 for the years ended December 31, 2007, 2006 and 2005, respectively, pertaining to related parties)	(13,647)	(14,129)	(7,129)
Other income (expense)	1,797	(1,109)	(901)
Gain on extinguishment of development financing obligation		31,592	
Gain on sale of product rights	5,860		
Net loss	(138,826)	(59,391)	(85,156)
Beneficial conversion feature		(21,920)	
Loss attributable to common stockholders	$ (138,826)	$ (81,311)	$ (85,156)
Loss per share attributable to common stockholders, basic and diluted	$ (10.04)	$ (6,254.69)	$ (14,192.67)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	13,829	13	6

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

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND

STOCKHOLDERS EQUITY (DEFICIT)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock Subject to Repurchase	Stockholders Equity (Deficit)					
	Shares	Amount	Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Compre-hensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balance at January 1, 2005	4,668,594	$ 64,009	$ 3,665	617,974	$	$	$	$ (30,923)	$ (30,923)
Lapse of repurchase rights to shares issued under restricted stock purchase agreements						53			53
Vesting of common stock subject to repurchase			2,259			(53)		(2,173)	(2,226)
Issuance of Series B convertible preferred stock for cash, net of issuance costs of $11	3,180,714	47,989							
Issuance of Series B Prime convertible preferred stock for cash, net of issuance costs of $136	3,445,768	51,864							
Comprehensive loss:									
Net loss								(85,156)	(85,156)
Unrealized gain on available-for-sale securities							4		4
Comprehensive loss									(85,152)
Balance at December 31, 2005	11,295,076	163,862	5,924	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			2,259			(2,226)			(2,226)
Issuance of Series B convertible preferred stock for cash, net of issuance costs of $5	3,180,707	47,995							
Issuance of Series B Prime convertible preferred stock for cash, net of issuance costs of $5	3,445,768	51,995							
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	17,921,551	$ 263,852	$ 8,183	623,986	$	$ 1,335	$ 12	$ (177,643)	$	(176,296)

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND

STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock Subject to Repurchase	Stockholders Equity (Deficit)					
				Common Stock		Additional	Accumulated Other		
	Shares	Amount	Amount	Shares	Amount	Paid-in Capital	Compre-hensive Income	Accumulated Deficit	Total Stockholders (Deficit) Equity
Balance at December 31, 2006	17,921,551	$ 263,852	$ 8,183	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			854			(834)			(834)
Conversion of convertible preferred stock to common stock and common stock subject to repurchase upon initial public offering	(17,921,551)	(263,852)	4,204	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 of $10,512				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		$	$ 13,241	24,620,829	$ 2	$ 371,440	$ 19	$ (316,469)	$ 54,992

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

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JAZZ PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2007	2006	2005
Operating activities			
Net loss	$ (138,826)	$ (59,391)	$ (85,156)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,309	710	479
Amortization of intangible assets	9,217	9,600	4,960
Intangible asset impairment	20,160		
Loss on disposal of property and equipment	6	481	
Fair value adjustment to acquired finished goods	54	775	1,584
Purchased in-process research and development			21,300
Non-cash interest expense	1,132	949	476
Revaluation of preferred stock warrant liability	(1,846)	1,092	901
Stock-based compensation expense	6,060	3,480	
Interest on development financing		1,147	445
Gain on extinguishment of development financing		(31,592)	
Gain on sale of product rights	(5,860)		
Changes in assets and liabilities:			
Accounts receivable	(250)	(1,783)	(249)
Inventories	459	(521)	(219)
Prepaid expenses and other current assets	329	(473)	1,158
Other assets	(14)	323	
Accounts payable	(2,587)	657	2,408
Accrued liabilities	15,843	2,492	(210)
Deferred revenue	(955)	14,917	
Deferred rent	(203)	(213)	(39)
Provision for government settlement	14,881		
Net cash used in operating activities	(81,091)	(57,350)	(52,162)
Investing activities			
Purchases of property and equipment	(3,149)	(1,682)	(1,413)
Proceeds from sale of property and equipment		150	
Purchases of available-for-sale securities	(10,848)	(1,705)	
Proceeds from sales of available-for-sale securities			3,450
Proceeds from maturities of available-for-sale securities	10,848		2,500
Cash paid for shares of Orphan Medical, Inc., net of cash acquired			(146,116)
Proceeds from maturites of long term restricted cash equivalents		1,705	
Decrease (increase) in restricted cash and investments	(1,664)	25	(12,175)
Proceeds from sale of product rights	10,150		
Net cash provided by (used in) investing activities	5,337	(1,507)	(153,754)
Financing activities			
Proceeds from issuances of Convertible Preferred Stock, net of issuance costs		99,990	99,853
Proceeds from employee stock purchases and exercise of stock options	995	10	
Proceeds from initial public offering	97,488		
Proceeds from line of credit	20,373	3,283	
Repayments under line of credit	(19,105)	(1,092)	
Proceeds from sale of senior secured notes, net of issuance costs (including $53,624 from related parties)			77,999
Proceeds from development financing		15,000	15,000
Net cash provided by financing activities	99,751	117,191	192,852

Net increase (decrease) in cash and cash equivalents	23,997	58,334	(13,064)
Cash and cash equivalents, at beginning of period	78,948	20,614	33,678
Cash and cash equivalents, at end of period	$ 102,945	$ 78,948	$ 20,614
Supplemental disclosure of cash flow information:			
Cash paid for interest (including $8,400, $8,363 and $4,263 for the years ended December 31, 2007, 2006 and 2005, respectively, paid to related parties)	$ 12,000	$ 12,000	$ 6,200
Supplemental disclosure of non-cash financing activities:			
Warrants to purchase Series BB Convertible Preferred Stock issued in conjuction with senior secured notes	$	$	$ 6,696
Beneficial conversion feature deemed dividend attributable to preferred stockholders	$	$ 21,920	$

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

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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 identifying, 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 opportunities and utilization of its specialty sales force to promote its products in its target markets.

Since its inception, the Company has built a commercial operation and assembled a portfolio that currently includes two marketed products, one product approved by the U.S. Food and Drug Administration (FDA) that is currently being launched and four 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 subsidiary, Orphan Medical, Inc. (Orphan Medical), after elimination of intercompany transactions and balances.

Significant Risks and Uncertainties

The Company has incurred significant losses from operations since its inception and expects losses to continue for the next several years. To achieve profitable operations, the Company must successfully identify, develop and commercialize its products. Products developed by the Company will require approval of the FDA or a foreign regulatory authority prior to commercial sales. The regulatory approval process is expensive, time consuming and uncertain, and any denial or delay of approval could have a material adverse effect on the Company. Even if approved, the Company s products may not achieve market acceptance and will face competition from both generic and branded pharmaceutical products. The Company will need to raise additional funds to support its operations, and such funding may not be available to it on acceptable terms, or at all. The Company may seek additional sources of financing through development financings, collaborations or public or private debt or equity financings, and may also seek to reduce expenses related to its operations.

The Company is currently launching Luvox CR, and cannot predict with certainty the timing or level of Luvox CR sales. If sales of Luvox CR do not reach the levels the Company expects, and if the Company does not generate additional cash resources from financings or partnering activities, the Company may be unable to meet its cash requirements under its current operating plan. If product sales do not meet the Company s expectations and the Company does not raise additional funds, the Company will need to reduce its planned expenditures, perhaps significantly, to preserve cash. If necessary, the Company would implement, beginning as early as the third quarter of 2008, appropriate plans and measures to quickly reduce discretionary spending and capital expenditures, terminate or slow one or more product development programs, reduce headcount, license or sell some of its product candidates or products, or implement a combination of these and other cost cutting measures.

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

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 and Fair Value of Financial Instruments

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 93%, 90% and 88% of gross accounts receivable as of December 31, 2007, 2006 and 2005, respectively.

The fair value of financial instruments, including cash, cash equivalents, marketable investments, accounts receivable, accounts payable, accrued liabilities and senior secured notes approximate their carrying value.

Cash Equivalents, Restricted Cash and Available-for-Sale 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 and available-for-sale securities, the use of which is restricted either by contract or agreement. At December 31, 2007, the Company held a certificate of deposit in the amount of $1.1 million as a single entry import bond, held a money market account and a certificate of deposit in the amounts of $775,000 and $85,000, respectively, as collateral securing two letters of credit and had a $12.0 million investment account which was restricted under the agreement governing the Company s senior secured notes. See Note 20 for information related to the expansion of our senior debt.

Available-for-sale 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 available-for-sale securities are classified as available-for-sale and are recorded at fair value, based on quoted market prices. Unrealized gains and losses, net of tax, are recorded in other comprehensive income and included as a separate component of stockholders 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 available-for-sale securities are included in interest income in the statement of operations. Realized gains and losses on sales of available-for-sale 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. 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 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, since the Company could not reasonably estimate the probability that the Company would obtain a future benefit from these costs. 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 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 an 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 concluded that no impairment existed as of October 1, 2007. Management will also test for impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There have been no changes since October 1, 2007 that would cause management to reevaluate its conclusion.

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. As more fully disclosed in Note 6, in December 2007 the Company recorded a charge of $20.2 million to reflect an impairment in the fair value of the intangible asset associated with Antizol.

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 150-5), an interpretation of

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. Pursuant to FSP 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 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 charges of $1.1 million and $901,000 in other income (expense), net, during the years ended December 31, 2007, 2006 and 2005, 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 at its then fair value.

Deferred Rent

The Company recognizes rent expense on a straight-line basis over the noncancelable term of its operating lease and, accordingly, records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. The Company also records landlord-funded lease incentives, such as reimbursable leasehold improvements, as a deferred rent liability which is amortized as a reduction of rent expense over the noncancelable terms of its operating lease.

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 are recorded as deferred revenues and recognized when earned.

Product Sales, Net

Revenues from sales of Xyrem within the U.S. are recognized upon transfer of title, which occurs when the Company s specialty pharmaceutical distributor removes product from the Company s consigned inventory location at its facility for shipment to a patient. Antizol is, and prior to the Company s sale of the Company s rights Cystadane was, shipped to the Company s wholesaler customers in the U.S. with free on board destination shipping terms, and the Company recognizes revenues when delivery occurs. 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 the 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 a customer rebate. Calculating these items involves estimates and judgments based on sales or invoice data and historical experience. The Company s product returns have been infrequent and immaterial.

Royalties, Net

The Company receives royalties from third parties based on sales of its products under out-licensing and distributor 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. For those arrangements where royalties are not reasonably estimable, the Company recognizes revenues upon receipt of royalty statements from the licensee or distributor.

Contract Revenues

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 recognized ratably over the 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 performance obligations are completed.

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 insurance, FDA user fees, freight, shipping, handling and storage costs, and salaries and related costs of employees involved with production. The Company s product exchange policy for Antizol allows and, prior to the Company s sale of the Company s rights to Cystadane, the Company s product exchange policy for Cystadane allowed, customers to return expired product for exchange up to six months before or one year after the product s expiration date. These expiration date returns are exchanged for replacement product, and the estimated cost of such exchanges is included in cost of product sales. Amounts accrued for replacement product have not been material to date. In addition, as part of the acquisition of Orphan Medical, the Company recorded finished goods on-hand at the acquisition date at fair value, which is defined as inventory valued at estimated selling prices less the sum of (a) costs of disposal and (b) reasonable profit allowance for the selling effort of the acquiring entity. The fair value of inventory acquired is recorded as cost of product sales when the related product revenues are recorded. Excluded from cost of product sales as shown on the consolidated statements of operations is amortization of developed technology of $7.5 million, $7.9 million and $4.1 million for the years ended December 31, 2007, 2006 and 2005, respectively. Also excluded from cost of product sales is a charge of $20.2 million related to the impairment of the intangible asset associated with Antizol which is described in more detail in Note 6.

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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and Development

The Company s research and development expenses consist of expenses incurred in identifying, developing and testing its 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 salaries, 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, since the Company could not reasonably estimate the probability that the Company will obtain a future benefit from these costs. All direct manufacturing costs incurred after approval have been capitalized into inventory.

In-Process Research and Development

In connection with the acquisition of Orphan Medical, the Company recorded a charge of $21.3 million for acquired in-process research and development during the year ended December 31, 2005. This amount represented the estimated fair value related to three incomplete product candidate development projects for which, at the time of the acquisition, technological feasibility had not been established and there was no alternative future use.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses for the years ended December 31, 2007, 2006 and 2005 were $7.3 million, $2.3 million and $551,000, respectively.

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, 2007, 2006 and 2005, the difference between comprehensive loss and net loss represented unrealized gains on available-for-sale securities.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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,		
	2007	2006	2005
	(In thousands, except per share data)		
Numerator:			
Loss attributable to common stockholders	$ (138,826)	$ (81,311)	$ (85,156)
Denominator:			
Weighted-average common shares outstanding	14,594	620	618
Less: weighted-average common shares outstanding subject to repurchase	(765)	(607)	(612)
Weighted-average common shares used in computing loss per share attributable to common stockholders, basic and diluted	13,829	13	6
Loss per share attributable to common stockholders, basic and diluted	$ (10.04)	$ (6,254.69)	$ (14,192.67)

The following convertible preferred stock, stock options, restricted stock units, common stock subject to repurchase and warrants 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,		
	2007	2006	2005
Series A convertible preferred stock (as if converted)		1,355	1,355
Series B convertible preferred stock (as if converted)		7,952	4,771
Series B Prime convertible preferred stock (as if converted)		8,614	5,169
Warrants to purchase Series BB convertible preferred stock (as if exercised and converted)		786	786
Warrants to purchase common stock (as if exercised and converted)	786		
Options to purchase common stock	3,380	1,597	1,457
Common stock subject to repurchase	879	604	610
Restricted stock units	119		

Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements using the intrinsic value method of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and related interpretations, and complied with the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, (SFAS 123) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure, an amendment to SFAS Statement No. 123* (SFAS 148). Under APB 25 compensation expense for employees is based on the excess, if any, of the fair value of the Company s common stock over the exercise price of the option on the date of grant. Prior to January 1, 2006, no stock-based compensation expense was recorded under APB 25.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment* (SFAS 123R), which requires compensation expense related to share-based transactions, including employee stock options, to be measured and recognized in the financial statements based on fair value. SFAS 123R revises SFAS 123, as amended, and supersedes APB 25. The Company adopted SFAS 123R using a modified version of prospective application. Under modified prospective application, SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the required effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the required effective date are recognized as the requisite service is rendered on or after the required effective date. The compensation expense for that portion of awards is based on the grant-date fair value of those awards. The compensation expense for awards with grant dates prior to January 1, 2006, are attributed to periods beginning on or after the effective date using the attribution method that was used under SFAS 123, except that the method of recognizing forfeitures only as they occur is not continued.

The Company is using the straight-line method to allocate compensation cost to reporting periods under SFAS 123 and SFAS 123R. Compensation cost under the Company s employee stock purchase program was recorded using the ratable method.

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

The Company accounts for potentially beneficial conversion features under 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.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 157, Fair Value Measurements, or SFAS 157. SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and was adopted by the Company effective January 1, 2008. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, or SFAS 159. SFAS 159 provides companies with an option to report selected financial assets and liabilities at fair value. The objective of SFAS 159 is to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. Most of the provisions in SFAS 159 are elective; however, the amendment to FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities,

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

applies to all entities with available-for-sale and trading securities. SFAS 159 is effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. The Company is currently evaluating the effect that the adoption of SFAS 159 will have on its results of operations and financial position.

In June 2007, the FASB ratified Emerging Issues Task Force, or EITF, 07-3, Accounting for NonRefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. EITF 07-3 is effective, on a prospective basis, for fiscal years beginning after December 15, 2007 and was adopted by the Company effective January 1, 2008. The Company is currently evaluating the effect that the adoption of EITF 07-3 will have on its consolidated results of operations and financial position.

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 No. 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 No. 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 No. 141(R) and SFAS No. 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption is prohibited. The Company will evaluate the effect on its consolidated financial statements, if any, upon adoption of SFAS 141(R) and SFAS 160.

3. Cash, Cash Equivalents, Restricted Cash and Available-For-Sale Securities

Cash, cash equivalents, restricted cash and available-for-sale securities, all of which are considered as available-for-sale securities, consisted of the following as of December 31, 2007 and 2006 (in thousands):

	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 available-for-sale securities	$ 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	December 31, 2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 251	$	$	$ 251
Obligations of U.S. government agencies	35,107	10		35,117
Corporate debt securities	17,180	2		17,182
Other debt securities, primarily money market funds	38,673			38,673
Total available-for-sale securities	$ 91,211	$ 12	$	91,223
Amounts classified as cash and cash equivalents				78,948
Amounts classified as restricted cash				275
Amounts classified as long-term restricted cash				12,000
Total				$ 91,223

All available-for-sale securities held as of December 31, 2007 and 2006 had contractual maturities of less than one year.

Since inception, there have been no material realized gains or losses on available-for-sale securities. No available-for-sale securities held as of December 31, 2007 or 2006 had been in a continuous unrealized loss position for more than 12 months. The aggregate fair value of available-for-sale securities held at December 31, 2007 and 2006 which had unrealized losses was $10.4 million and $1.6 million, respectively. The amount of the unrealized loss at December 31, 2007 and 2006 was immaterial and the Company does not believe that the impairment is other than temporary. The fair value of available-for-sale securities is determined using quoted prices in active markets.

4. Certain Balance Sheet Items

Inventories consist of the following (in thousands):

	December 31,	
	2007	2006
Raw materials	$ 500	$ 541
Finished goods	1,713	2,485
Total inventories	$ 2,213	$ 3,026

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

	December 31,	
	2007	2006
Leasehold improvements	$ 977	$ 700
Computer equipment	1,504	873
Computer software	2,517	1,271
Furniture and fixtures	208	182
Construction-in-progress	1,257	316

Total	6,463	3,342
Less accumulated depreciation and amortization	(2,522)	(1,235)
Property and equipment, net	$ 3,941	$ 2,107

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Accrued liabilities consist of the following (in thousands):

	December 31, 2007	2006
Accrued research and development expense	$ 12,663	$ 5,119
Accrued personnel expense	6,480	4,322
Accrued sales and marketing expense	3,905	783
Accrued general and administrative expense	1,663	1,440
Liability under government settlement	1,969	
Other	2,367	1,279
Total accrued liabilities	$ 29,047	$ 12,943

5. Acquisition and Sale of Product Rights

Acquisition of Orphan Medical

On June 24, 2005, the Company acquired Orphan Medical, a developer and marketer of orphan drug products, primarily to establish a commercial presence through a specialty pharmaceutical sales organization focused on neurologists and psychiatrists. Orphan Medical marketed and sold three products and was conducting clinical trials in order to expand the potential use of one of those products to additional indications. The acquisition was accounted for as a business combination using the purchase method of accounting. Accordingly, the results of Orphan Medical are included in the Company s consolidated financial statements since the date of acquisition.

The purchase price was comprised of cash consideration (net of cash acquired) of $145.4 million plus direct acquisition costs of $750,000 and was allocated to the assets purchased and liabilities assumed based upon their respective fair values as follows (in thousands):

Accounts receivable	$ 3,348
Inventories	4,717
Other current assets	2,714
Noncurrent assets	112
Liabilities	(7,988)
Intangible assets	83,700
Goodwill	38,213
In-process research and development	21,300
Total fair value of assets acquired, net of liabilities assumed	$ 146,116

Liabilities of $8.0 million as shown above included $4.0 million of restructuring charges related primarily to employee severance payments and the closure of facilities, of which no amounts remained unpaid as of December 31, 2007.

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Management performed a valuation of identifiable intangible assets acquired in the transaction. The estimated fair value of intangible assets identified and the useful lives assigned at the time of acquisition are as follows (in thousands):

	Gross Carrying Amount	Weighted-Average Estimated Useful Life (Years)
Developed technology Xyrem	$ 39,700	9.5
Developed technology Antizol	31,100	9.5
Developed technology Cystadane	4,300	9.5
Agreements not to compete	5,600	4.4
Trademarks	2,600	9.5
Other	400	4.5
Amortizable intangible assets	$ 83,700	9.1

During the year ended December 31, 2005, the Company recorded a charge of $21.3 million for acquired in-process research and development. This amount represented the estimated fair value related to three incomplete product candidate development projects for which technological feasibility had not been established and that had no alternative future use at the time of acquisition. This charge is not deductible for federal tax purposes. The fair value of the in-process research and development was determined using the income approach. This method requires a forecast of all the expected future net cash flows associated with the in-process technology discounted to present value by applying an appropriate discount rate. The discount rate used reflects the weighted-average cost of capital for companies in the Company s industry, as well as specific risks associated with the cash flows being discounted.

In January 2005, Orphan Medical submitted a supplemental New Drug Application, or sNDA, to the FDA seeking an expanded label indication for Xyrem for the treatment of excessive daytime sleepiness in patients with narcolepsy. At the time of the acquisition, the FDA had not yet approved the sNDA. The Company used a discount rate of 26% to calculate the fair value of the expanded label indication for Xyrem and accounted for $15.2 million associated with the expanded label indication as in-process research and development expense. The sNDA was approved by the FDA in November 2005. At the time of acquisition, Orphan Medical was also conducting a Phase II clinical trial to evaluate the use of sodium oxybate, the active pharmaceutical ingredient in Xyrem, to treat fibromyalgia. The Company used a 50% discount rate to calculate the fair value associated with this development project and accounted for $5.9 million associated with the project as in-process research and development. In August 2006, the Company initiated a Phase III clinical trial of sodium oxybate for the treatment of fibromyalgia which is currently ongoing. In addition, at the time of acquisition, Orphan Medical was conducting initial research into new dosage forms of Xyrem which is currently ongoing. The Company used a 50% discount rate to calculate the fair value of these research efforts and accounted for $200,000 associated with this research as in-process research and development expense.

The excess of the purchase price over the fair value of the net tangible and identifiable intangible assets was recorded as goodwill. The primary factors contributing to the existence of goodwill relate to Orphan Medical s sales force and commercial infrastructure. During the year ended December 31, 2006 the Company finalized its estimates of the assets acquired and liabilities assumed and recorded a decrease in goodwill of $670,000. The total amount of goodwill recorded in connection with the acquisition was $38.2 million, none of which will be deductible for federal tax purposes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Sale of Product Rights

In March 2007, the Company agreed to sell 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.

In December 2007, the Company sold its rights to receive royalties on another product for $1.2 million in cash and recorded a gain of $715,000.

6. Goodwill and Intangible Assets

The gross carrying amount of goodwill was $38.2 million for the years ended December 31, 2007 and 2006. The gross carrying amounts and net book values of the intangible assets are as follows (in thousands):

	December 31, 2007			December 31, 2006		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Developed technology	$ 42,415	$ 10,499	$ 31,916	$ 75,100	$ 11,970	$ 63,130
Agreements not to compete	5,600	3,389	2,211	5,600	2,042	3,558
Trademarks	2,600	687	1,913	2,600	414	2,186
Other				400	134	266
Total	$ 50,615	$ 14,575	$ 36,040	$ 83,700	$ 14,560	$ 69,140

Future amortization costs per year for the Company s existing intangible assets other than goodwill as of December 31, 2007 are estimated as follows (in thousands):

Year Ended December 31,	Estimated Amortization Expense
2008	$ 6,856
2009	6,582
2010	4,822
2011	4,445
2012	4,445

In March 2007, as discussed in Note 5, the Company sold its rights to the Cystadane product and as a result reduced the gross carrying amount and accumulated amortization of this intangible asset by $4.3 million and $761,000, respectively. In December 2007, the Company sold its rights to receive royalties on another product and as a result reduced the gross carrying amount and accumulated amortization of this intangible asset by $400,000 and $215,000, respectively.

In December 2007, a generic fomepizole product 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. Prior to the impairment, the remaining useful life of the Antizol intangible asset was approximately 7 years. As a result of the impairment, the remaining useful life was reduced to two years and the net book value of the intangible asset associated with Antizol was $2.7 million as of December 31, 2007. The fair value of the intangible asset was calculated using the income approach. The key assumptions used to determine the fair value of the intangible asset associated with Antizol included: (a) revised estimates of future cash flows and (b) a discount rate of 14%. The discount rate

reflects the Company s expectations of future cash flows related to Antizol and an appropriate risk premium.

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Debt and Financing Obligations

Line of Credit

In September 2006, the Company entered into a one year line of credit agreement with a financial institution which was extended and then renewed through November 2008. Under the line of credit, the Company could borrow up to 80% of eligible receivables up to a maximum borrowing limit of $5.0 million. Borrowings under the line of credit bore interest at the lender s prime rate, which was 7.25% and 8.25% at December 31, 2007 and 2006, respectively. The Company was subject to certain financial and operating covenants under the credit agreement. The lender had a security interest in all of the Company s assets, with the exception of intellectual property. As of December 31, 2007 and 2006, $3.5 million and $2.2 million, respectively, were outstanding under the line of credit. In connection with the expansion of our senior debt on March 17, 2008, the Company terminated the $5.0 million line of credit. See Note 20 for information related to the expansion of our senior debt. On March 28, 2008, the $5.0 million line of credit was reinstated.

Senior Secured Notes

In June 2005, in order to partially finance the acquisition of Orphan Medical, a wholly-owned subsidiary of the Company issued $80.0 million aggregate principal amount of senior secured notes (the notes) and warrants (the warrants) to certain third parties, some of whom were affiliated with investors in the Company. As a result of the reverse stock split and the conversion of preferred stock into common stock in connection with the Company s initial public offering in June 2007, the warrants are exercisable for 785,728 shares of common stock at an exercise price of $20.36 per share. The notes accrued interest at a rate of 15% per annum, payable quarterly in arrears. The principal on the notes was due in full on June 24, 2011 and could be repaid by the Company at any time, at certain premiums over the principal amount.

The Company estimated the fair value of the warrants to be $6.7 million using the Black-Scholes option pricing model with the following assumptions at the time of issuance: risk free interest rate of 3.96%, volatility of 60%, dividend yield of 0%, and an expected life of seven years. For additional information on the determination of fair value for the warrants as of June 6, 2007 and December 31, 2006, see Note 11. The discount to the note was scheduled to accrete to zero over the life of the notes using the effective interest method and was included as a component of interest expense. Total issuance costs of $2.0 million were allocated to the notes and the warrants based on their relative fair values. Of the total issuance costs, $1.8 million was allocated to the notes and included in other assets and amortized to interest expense using the effective interest method.

The Company and all existing and future domestic subsidiaries fully and unconditionally guaranteed repayment of the notes. The notes and each guarantee were secured by a lien and security interest in substantially all of the Company s and each subsidiary s assets. The subsidiary of the Company that issued the notes was required to maintain a minimum cash balance equal to 15% of the outstanding principal amount on the notes. This amount was $12.0 million at December 31, 2007 and 2006 and is reflected as long-term restricted cash and investments on the Company s consolidated balance sheet. The notes contain customary covenants including limitations on the Company s ability to pay dividends, make investments or other restricted payments, incur debt, grant liens, sell assets and enter into sale-leaseback transactions. Upon the occurrence of certain events of default under the notes, including a default by the Company in payment of principal or interest on the notes, a bankruptcy filing by the Company, or a change in control of the Company, the Company could be required to repay the notes at a premium. The repayment premium was 23% and 30% of the principal amount of the notes as of December 31, 2007 and 2006, respectively, and was scheduled to reduce to zero ratably over the term of the notes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On March 17, 2008, the Company expanded its senior debt arrangement. See Note 20 for information related to the expansion of our senior debt.

Development Financing Obligation

In August 2005, the Company entered into an agreement pursuant to which a third party agreed to provide $30.0 million to partially fund a Phase III clinical trial of a product candidate in development in exchange for the Company s agreement to repay the third party $37.5 million subject to, and conditional upon, approval by the FDA to market the product in the U.S. In addition, the Company agreed to pay royalties at specified rates based on sales of the product within the U.S. The Company received $15.0 million in 2005 and $15.0 million in 2006 under the agreement. In June 2006, following analysis of the results of the Phase III clinical trial, the Company notified the third party of its intention to discontinue development of the product candidate. As a result, the Company recorded a gain of $31.6 million in 2006 resulting from the extinguishment of liabilities related to this transaction, which represented principal and interest accrued as of the date notice that development would be discontinued was provided to the third party. Prior to this extinguishment of liabilities in 2006, the Company had recorded interest of $1.1 million and $445,000 during the years ended December 31, 2006 and 2005, respectively, using the effective interest method.

8. Commitments and Contingencies

Indemnification

In the normal course of business, the Company enters into contracts and 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 and directors and the officers and directors of Orphan Medical 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, 2007 and 2006. 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 an office facility in Palo Alto, California which expires in August 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. In March 2007, the Company entered into a lease agreement for approximately 13,000 square feet of office space in Palo Alto, California. The term expires in August 2008. In August 2007, the Company entered into a lease agreement for approximately 11,000 square feet of office space in Palo Alto, California, which expires in August

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2009. 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 $2.0 million, $1.3 million and $930,000 for the years ended December 31, 2007, 2006 and 2005, respectively. Future minimum lease payments under the Company s noncancelable operating leases at December 31, 2007, are as follows (in thousands):

Year ended December 31,	Lease Payments
2008	$ 2,082
2009	960
2010	387
2011	71
Total	$ 3,500

The Company uses third party contract manufacturers to manufacture products. As of December 31, 2007 and 2006, the Company had $7.0 million and $1.5 million, respectively, of noncancelable purchase commitments under agreements with contract manufacturers due in 2008.

Legal Proceedings

In April 2006, the Company and its wholly owned subsidiary, Orphan Medical, Inc., 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 April 2006, a physician who was a speaker for Orphan Medical, and for a short time for the Company, was indicted by a federal grand jury in the United States District Court for the Eastern District of New York. The indictment includes allegations that the physician engaged in a scheme with Orphan Medical sales representatives and other Orphan Medical employees to promote and obtain reimbursement for Xyrem for medical uses not approved for marketing by the United States Food and Drug Administration, or FDA. In March 2007, in the same federal court, a former Orphan Medical regional sales manager, who also worked for a short time for the Company, pled guilty based on similar allegations to introducing a misbranded drug into interstate commerce. This investigation has resulted in adverse publicity for Xyrem and for the Company.

On July 13, 2007, the Company entered into (i) a civil settlement agreement (the Civil Settlement Agreement) with the United States of America, acting through the United States Department of Justice, the United States Attorney s Office for the Eastern District of New York, the Office of Inspector General of the Department of Health and Human Services (HHS-OIG), the United States Office of Personnel Management and the United States Department of Defense TRICARE Management Activity to resolve the governmental investigation related to the promotion of Xyrem and (ii) a non-prosecution agreement with the United States Attorney s Office for the Eastern District of New York (the Non-prosecution Agreement) under which the United States Attorney s Office agreed that the Company would not be prosecuted for the matters that were the subject of the investigation. Orphan Medical, which the Company acquired in June 2005, entered into (i) a plea agreement with the United States Attorney s Office for the Eastern District of New York (the Plea Agreement), under which Orphan Medical pled guilty, on July 13, 2007, to one felony count of introducing a misbranded drug into interstate commerce and (ii) the Civil Settlement Agreement. The Company expects that both Jazz Pharmaceuticals and Orphan Medical will also enter into agreements with Medicaid participating states, although to date the states have not provided the Company with any drafts of such agreements.

Pursuant to the Civil Settlement Agreement and the Plea Agreement, payments totaling approximately $20.0 million are required to be made over the period from July 20, 2007 through January 15, 2012. The total includes payments to Federal healthcare programs and Medicaid participating states, as well as restitution and fines. In

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

addition, under the Non-prosecution Agreement, the Company agreed to guarantee payment by Orphan Medical of the amounts due under the Plea Agreement. The total payments due under the Civil Settlement Agreement and the Plea Agreement are payable 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. All remaining amounts due under the Civil Settlement Agreement 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. In addition, all or a portion of the remaining amounts due under the Civil Settlement Agreement could be accelerated if the Company has net income in any year. Orphan Medical, which no longer directly markets products, may be excluded from participation in Federal healthcare programs as a result of the settlement.

The Company also entered into a five-year corporate integrity agreement with HHS-OIG (the Corporate Integrity Agreement) pursuant to which the Company agreed, among other things, to keep in place and continue the Company s current compliance program which includes a compliance committee, a compliance officer, a code of conduct, comprehensive compliance policies, training and monitoring, a compliance hotline, an open door policy and a disciplinary process for compliance violations. The Company has agreed to provide periodic reports to HHS-OIG and the Company s compliance program will be reviewed by an independent review organization.

The settlement is neither an admission of liability by the Company nor a concession by the United States that its claims are not well founded. Participation in Federal healthcare programs by Jazz Pharmaceuticals, which was not prosecuted, will not be affected by the settlement. In the event of an uncured material breach or deliberate violation, as the case may be, of the Civil Settlement Agreement, the Corporate Integrity Agreement or the Non-prosecution Agreement, the Company could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

The Plea Agreement was approved by the United States District Court for the Eastern District of New York on July 13, 2007.

While the Company has reached a settlement agreement with the United States Attorney s Office, and the other government agencies described above, the Company might still be subject to regulatory and/or enforcement action by federal agencies that are not parties to the settlement, private insurers and states attorneys general with respect to activities covered by the settlement. The Company cannot predict whether these actions are likely to occur, nor can the Company reasonably estimate the amount of any fines or penalties that might result from an adverse outcome.

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%. The non-current portion of this provision as of December 31, 2007 was $14.9 million and the current portion, which is included in accrued liabilities, was $2.0 million.

On April 10, 2006, Little Gem Life Sciences LLC, individually and purportedly on behalf of a class of persons similarly situated, filed a complaint against Orphan Medical and former officers of Orphan Medical in the Untied States District Court for the District of Minnesota. The complaint alleges that the defendants made false and misleading statements in the proxy statement prepared by Orphan Medical in connection with the solicitation of proxies to be voted at the special meeting of Orphan Medical stockholders held on June 22, 2005. The purpose of the special meeting was to consider and vote upon a proposal to adopt the definitive merger agreement pursuant to which the Company acquired Orphan Medical. The plaintiff seeks damages for itself and the putative class, in an unspecified amount, together with interest, litigation costs and expenses, and its attorneys fees and other disbursements, as well as unspecified other and further relief. On October 25, 2006, the

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

defendants filed a motion to dismiss the complaint and oral argument on the motion was heard by the United States District Court for the District of Minnesota. On February 16, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint, with leave to amend. On March 14, 2007, the plaintiff filed an amended complaint, and the defendants responded with a motion to dismiss on March 16, 2007. Oral argument on the motion was heard on June 8, 2007. On September 13, 2007, the United States District Court for the District of Minnesota granted the defendants motion to dismiss the complaint with prejudice. On September 28, 2007, the plaintiff filed a Notice of Appeal to the United States Court of Appeals for the Eighth Circuit. On November 21, 2007 the plaintiff filed its brief with the United States Court of Appeals for the Eighth Circuit. On December 21, 2007 the defendants filed their brief with the United States Court of Appeals for the Eighth Circuit. On January 8, 2008 the plaintiff filed a reply brief. Oral arguments have not yet been scheduled. The Company cannot predict or determine the outcome of this matter or reasonably estimate the amount of any judgments or payments that might result from an adverse outcome.

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

9. Collaboration and License Agreements

In January 2007, the Company entered into a product license agreement with Solvay Pharmaceuticals, Inc. (Solvay) for the rights to market Luvox CR and Luvox in the United States. The Company made a $2.0 million payment upon execution of the agreement, and agreed to make additional payments of up to $136.0 million upon achievement of development and commercial milestones. Upon approval by the FDA and the commercial launch of Luvox CR, the Company is obligated to make payments under this agreement of $41.0 million in 2008. In addition, the Company is required to pay Solvay royalties on commercial sales at specified rates. See Note 20 for information regarding the timing of expected payments.

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. The Company will owe a $5.0 million milestone payment to GlaxoSmithKline upon the enrollment of the first patient in a JZP-4 Phase II clinical trial, which the Company expects to occur in the third quarter of 2008.

The Company paid and expensed as research and development $10.4 million during the year ended December 31, 2005 upon achievement of development milestones under the terms of three agreements which have since been terminated and under which no future obligations existed at December 31, 2006. In August 2007, $1.3 million was returned to the Company from a third party under a contract which had previously been terminated. 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. The Company currently has two such agreements pursuant to which it has agreed to pay up to $7.9 million upon achievement of development and commercial milestones.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Product License

In June 2006, the Company entered into an agreement with UCB that amended and restated a prior agreement between Orphan Medical and a predecessor of UCB. Under the terms of the amended agreement, UCB has the right to market Xyrem for the treatment of narcolepsy and JZP-6 for the treatment of fibromyalgia in 54 countries outside of the United States. UCB made nonrefundable milestone payments to the Company of $2.5 million in November 2005, $0.5 million in June 2006, $2.0 million in March 2007 and $7.5 million in September 2007. 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 and $463,000 related to these upfront payments during the years ended December 31, 2007 and 2006, respectively. The remaining $13.4 million was recorded as deferred revenues as of December 31, 2007 and is being recognized ratably through 2019, the expected performance period under the agreement. There has been no change in the expected performance period since its establishment in 2006 at the time of the initial upfront payment. The amended agreement requires UCB to make additional milestone payments of up to $138.5 million, of which up to $6.0 million relate specifically to Xyrem for the treatment of narcolepsy, up to $32.5 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.

11. Preferred Stock Warrant Liability

In June 2005, in connection with the issuance of the Company s $80.0 million aggregate principal amount senior secured notes, the Company issued warrants to purchase 785,728 shares of convertible preferred stock at an exercise price of $20.36 per share. The warrants are exercisable, at the option of the holders, at any time until June 24, 2012, and were recorded as a preferred stock warrant liability. Prior to the Company s initial public offering, the preferred stock warrant liability was revalued at the end of each reporting period to fair value using the Black Scholes option pricing model. 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 at its then fair value.

The Company recorded a benefit of $1.8 million in other income during the year ended December 31, 2007 and other expense of $1.1 million and $901,000 during the years ended December 31, 2006 and 2005 to reflect changes the fair value of the preferred stock warrant liability.

The fair value of the warrants was estimated to be $6.7 million at June 6, 2007, the date the liability was reclassified to stockholders equity, and $8.5 million at December 31, 2006. The following assumptions were used to estimate the fair value of the warrants:

	June 6, 2007	December 31, 2006
Series BB preferred stock fair value	$ 17.59	$ 19.37
Volatility	54%	59%
Contractual term (years)	5.1	5.5
Risk-free rate	4.9%	4.7%
Expected dividend yield	0.0%	0.0%

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Convertible Preferred Stock and Preferred Stock

In connection with the Company s initial public offering in June 2007 all shares of convertible preferred stock were converted to common stock.

At December 31, 2007 the Company had 20,000,000 shares, $0.0001 par value, of authorized preferred stock none of which was issued or outstanding. The Company s board of directors has the authority, without further action by the stockholders, to issue from time to time preferred stock in one or more series, to fix the number of shares of any such series and the designation thereof and to fix the rights, preferences, privileges and restrictions granted to or imposed upon such preferred stock, including dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption, redemption prices, liquidation preference and sinking fund terms.

13. Common Stock

Reverse Stock Split

On May 15, 2007, the Company filed a third amended and restated certificate of incorporation with the Delaware Secretary of State effecting a 1-for-11.06701 reverse split of the Company s preferred and common stock. All share and per share amounts have been retroactively restated in these financial statements and notes for all periods presented.

Initial Public Offering

On June 6, 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

On June 6, 2007, the Company filed a fourth amended and restated certificate of incorporation which authorizes the Company to issue 150,000,000 shares of common stock. The Company has issued certain shares of its common stock under restricted stock purchase agreements with its executives and a non-employee director and upon the early exercise of stock options. Under the terms of these restricted stock purchase agreements and exercised stock options, the Company has the option to repurchase unvested shares of common stock at the initial purchase price upon the termination of a holder s services to the Company. The number of shares subject to repurchase is reduced ratably over 48 months from the date of purchase or, in the case of stock options early exercised, the date of grant of the stock option. Unvested shares are subject to a right of repurchase at cost upon termination of employment unless the Company terminates the holder without cause, the holder terminates employment under certain conditions or under specific circumstances related to a change in control. The original purchase price paid for these shares are recorded as a liability. As of December 31, 2007 and 2006, the Company had recorded a liability of $29,000 and $98,000, respectively, associated with 1,932 and 62,127 unvested shares, respectively.

In February 2004, each of the Company s executive officers entered into an employment agreement which permits the executive officer or the officer s estate to require the Company to repurchase vested shares at fair market

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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 is recorded as common stock subject to repurchase as such shares vest. The excess of the Agreement Date Fair Value over the original purchase price paid for such shares is charged against additional paid-in capital or, to the extent additional paid-in capital is insufficient, as an increase to stockholders deficit as such shares vest. In addition, upon completion of the company s initial public offering, 278,609 shares of preferred stock held by the Company s executive officers, which are also subject to their employment agreements, were reclassified from preferred stock to common stock subject to repurchase. As of December 31, 2007 and 2006, the Company had recorded $13.2 million and $8.2 million as common stock subject to repurchase, respectively, associated with 877,458 and 542,337 vested shares held by executive officers, respectively.

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

	As of December 31, 2007
2007 Equity Incentive Plan	4,407,194
2007 Employee Stock Purchase Plan	280,325
2007 Non-Employee Directors Stock Option Plan	200,000
Conversion of warrants	785,728
Total reserved shares of common stock	5,673,247

14. Stock-Based Compensation

2007 Equity Incentive Plan

The board of directors adopted the 2007 Equity Incentive Plan (the 2007 Plan) in May 2007, and the Company s stockholders approved the 2007 Plan in May 2007. The 2007 Plan will terminate on April 30, 2017, unless sooner terminated by the board of directors. The 2007 Plan 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, which may be granted to employees, including officers, non-employee directors and consultants.

Prior to the 2007 Plan, the Company s board of directors had adopted and the stockholders had approved the 2003 Equity Incentive Plan (the 2003 Plan) in March 2003. The only activity under the 2003 Plan prior to the adoption of the 2007 Plan was related to the grant of stock options to employees and a non-employee director, all of which will expire ten years from the date of grant if not exercised. The 2003 Plan was terminated in 2007. All the outstanding awards continue to be governed by their existing terms.

Share Reserve. The aggregate number of shares of the Company s common stock that may be issued pursuant to stock awards under the 2007 Plan is 4,407,794 shares. The share reserve consists of 2,125,042 shares reserved for issuance under the 2003 Plan less 217,248 shares expired under the 2003 Plan, plus an additional 2,500,000 shares reserved for issuance under the 2007 Plan. The number of shares of the Company s common stock reserved for issuance will automatically increase on January 1, from January 1, 2008 through 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, 2008, the number of shares reserved for issuance under the 2007 Plan increased by 1,107,937 shares pursuant to this automatic share increase provision. The maximum number of shares that may be issued pursuant to the exercise of incentive stock options

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

under the 2007 Plan is equal to the total share reserve, as increased from time to time pursuant to annual increases and shares subject to options granted under the 2003 Plan that expire without being exercised in full. Options granted to employees vest ratably over service periods of four to five years and expire no more than ten years after the date of grant.

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). A total of 350,000 shares of the Company s common stock were initially authorized for issuance under the ESPP. The ESPP allows eligible employee participants to purchase shares of the Company s common stock at a discount through payroll deductions. The ESPP consists of a fixed offering period, generally 24 months with four purchase periods within each offering period. Purchases are generally made on the last trading day of each November and May. The fair value of awards under the ESPP was estimated at the grant date using the Black Scholes option 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 1.3 years. As of December 31, 2007, total compensation cost related to awards under the ESPP not yet recognized was $2.3 million, which is expected to be allocated to expense and production costs over a weighted-average period of 1.3 years. As of December 31, 2007, the aggregate number of shares of the Company s common stock that may be issued pursuant to stock awards under the 2007 ESPP is 280,325 shares.

Share Reserve. 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 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, 2008, 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

The Company s board of directors adopted, and the Company s shareholders approved, the 2007 Non-Employee Directors Stock Option Plan (the 2007 Directors Option Plan) in May 2007. 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 over their period of service on the board of directors. The aggregate number of shares of common stock that may be issued initially under the 2007 Directors Option Plan is 200,000 shares. The number of shares of common stock reserved for issuance will automatically increase on January 1, from January 1, 2008 through January 1, 2017. On January 1, 2008, the number of shares reserved for issuance under the 2007 Directors Plan increased by 66,583 shares pursuant to this automatic share increase provision. In addition, the 2007 Directors Option Plan provides the source of shares to fund distributions under the Directors Deferred Compensation Plan described below.

Directors Deferred Compensation Plan

The Company s board of directors adopted the Directors Deferred Compensation Plan (the Directors Plan) in May 2007. 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 fair market value of the Company s common stock on the date the retainer fees are deemed earned. Any distributions

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 fair value per share of $12.75. For the year ended December 31, 2007, total compensation cost related to phantom shares of common stock granted under the Directors Plan was approximately $211,000.

Change in Accounting Principle Stock Based Compensation Under SFAS 123R

Effective January 1, 2006, the Company adopted SFAS 123R, which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value.

Under both SFAS 123 and SFAS 123R the Company elected to use the Black-Scholes valuation model to calculate the fair value of stock options. The fair value of stock options was estimated at the grant date with using the following assumptions:

	Year Ended December 31,		
	2007	2006	2005
Weighted-average volatility	56%	61%	60%
Weighted-average expected term (years)	6.1	6.0	5.0
Range of risk-free rates	3.4-4.9%	4.6-5.1%	3.9-4.4%
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, 2007, 2006 and 2005 was $8.42, $10.68 and $8.66, respectively.

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, 2007, the expected term was estimated using the short-cut method allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107, Share-Based Payment.

As the Company has 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

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 assumptions the Company used to estimate the fair value of grants under the Company s employee stock purchase plan were similar to those used for stock options grants.

Stock-based compensation expense recognized under SFAS 123R related to stock options, RSUs, phantom shares of common stock granted under the Directors Plan and awards under the Company s ESPP was as follows (in thousands):

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

No income tax benefit was recognized in the statement of operations for the years ended December 31, 2007 and 2006. Employee stock-based compensation costs of $43,000 and $18,000 as of December 31, 2007 and 2006, 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, 2007 was $13.7 million and the weighted-average period over which these grants are expected to vest is 3.3 years.

The following table summarizes activity under all of the Company s stock option plans as of December 31, 2007, 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, 2007	1,597,334	$ 21.62		
Options granted	1,869,485	14.59		
Options exercised	(5,617)	13.64		
Options forfeited	(63,037)	14.64		
Options expired	(18,225)	15.67		
Outstanding at December 31, 2007	3,379,940	17.91	8.1	2,045
Vested and expected to vest at December 31, 2007	3,081,817	18.18	8.0	1,796
Exercisable at December 31, 2007	1,354,688	22.29	6.3	236

Aggregate intrinsic value shown 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 2007 and 2006 were $16,000 and $90,000, respectively. No stock options were exercised during 2005.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes information about stock options outstanding as of December 31, 2007:

	Options Outstanding		Options Exercisable
Exercise Prices	Number of Shares	Weighted-Average Remaining Contractual Life (Years)	Number of Shares
$1.11	14,986	4.9	14,986
$12.75 - $14.20	1,327,493	9.6	16,665
$15.09	852,990	6.3	784,161
$15.44 - $19.37	730,925	8.9	104,218
$30.18	226,773	6.1	217,329
$45.27	226,773	6.1	217,329
	3,379,940	8.1	1,354,688

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 restricted stock units (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 year ended December 31, 2007 was $13.25. No RSUs were granted prior to 2007.

As of December 31, 2007, the total remaining unrecognized compensation cost related to non-vested RSUs was $1.2 million which is expected to be recognized over a weighted-average period of 3.6 years.

A summary of RSU activity as of December 31, 2007, and changes during the year then ended is presented below:

	Number of Restricted Stock Units	Weighted-Average Grant-Date Fair Value	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2007		$		
RSUs granted	123,991	13.25		
RSUs exercised				
RSUs forfeited	(4,950)	13.25		
RSUs expired				
Outstanding at December 31, 2007	119,041	13.25	2.1	1,750
Vested and expected to vest at December 31, 2007	99,635	13.25	2.0	1,465
Exercisable at December 31, 2007				

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounting and Disclosures Under APB 25 and SFAS 123

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements using the intrinsic value method of APB 25 and related interpretations in accounting for its employee stock options and complied with the disclosure-only provisions of SFAS 123, as amended by SFAS 148. No stock-based compensation expense was recorded under APB 25 during the year ended December 31, 2005.

The pro forma information required to be disclosed under SFAS 123 for the year ended December 31, 2005 is as follows (in thousands, except per share data):

	Year Ended December 31, 2005
Loss attributable to common stockholders, as reported	$ (85,156)
Add: Employee stock-based compensation using the intrinsic value method	
Less: Total employee stock compensation calculated using the fair-value method	(2,934)
Pro forma loss attributable to common stockholders	$ (88,090)
Loss per share attributable to common stockholders, basic and diluted	
As reported	$ (14,192.67)
Pro forma	$ (14,681.67)

15. 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, 2007	2006
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 90,859	$ 58,474
Federal and state tax credit carryforwards	11,299	9,876
Deferred contract revenues	5,405	5,453
Acquired capitalized research and development	3,409	3,889
Other	8,660	2,631
Total deferred tax assets	119,632	80,323
Deferred tax liabilities:		
Acquired intangible assets	(13,953)	(24,328)
Other		(457)

Total deferred tax liabilities	(13,953)	(24,785)
Valuation allowance	(105,679)	(55,538)
Net deferred tax assets	$	$

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 $50.1 million, $19.9 million and $24.6 million for the years ended December 31, 2007, 2006 and 2005, respectively.

At December 31, 2007, the Company had net operating loss carryforwards for federal income tax purposes of approximately $240.7 million which expire in the period from 2008 to 2027, and federal tax credits of approximately $11.7 million which expire in the period from 2008 to 2027. Approximately $3.9 million of federal net operating losses and $0.2 million of federal tax credits expire in the next five years. The Company also has state net operating loss carryforwards of approximately $177.9 million which expire beginning in 2013 and state tax credits of approximately $2.6 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 $37.0 million of the net operating loss carryforward is only available ratably through 2018 based upon the annual limitation under Section 382 of the Internal Revenue Code. Similarly, approximately $5.0 million of tax credits are only available from 2019 to 2024.

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. A reconciliation of the unrecognized tax benefits recorded for 2007 follows (in thousands):

Balance at January 1, 2007	$ 1,500
Additions based on tax positions related to the current year	560
Additions (reductions) for tax positions of prior years	
Settlements	
Lapse of applicable statute of limitations	
Balance at December 31, 2007	$ 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 tax federal examination. The Company files income tax returns in the United States and various states, which typically have three tax years open at any point in time.

16. Related Party Transactions

In June 2005, the Company issued senior secured notes in the aggregate principal amount of $80.0 million with interest payable on the notes at the rate of 15% per year, payable quarterly in arrears. The notes are due and payable on June 24, 2011. As of December 31, 2006, KKR TRS Holdings, Inc., an entity affiliated with Kohlberg Kravis Roberts & Co. L.P., (KKR), a significant stockholder, and LB I Group, an entity affiliated with Lehman Brothers Holdings Inc., held $25.0 million and $31.0 million, respectively, in principal amount of these senior secured notes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

During 2007, KKR TRS Holdings, Inc. transferred its interest in the notes to another entity affiliated with KKR, KKR Financial Holdings, III, LLC. As of December 31, 2007, KKR Financial Holdings, III, LLC and LB I Group held $25.0 million and $31.0 million, respectively, in principal amount of these senior secured notes. The interest expense recognized with respect to notes held by entities affiliated with KKR during the years ended December 31, 2007, 2006 and 2005 was $4.1 million, $4.0 million and $2.1 million, respectively. The interest expense recognized with respect to notes held by LB I Group during the years ended December 31, 2007, 2006 and 2005 was $5.1 million, $5.0 million and $2.5 million, respectively. No payments of principal were made in either of these periods. As of December 31, 2007, entities affiliated with KKR and LB I Group owned warrants to purchase 245,540 and 304,469 shares of the Company s common stock, respectively. See Note 20 for information related to the expansion of our senior debt.

17. 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, 2007.

18. 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,		
	2007	2006	2005(3)
Xyrem	$ 39,018	$ 29,049	$ 11,200
Antizol(1)	14,153	12,813	6,782
Cystadane(2)	365	1,437	814
Total	$ 53,536	$ 43,299	$ 18,796

(1) Includes sales of Antizol-Vet, which were $251,000, $313,000 and $99,000 in 2007, 2006 and 2005, respectively.
(2) The Company sold its rights to Cystadane to a third party in March 2007.
(3) Includes only approximately six months of product sales since prior to the acquisition of Orphan Medical in June 2005 the Company had no product sales.

The Company had no product sales or other revenues prior to the acquisition of Orphan Medical in June 2005.

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

	Year Ended December 31,		
	2007	2006	2005
United States	$ 53,132	$ 42,326	$ 18,305
Europe	11,856	1,757	3,020
All other	315	773	117

Total	$ 65,303	$ 44,856	$ 21,442

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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,		
	2007	2006	2005
Express Scripts	59%	65%	51%
UCB Pharma Limited	18%	*	12%
Cardinal Health	*	12%	*
AmerisourceBergen	*	*	15%

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

19. Quarterly Financial Data (Unaudited)

The following interim financial information presents the 2007 and 2006 results of operations on a quarterly basis (in thousands, except per share amounts):

	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	(19,584)	(39,863)	(19,359)	(60,020)
Loss attributable to common stockholders	(19,584)	(39,863)	(19,359)	(60,020)
Basic and diluted income (loss) per share attributable to common stockholders	(851.48)	(5.27)	(0.82)	(2.53)

	2006			
	March 31	June 30	September 30	December 31
Revenues	$ 9,837	$ 11,074	$ 11,496	$ 12,449
Operating loss	(19,245)	(21,076)	(20,600)	(17,131)
Net income (loss)	(22,379)	(24,134)	7,657	(20,535)
Net income (loss) attributable to common stockholders	(25,880)	(24,134)	7,657	(38,954)
Basic income (loss) per share attributable to common stockholders	(2,875.56)	(2,194.00)	638.08	(2,043.15)
Diluted income (loss) per share attributable to common stockholders	(2,875.56)	(2,194.00)	0.57	(2,043.15)

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

Charges of $3.5 million in the three months ended March 31, 2006 and $18.4 million in the three months ended December 31, 2006 related to a beneficial conversion feature;

A gain of $31.6 million in the three months ended September 30, 2006 resulting from the extinguishment of liabilities related to a development financing;

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 payments under the government settlement recorded in the three months ended June 30, 2007;

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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.

20. Subsequent Events

FDA Approval of Luvox CR

On February 28, 2008, the U.S. Food and Drug Administration (FDA) approved once-daily Luvox CR (fluvoxamine maleate) Extended Release Capsules for the treatment of obsessive compulsive disorder and social anxiety disorder (SAD) in adults. In January 2007, Jazz Pharmaceuticals licensed the right to market Luvox CR in the U.S. from Solvay Pharmaceuticals. In March 2008, the license agreement was amended to provide for Jazz Pharmaceuticals to pay Solvay Pharmaceuticals $10.0 million on March 28, 2008; $10.0 million on April 7, 2008; $10.5 million on September 30, 2008; and $10.5 million on December 31, 2008. Luvox CR s FDA approval included a commitment for two Phase IV clinical trials, one in adolescent patients with SAD and the other a duration of effect study in patients with SAD.

Debt Expansion

On March 17, 2008, JPI Commercial, LLC, or JPIC, a wholly-owned subsidiary of the Company, 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. We paid an $0.8 million arrangement fee and incurred other expenses in connection with the transaction. The Company will use the net proceeds to fund milestone payments due under a license agreement with Solvay Pharmaceuticals, to fund Luvox CR launch expenses and for general corporate purposes. The notes 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. In the transactions, the Company guaranteed the repayment obligations of JPIC and granted the note holders a security interest in all of the Company s assets and those of the Company s wholly-owned subsidiaries. The Company is not required to maintain a restricted cash balance under the new arrangement; however, if at any time after the quarter ending on March 31, 2009, the Company s product sales do not reach certain specified levels, JPIC would be required to maintain a restricted cash balance equal to 15% of the then outstanding principal amount of notes. The Company has also agreed to restrictions on working capital borrowings, dividends and certain other payments. Under the agreement, the Company may borrow up to $15.0 million secured by its accounts receivable and inventory. JPIC may be required, upon the occurrence of certain events and if the Company s annualized net product sales fall below a certain specified level, to redeem a portion of the notes, and may be required to repurchase or redeem a portion or all of the notes upon the occurrence of certain customary events.

Subject to satisfying conditions related to the Company s net product sales and certain closing conditions, prior to January 31, 2009 the Company has the option to sell up to $30.0 million aggregate principal amount of senior secured notes and warrants to purchase shares of the Company s common stock at an exercise price based upon the closing stock price prior to the sale of the notes and warrants.

In connection with the expansion of the senior debt, the Company terminated a $5.0 million line of credit. The line of credit was reinstated on March 28, 2008.

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JAZZ PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Prior to the issuance of the new notes on March 17, 2008, 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 on March 17, 2008, 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. Subject to certain conditions and if the Company exercises its option, LB I Group is also obligated to purchase notes with an aggregate principal amount of up to $27.0 million. The Company paid LB I Group Inc. an arrangement fee of $0.8 million in connection with the issuance of the new notes. Subsequent to the issuance of the new notes, entities affiliated with Kohlberg Kravis Roberts & Co. L.P. held notes with an aggregate principal amount of $7.1 million and warrants to purchase 70,156 shares of common stock exercisable at $20.36 per share.

Lease Extension

On February 26, 2008 the Company exercised its option to extend the lease on its corporate office building located in Palo Alto California for one year beginning August 31, 2008. In connection with this extension, the Company will pay an additional approximately $816,000 in lease payments during the one year extension. In addition to these lease payments, the Company is obligated to pay for operating expenses for the leased property.

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Schedule II

Valuation and Qualifying Accounts

(In thousands)

	Balance at beginning of period	Additions(3)	Additions charged to costs and expenses(4)	Deductions	Balance at end of period
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
For the year ended December 31, 2005					
Allowance for doubtful accounts(1)	$	$ 25	$ 14	$ (14)	$ 25
Allowance for sales discounts(1)		62	381	(372)	71
Allowance for chargebacks(1)		25	57	(56)	26
Allowance for customer rebates(1)					
Allowance for wholesaler fees(2)		134	64	(45)	153
Allowance for government rebates(2)		115	135	(162)	88

Notes

(1) shown as a reduction of accounts receivable
(2) included in accrued liabilities
(3) amounts represent the liabilities assumed as a result of the acquisition of Orphan Medical, Inc. on June 24, 2005
(4) all charges except doubtful accounts are reflected as a reduction of revenue

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EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.(8)
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.
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(7)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.
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.
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.
4.5D	Form of Common Stock Warrant of the Registrant.
4.5E#	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.
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.(8)
10.3+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel R Saks.(8)
10.4+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert M Myers.(8)
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew K Fust.(8)
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol A Gamble.(8)
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne L T Wissel.(8)
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.(8)
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce C Cozadd.(8)
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce C Cozadd.(8)

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Exhibit Number	Description of Document
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C Cozadd.(8)
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C Cozadd.(8)
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel R Saks.(8)
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel R Saks.(8)
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel R Saks.(8)
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert M Myers.(8)
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.(8)
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert M Myers.(8)
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew K Fust.(8)
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol A Gamble.(8)
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.(9)
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.(8)
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.(10)
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(9)
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.(9)
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.(11)

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Exhibit Number	Description of Document
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.(11)
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.(11)
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.(11)
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.(10)
10.42	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(10)
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(9)
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(9)
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.(11)
10.46	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(10)
10.47	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(11)
10.48	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(11)
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.(10)
10.50	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(10)
10.51	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(11)
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.(11)
10.53	Sublease Agreement, dated as of February 25, 2007, by and between Xerox Corporation and the Registrant.(11)
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.(9)
10.55+	Directors Deferred Compensation Plan.(3)
10.56+	Non-Employee Director Compensation Arrangements.(3)
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.(12)
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.(12)
10.57C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.(12)

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Exhibit

Number	Description of Document
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.(12)
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)
10.61+	Non-Employee Director Compensation Arrangements, as modified on July 18, 2007.(1)
10.62+	Amendment No. 2 to Employment Agreement, effective on September 1, 2007, by and between the Registrant and Bruce C. Cozadd.(13)
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.(13)
10.64+	Form of Restricted Stock Unit Award under the Registrant s 2007 Equity Incentive Plan.(13)
10.65+	Non-Employee Director Compensation Arrangements, as modified on December 18, 2007.
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.
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.
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.
10.69#	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.
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 Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

+ 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. 333-33500) 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.

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(4) Incorporated herein by reference to Exhibit 4.3 to the Registrant s quarterly report on Form 10-Q (File No. 333-33500) for the period ended June 30, 2007, as filed with the SEC on August 10, 2007.
(5) Incorporated by reference to Exhibit 4.4 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 Exhibit 4.5 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 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.
(8) 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.
(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 May 24, 2007.
(10) 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.
(11) 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.
(12) 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.
(13) Incorporated herein by reference to the same numbered exhibit to the Registrant s quarterly report on Form 10-Q (File No. 000-33500) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
* 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.