JAZZ PHARMACEUTICALS INC
Form S-3
June 11, 2008
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As filed with the Securities and Exchange Commission on June 11, 2008

Registration No. 333-_____

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

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)

Samuel R. Saks, M.D.

Chief Executive Officer

Jazz Pharmaceuticals, Inc.

3180 Porter Drive

Palo Alto, CA 94304

(650) 496-3777

(Name, address, including zip code, and telephone number,

including area code, of agent for service)

Copies to:

Carol A. Gamble, Esq.
Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304
(650) 496-3777

Suzanne Sawochka Hooper, Esq.
Cooley Godward Kronish LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155
(650) 843-5000

Approximate date of commencement of proposed sale to the public:

From time to time after the effective date of this registration statement

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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 Smaller reporting company ¨

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common Stock, par value $.0001 per share	3,562,192 shares(3)	$7.02	$25,006,587.84	$982.76

(1) Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457 promulgated under the Securities Act. The offering price per share and the aggregate offering price are based upon the average of the high and low prices of the Registrant s common stock as reported on the NASDAQ Global Market on June 9, 2008.

(3) Includes of 562,192 shares of common stock that may be issued upon the exercise of outstanding warrants issued in a private placement of senior secured notes and warrants in March 2008 and up to 3,000,000 shares of common stock that may be issued upon the exercise of warrants that will be issued by the Registrant if its wholly-owned subsidiary elects to issue additional senior secured notes.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated June 11, 2008

PROSPECTUS

3,562,192 Shares

Common Stock

This prospectus relates to the disposition from time to time of up to 3,562,192 shares of our common stock issuable upon the exercise of outstanding warrants acquired in connection with a private placement of senior secured notes and warrants and warrants which may be issued to the selling stockholders in the event that our wholly-owned subsidiary elects to issue and sell additional senior secured notes to the selling stockholders, which it may do at its option, subject to certain conditions. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders.

The selling stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell their shares of common stock in the section titled Plan of Distribution on page 29. We will not pay any underwriting discounts or commissions in this offering.

Our common stock is traded on the NASDAQ Global Market under the symbol JAZZ. On June 9, 2008, the last reported sale price of our common stock on the NASDAQ Global Market was $6.75.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors beginning on page 3 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 20 .

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ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the selling stockholders have not, authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. The information in this prospectus is accurate only as of the date of this prospectus and any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of our common stock.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus, before making an investment decision.

JAZZ PHARMACEUTICALS, INC.

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 three marketed products and four product candidates in various stages of clinical development. We also have additional product candidates in earlier stages of development.

Our marketed products are:

Xyrem® (sodium oxybate) oral solution. Xyrem is the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both 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 13 countries.

Luvox® CR (fluvoxamine maleate extended release capsules). Once-daily Luvox CR was approved by the FDA for the treatment of both obsessive compulsive disorder and social anxiety disorder on February 28, 2008. We shipped initial quantities of Luvox CR to wholesalers in March 2008 and began promoting the product through our specialty sales force in April 2008. Luvox CR is a once-daily extended release formulation of fluvoxamine, a selective serotonin reuptake inhibitor. 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 the remainder of 2008, we expect to continue to make significant expenditures relating to the commercialization 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. A generic form of fomepizole was introduced into the market in December 2007 and other generic forms of fomepizole have been approved by the FDA. As a result, we expect that sales of Antizol will decrease substantially during the remainder of 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

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expect preliminary data in the fourth quarter of 2008 from the first Phase III pivotal clinical trial, for which we have completed patient enrollment at 550 subjects. 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 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.

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.

We were incorporated in California in March 2003, and we reincorporated in Delaware in January 2004. Our principal executive office is located at 3180 Porter Drive, Palo Alto, California 94304. Our telephone number is (650) 496-3777. Our website address is www.jazzpharmaceuticals.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

Unless the context indicates otherwise, as used in this prospectus, the terms Jazz Pharmaceuticals, we, us and our refer to Jazz Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries. We use Jazz Pharmaceuticals®, Xyrem®, Antizol®, Luvox® and the Jazz Pharmaceuticals logo as trademarks in the United States and other countries. We have licensed the right to use the registered trademarks Antizol® from Mericon Investment Group, Inc. and Luvox® from Solvay Pharmaceuticals, Inc. All other trademarks or trade names referred to in this prospectus are the property of their respective owners.

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R ISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below, and all other information contained in or incorporated by reference in this prospectus, before deciding whether to buy our common stock. If any of the following risks actually occur, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and could result in a complete loss of your 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, paid $10.0 million on March 28, 2008 and $10.0 million on April 7, 2008, and will pay Solvay $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 are being 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, Inc., or 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, 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 supplemental new drug application, or sNDA for Cymbalta (duloxetine) in August 2007, and Forest Laboratories (with Cypress Bioscience) filed an NDA for milnacipran in December 2007 seeking FDA approval for the

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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 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.

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In addition, our product candidates are subject to competition for clinical study sites and patients from other therapies under development that may delay the enrollment in or initiation of our clinical trials. 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 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.

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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 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 an agreement with the central pharmacy for Xyrem, Express Scripts, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem, and our sales, would be adversely affected. Changing central pharmacy distributors could take a significant amount of time. In addition, sodium oxybate, the active pharmaceutical ingredient in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. The new 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 commercialized products and product candidates. Our suppliers

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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.

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.

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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.

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.

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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, 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 are marketing 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 other 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 other products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR. 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 (with Cypress Bioscience) 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.

A generic form of fomepizole was introduced into the market in December 2007; other generic forms of fomepizole have been approved by the FDA. We expect sales of Antizol to decline significantly for the remainder of 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.

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.

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

Our success depends in part on our continued ability to retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry key person insurance. 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 recently reduced the number of non-sales employees in our company in connection with efforts to focus, in the near term, on our commercial products and later-stage product candidates. Competition for qualified personnel in the life sciences industry is intense, and 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 need to hire additional personnel to expand our development, clinical and commercial activities, or to support those activities, we may not be able to attract and retain quality personnel on acceptable terms.

If we need to accelerate our activities or expand our business, and cannot recruit qualified employees when we need them, our key activities could be delayed. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage our personnel resources effectively, and our failure to do so could adversely affect our business, financial condition, results of operations and growth prospects.

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

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

Risks Related to Our Intellectual Property

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, their use and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties 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 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.

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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;
- 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.

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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 Prescription Drug User Fee Act, or PDUFA, deadlines for completing reviews of NDAs. If the FDA were to miss a PDUFA deadline for one of our products, delaying the approval and launch, the delay could have a material adverse effect on our business.

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

If we receive regulatory approvals to sell our products, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of our products, or impose requirements for burdensome post-approval study commitments. The terms of any product approval, including labeling, may be more restrictive than we desire and could affect the marketability of the product or otherwise reduce the size of the potential market for that product. Following any regulatory approval of our products, we will be subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. In addition, if the FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with any of our products in the 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.

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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 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

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incorrect, or changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected average manufacturing price or best price for that quarter. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. In addition to retroactive rebates (and interest, if any), if we are found to have knowingly submitted false information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

Federal law requires that any company that participates in the Medicaid rebate program extend comparable discounts to qualified purchasers under the Public Health Services pharmaceutical pricing program requiring us to sell our products at prices lower than we otherwise might be able to charge. The Public Health Services pricing program extends discounts comparable to the Medicaid rebates to a variety of community health clinics and other entities that receive health services grants from the Public Health Services, as well as hospitals that serve a disproportionate share of poor patients and children.

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

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract strategic partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations and private health insurers. Third party payors decide which drugs they will pay for and establish reimbursement levels. Third party payors are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefits coverage and reimbursement policies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Even with studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third party payors may not provide coverage and reimbursement for our products, in whole or in part. We cannot predict actions third party payors may take, or whether they will limit the coverage and level of reimbursement for our products or refuse to provide any coverage at all. For example, because Luvox CR is competing in a market with both branded and generic products, reimbursement by government and private payors may be more challenging than for new chemical entities. We cannot be sure that reimbursement amounts 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.

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 and Luvox CR, and the market participants to whom we expect to sell most of our future products, have undergone significant consolidation, marked by mergers and acquisitions among wholesale distributors and the growth of large retail drugstore chains. As a result, a small number of large wholesale distributors control a significant share of the

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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 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.

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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 and the three months ended March 31, 2008 was $138.8 million and $46.7 million, respectively, and we had an accumulated deficit of $363.2 million at March 31, 2008. We expect our operating expenses to continue at similar rates, and they could increase, over the next several years as we continue to market Luvox CR, develop, acquire or in-license additional products or product candidates, conduct clinical trials for our product candidates, undertake research and development activities, seek regulatory approvals and engage in commercialization preparation activities in anticipation of potential FDA approval of our product candidates. We may 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.

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 further reduce operations.

As of March 31, 2008, we had approximately $105.2 million in cash, cash equivalents and marketable securities. Our net cash used in operations for the three months ended March 31, 2008, and the year ended December 31, 2007 was approximately $38.2 million and $81.1 million, respectively. Substantially all of our net product sales 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 recently reduced our activities to focus on our commercial products and later stage product candidates, including a reduction in the size of our work force. Even with this change, we must continue to commit substantial resources to costly and time-consuming product development and clinical trials of our product candidates and significant funds to our commercial operations. We believe that our current cash and cash equivalents and interest earned thereon, together with future financings, the proceeds available under the committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge, that we entered into on May 7, 2008 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;
- 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.

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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 exercise our right to draw down amounts under the CEFF, Kingsbridge will not be obligated to purchase shares of our common stock under the CEFF unless certain conditions are met, which include: a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; and the effectiveness of a registration statement that we have filed with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant that we issued to Kingsbridge. 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 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. We recently implemented plans to reduce our expenditures by focusing on our commercial products and later stage product candidates and eliminating some jobs. If necessary, we would implement, beginning as early as the third quarter of 2008, appropriate plans and additional measures to quickly reduce discretionary spending and capital expenditures, terminate or slow additional product development programs, further 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 $40.0 million of additional secured indebtedness in connection with the sale of senior secured notes and warrants and the exchange of existing senior debt which increased our aggregate senior debt to $120.0 million at face value. 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;

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;

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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, including shares issued under the CEFF, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. In addition, the perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. As of May 9, 2008, we had 24,622,636 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 18,622,636 shares of common stock outstanding as of May 9, 2008, 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 May 9, 2008, the holders of up to approximately 19,306,128 shares of common stock, based on shares outstanding as of that date, including 1,787,920 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, of which this prospectus is a part, 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 and use our reasonable best efforts to cause such registration statement to become and remain effective. The registration rights agreement entered into in connection with the CEFF requires that we use commercially reasonable efforts to have the registration statement in connection with the CEFF declared effective and ensure that it remains effective for the term of such agreement. In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under our stock option and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

The CEFF may result in dilution to our stockholders.

Pursuant to the CEFF, Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of $75.0 million of our common stock or 4,922,064 shares of our common stock over a three-year period. We are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement that we have filed with the SEC registering for resale the shares of common stock to be issued under the CEFF and the shares underlying the warrant we issued to Kingsbridge. If we deliver a blackout notice in the 15 trading days following a settlement of a draw down, then we must make a blackout payment to Kingsbridge, or issue Kingsbridge additional shares of our common stock in lieu of this payment. If we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to ten percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

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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 May 9, 2008, our executive officers and directors, together with their respective affiliates, beneficially owned 64.0% 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 LLC have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel must continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may incur substantial costs to maintain the same or similar coverage.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. 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.

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;

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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.

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DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain certain forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 with respect to our financial condition, results of operations and business. Words such as anticipates, expects, intends, plans, predicts, believes, seeks, estimates, could, would, will, may, potential, should, and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this prospectus and the other documents incorporated by reference that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 in Item 1A under Risk Factors as well as in Item 7A Qualitative and Quantitative Disclosures About Market Risk, our Quarterly Report on Form 10-Q for the period ended March 31, 2008 in Part II, Item 1A under Risk Factors as well as in Part I, Item 3 Qualitative and Quantitative Disclosures About Market Risk and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- the launch of Luvox CR and our anticipated sales and marketing efforts;
- the future performance from Xyrem sales efforts;
- the progress and results of our research and development programs;
- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the results and timing of our clinical trials and the commencement of future clinical trials; and
- submission and timing of applications for regulatory approval.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this prospectus or, in the case of documents incorporated by reference, as of the date of such documents. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our common stock by the selling stockholders pursuant to this prospectus. The shares covered by this prospectus are issuable upon exercise of warrants to purchase up to 3,562,192 shares of our common stock issued pursuant to a senior secured note and warrant purchase agreement described below under the heading **Private Placement of Senior Secured Notes and Warrants** . Warrants to purchase 562,192 shares of our common stock are issued and outstanding at an exercise price of $14.23 per share. Additional warrants to purchase up to a maximum of 3,000,000 shares of our common stock shall be issued if our wholly-owned subsidiary issues and sells additional senior secured notes to the purchasers of the senior secured notes and warrants issued pursuant to the senior secured note and warrant purchase agreement. The actual number of shares of our common stock that may be purchased upon exercise of such additional warrants would be calculated based on the closing stock price prior to the issuance of such warrants at an exercise price based upon the closing stock price prior to the sale of the additional notes and warrants. The warrants are exercisable for cash or on a cashless basis. If the warrants are exercised on a cashless basis, we would issue fewer shares and not receive any cash payment from the selling stockholders upon any exercise of the warrants.

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PRIVATE PLACEMENT OF SENIOR SECURED NOTES AND WARRANTS

On March 14, 2008, we and JPI Commercial, LLC, or JPIC, our wholly-owned subsidiary, entered into a senior secured note and warrant purchase agreement among the purchasers named therein, us and JPIC, as well as certain related agreements. Under the terms of the senior secured note and warrant purchase agreement, JPIC issued and sold $40 million in aggregate principal amount of senior secured notes and we issued warrants to purchase 562,192 shares of our common stock at an exercise price of $14.23 per share on March 17, 2008. JPIC may, at its option, issue and sell up to an additional $30 million in aggregate principal amount of senior secured notes to the purchasers in a subsequent closing to occur not later than January 31, 2009. JPIC s ability to require the purchasers to acquire additional senior secured notes is subject to the satisfaction of certain conditions, none of which is in the control of the purchasers, including the following:

- our net products sales of our commercial products shall have reached certain levels by the end of 2008;
- the representations and warranties made by JPIC and us to the purchasers in the senior secured note and warrant purchase agreement as well as certain related agreements shall be accurate in all material respects as of the date such additional senior secured notes are issued and sold;
- JPIC and we shall have performed and complied with all agreements and conditions contained in the senior secured note and warrant purchase agreement required to be performed or complied with by it or us prior to the issuance and sale of such additional senior secured notes;
- no event of default, as set forth in the senior secured note and warrant purchase agreement, shall have occurred, nor shall any event have occurred or condition exist which would, with the lapse of time or giving of notice or both, become an event of default;
- no undisclosed event shall have occurred since December 31, 2006 which could reasonably be expected to have a material adverse effect on (i) the business, operation, affairs, financial condition, assets or properties of us and our subsidiaries taken as a whole; (ii) the ability of JPIC or us to perform our respective obligations under the senior secured note and warrant purchase agreement, senior secured notes, and warrants; or (iii) the validity or enforceability of the senior secured note and warrant purchase agreement or the senior secured notes or warrants;
- we shall have reserved sufficient shares of our common stock to issue upon exercise of the warrants to be issued in connection with the issuance and sale of such additional senior secured notes; and
- JPIC and we shall have delivered certain certifications and other documentation as of the date such additional senior secured notes are issued and sold.

In the event that JPIC elects to issue additional senior secured notes pursuant to the senior secured note and warrant purchase agreements in a subsequent closing, we will issue to the purchasers warrants to purchase an aggregate of such number of shares of our common stock as will equal (i) 20 percent of the aggregate principal amount of the additional senior secured notes issued in the subsequent closing divided by (ii) the exercise price of such warrant, which exercise price will equal the greater of (x) $2.00 or (y) the product of 1.2 times the volume weighted average price of our common stock for the period of 30 consecutive days ending on the date we and JPIC give the purchasers a required notice under the senior secured note and warrant purchase agreement for the consummation of the subsequent closing.

Each warrant issued pursuant to the senior secured note and warrant purchase agreement is exercisable for a period of five years from the date of issuance. The warrants may be exercised for cash or on a cashless basis, in which case we will deliver, upon exercise, the number of shares with respect to which the warrant is being exercised reduced by a number of shares having a value (based on a five day average of the closing sales price of our common stock) equal to the aggregate exercise price of the shares with respect to which the warrant is being exercised.

In connection with the initial sale and issuance of senior secured notes and warrants pursuant to the senior secured note and warrant purchase agreement, a total of $80 million in aggregate principal amount of outstanding senior secured notes of Orphan Medical, LLC, or Orphan, our wholly-owned subsidiary, were exchanged by the holders of such senior secured notes for the same principal amount of new senior secured notes under the senior secured note and warrant purchase agreement, such that the total aggregate principal amount of indebtedness issued under the senior secured note and warrant purchase agreement is $120.0 million with a possibility to increase to up to $150.0 million in a subsequent closing.

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In connection with the initial sale and issuance of senior secured notes and warrants pursuant to the senior secured note and warrant purchase agreement, we entered into a registration rights agreement with the purchasers pursuant to which we agreed to file, on or before June 6, 2008, a registration statement, of which this prospectus is a part, covering the resale of the 562,192 shares of our common stock underlying the warrants that we issued in connection with the initial sale of senior secured notes pursuant to the senior secured note and warrant purchase agreement, and up to 3,000,000 shares of our common stock underlying the warrants we may issue in the event JPIC elects to issue and sell additional senior secured notes and warrants in a subsequent closing pursuant to the senior secured note and warrant purchase agreement.

SELLING STOCKHOLDERS

The following table presents information regarding the selling stockholders, and the shares that each may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholders, and reflects holdings as of May 31, 2008. As used in this prospectus, the term selling stockholder includes a selling stockholder and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column Number of Shares Being Offered represents all of the shares that a selling stockholder may offer under this prospectus. A selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares of common stock beneficially owned prior to the offering shown in the table below is based both on an aggregate of 24,898,024 shares of our common stock outstanding on May 31, 2008, and on the assumption that all shares of common stock issuable upon exercise of the warrants held by or issuable to a particular selling stockholder pursuant to the Senior Secured Note and Warrant Purchase Agreement are outstanding as of that date. All share and per share amounts have been adjusted to give effect to the 1-for-11.06701 reverse stock split of our common stock and preferred stock effected on May 15, 2007.

	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares Being Offered	Shares of Common Stock Beneficially Owned After Offering	
Stockholders	Number	Percent		Number	Percent
LB I Group Inc.(1)	4,066,415(2)	14.21%	3,170,836	895,579	1.63%
Deep Cove Mezzanine, LLC(3)	255,085(4)	1.01%	205,977	49,108	*
General Electric Pension Trust(5)	263,952(6)	1.05%	185,379	78,573	*

* Less than one percent.

(1) The business address of LB I Group Inc. is 399 Park Avenue, New York, NY 10022. LB I Group Inc. is a wholly-owned subsidiary of Lehman Brothers Inc., which is a registered broker-dealer. LB I Group Inc. has represented to us that it is not acting as an underwriter in this offering, it purchased the shares it is offering under this prospectus in the ordinary course of business, and at the time of such purchase, it had no agreements or understandings, directly or indirectly, with any person to distribute the securities. Lehman Brothers Holdings Inc., a public reporting company, is the parent company of Lehman Brothers Inc.

(2) Includes 470,836 shares of our common stock that the selling stockholder has the right to acquire through the exercise of a warrant issued in connection with the initial sale of senior secured notes and warrants pursuant to the senior secured note and warrant purchase agreement on March 17, 2008, and an additional 2,700,000 shares of our common stock representing the maximum number of shares the selling stockholder may have the right to acquire through the exercise of a warrant that we would issue to the selling stockholder in a subsequent closing pursuant to the senior secured note and warrant purchase agreement. Also includes an aggregate of 550,010 shares of our common stock that the selling stockholder has the right to acquire through the exercise of warrants (the LB Prior Warrants), a portion of which were issued by us in connection with the sale of senior secured notes by Orphan in June 2005 and a portion of which were acquired by the selling stockholder from other purchasers of

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senior secured notes issued by Orphan in June 2005, which notes have been exchanged for senior secured notes pursuant to the senior secured note and warrant purchase agreement. Also includes 165,661 shares held by Lehman Brothers Healthcare Venture Capital L.P., or LBHVC, the general partner of which is Lehman Brothers Healthcare Venture Capital Associates L.P., the general partner of which is the selling stockholder. Also includes 142,858 shares held by Lehman Brothers Partnership Account 2000/2001, L.P., or LBPA, the general partner of which is the selling stockholder. Also includes 37,050 shares held by Lehman Brothers Offshore Partnership 2000/2001 L.P., or LB Offshore, the general partner of which is Lehman Brothers Offshore Partnership GP 2000/2001 L.P., the general partner of which is Lehman Brothers Offshore Partners Ltd., which is wholly-owned by the selling stockholder. The shares of our common stock underlying the LB Prior Warrants and the shares of common stock held by LBHVC, LBPA and LB Offshore are not being offered for resale pursuant to this prospectus.

(3) The business address of Deep Cove Mezzanine, LLC is 560 Oakwood Avenue, Suite 203, Lake Forest, IL 60045.

(4) Includes 48,082 shares that the selling stockholder has the right to acquire through the exercise of a warrant issued in connection with the initial sale of senior secured notes and warrants pursuant to the senior secured note and warrant purchase agreement on March 17, 2008, and an additional 157,895 shares of our common stock representing the maximum number of shares the selling stockholder may have the right to acquire through the exercise of a warrant that we would issue to the selling stockholder in a subsequent closing pursuant to the senior secured note and warrant purchase agreement. Also includes 49,108 shares of our common stock that the selling stockholder has the right to acquire through the exercise of a warrant (the DC Prior Warrant) issued by us in connection with the sale of senior secured notes by Orphan in June 2005, which notes have been exchanged for senior secured notes pursuant to the senior secured note and warrant purchase agreement. The shares of our common stock underlying the DC Prior Warrant are not being offered for resale pursuant to this prospectus.

(5) The business address of General Electric Pension Trust is c/o GE Asset Management Incorporated, 3001 Summer Street, Stamford, CT 06905. GE Asset Management Incorporated, or GEAM, is the investment manager of General Electric Pension Trust, or GEPT, and a wholly-owned subsidiary of General Electric Company, or GE. GEAM shares voting and dispositive power over the securities owned by GEPT and may be deemed to be the beneficial owner of the securities owned by GEPT for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended. GE expressly disclaims any voting or dispositive power over the securities owned by GEPT.

(6) Includes 43,274 shares that the selling stockholder has the right to acquire through the exercise of a warrant issued in connection with the initial sale of senior secured notes and warrants pursuant to the senior secured note and warrant purchase agreement on March 17, 2008, and an additional 142,105 shares of our common stock representing the maximum number of shares the selling stockholder may have the right to acquire through the exercise of a warrant that we would issue to the selling stockholder in a subsequent closing pursuant to the senior secured note and warrant purchase agreement. Also includes 78,573 shares of our common stock that the selling stockholder has the right to acquire through the exercise of a warrant (the GEPT Prior Warrant) issued by us in connection with the sale of senior secured notes by Orphan in June 2005, which notes have been exchanged for senior secured notes pursuant to the senior secured note and warrant purchase agreement. The shares of our common stock underlying the GEPT Prior Warrant are not being offered for resale pursuant to this prospectus.

Relationship with LB I Group Inc.

LB I Group Inc., or LB I, which serves as the collateral agent under the senior secured note and warrant purchase agreement, is a wholly-owned subsidiary of Lehman Brothers Inc., a wholly-owned subsidiary of Lehman Brothers Holdings, Inc. and an entity which, along with Lehman Brothers Holdings, Inc. is affiliated with certain of our stockholders. LB I received an arrangement fee of $800,000 in connection with the transactions contemplated by the senior secured note and warrant purchase agreement. Immediately prior to the closing of the initial sale of senior secured notes and warrants pursuant to the senior secured note and warrant purchase agreement, LB I held a majority of the senior secured notes issued by Orphan, and LB I currently holds a majority of the senior secured notes issued pursuant to the senior secured note and warrant purchase agreement (including senior secured notes issued in exchange for the senior secured notes of Orphan). In the event that JPIC elects to issue and sell additional senior secured notes pursuant to the senior secured note and warrant purchase agreement, LB I will be obligated to purchase up to $27.0 million principal amount of the additional $30.0 million aggregate senior secured notes that may be issued at such subsequent closing.

Based on information supplied to us by LB I, the beneficial ownership of our common stock by LB I, Lehman Brothers Holdings, Inc. and their affiliates as of June 2, 2008 is as follows: 1,020,846 shares that LB I has the right to acquire through the exercise of warrants; 234 shares held by Lehman Brothers Inc., a wholly-owned subsidiary of Lehman Brothers Holdings Inc.; 25 shares held by Lehman Brothers OTC Derivatives Inc., a wholly-owned subsidiary of Lehman Brothers Holdings Inc.; 3,000 shares held by Lehman Brothers Special Financing Inc., a wholly-owned subsidiary of Lehman Brothers Inc., a wholly-owned subsidiary of Lehman Brothers Holdings Inc.; 165,661 shares held by LBHVC; 317,076 shares held by Lehman Brothers P.A., LLC, a wholly-owned subsidiary of Property Asset Management Inc., a wholly-owned subsidiary of Lehman ALI Inc., a wholly-owned subsidiary of Lehman Brothers Holdings Inc.; 142,858 shares held by LBPA; and 37,050 shares held by LB Offshore. LB I provided us information only as of June 2, 2008. Information with respect to the beneficial ownership of reporting persons above other than LB I may have changed since June 2, 2008.

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During the period from February 2004 to December 2006, we sold an aggregate of 662,645 shares of Series B Preferred Stock to entities affiliated with Lehman Brothers Holdings Inc., at a per share price of $15.09, which were converted into an equal number of shares of our common stock in connection with the closing of our initial public offering in June 2007. In June 2005, in connection with the issuance of senior secured notes by Orphan, including $30.0 million in principal amount to LB I Group Inc., we issued a warrant to purchase 294,648 shares of our Series BB Preferred Stock to LB I. In March 2006, LB I purchased an additional $1.0 million of senior secured notes issued by Orphan from a third party and received an additional warrant to purchase 9,822 shares of our Series BB Preferred Stock. The aggregate warrants to purchase 304,470 shares of Series BB Preferred Stock were converted into warrants to purchase an equal number of shares of our common stock in connection with the closing of our initial public offering in June 2007. In March 2008, LB I purchased an additional $25.0 million of senior secured notes issued by Orphan from third parties and received an additional warrant to purchase 245,540 shares of our common stock. The senior secured notes issued by Orphan have been exchanged for senior secured notes pursuant to the senior secured note and warrant purchase agreement.

On May 31, 2007, our Registration Statement on Form S-1/A was declared effective for our initial public offering, pursuant to which we sold 6,000,000 shares of our common stock at a public offering price of $18.00 per share. Lehman Brothers Inc. acted as a representative of the underwriters in the initial public offering.

LB I is under common control with Lehman Brothers Inc., a registered broker-dealer. LB I has represented to us that the securities held by it were purchased in the ordinary course of business and that at the time of purchase of the securities held by it, it did not have any agreements or understandings, directly or indirectly, with any person to distribute the securities held by it.

With the exception of the foregoing, LB I has not had any position, office or other material relationship with us or our affiliates in the past three years.

Relationship with Deep Cove Mezzanine, LLC

In the event that JPIC elects to issue and sell additional senior secured notes pursuant to the senior secured note and warrant purchase agreement, Deep Cove Mezzanine LLC will be obligated to purchase up to $1.6 million principal amount of the additional $30.0 million aggregate senior secured notes that may be issued at such subsequent closing.

During the period from February 2004 to December 2006, we sold an aggregate of 477,106 shares of Series B Preferred Stock to Waud Capital Partners, L.P. and 53,011 shares of Series B Preferred Stock to Waud Capital Affiliates, L.L.C., entities affiliated with Deep Cove Mezzanine, LLC, at a per share price of $15.09, which were converted into an equal number of shares of our common stock, respectively, in connection with the closing of our initial public offering in June 2007. In June 2005, in connection with the issuance of senior secured notes by Orphan, including $5.0 million in principal amount to Deep Cove Mezzanine, LLC, we issued the DC Prior Warrant to Deep Cove Mezzanine, LLC. The senior secured notes issued by Orphan have been exchanged for senior secured notes pursuant to the senior secured note and warrant purchase agreement.

With the exception of the foregoing, Deep Cove Mezzanine, LLC has not had any position, office or other material relationship with us or our affiliates in the past three years.

Relationship with General Electric Pension Trust

In the event that JPIC elects to issue and sell additional senior secured notes pursuant to the senior secured note and warrant purchase agreement, General Electric Pension Trust will be obligated to purchase up to $1.4 million principal amount of the additional $30.0 million aggregate senior secured notes that may be issued at such subsequent closing.

In June 2005, in connection with the issuance of senior secured notes by Orphan, including $8.0 million in principal amount to General Electric Pension Trust, we issued the GEPT Prior Warrant to General Electric Pension Trust. The senior secured notes issued by Orphan have been exchanged for senior secured notes pursuant to the senior secured note and warrant purchase agreement.

With the exception of the foregoing, General Electric Pension Trust has not had any position, office or other material relationship with us or our affiliates in the past three years.

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PLAN OF DISTRIBUTION

We are registering 3,562,192 shares of common stock under this prospectus issuable upon exercise of the warrants to permit the resale of these shares of common stock by the holders thereof from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may decide not to sell any shares. The shares may be sold directly or through broker-dealers acting as a principal or agent, or pursuant to a distribution by one or more underwriters on a firm commitment or best-efforts basis. The selling stockholders may from time to time offer some or all of the shares of common stock through brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholders may arrange for other broker-dealers to participate. The selling stockholders may be underwriters within the meaning of the Securities Act. Any brokers, dealers or agents who participate in the distribution of the shares of common stock may also be deemed to be underwriters, and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts or commissions under the Securities Act. A selling stockholder may effect resales of our common stock through any one or more registered broker-dealers.

The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made over the NASDAQ Global Market, in the over-the-counter market, or on any other national securities exchange on which our shares are listed or traded or in transactions otherwise than on these exchanges or systems, or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold according to one or more of the following methods:

- a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus;
- an over-the-counter distribution in accordance with the rules of NASDAQ;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- in an exchange distribution in accordance with the rules of the applicable exchange;
- in privately negotiated transactions;
- in underwritten transactions;
- through the settlement of short sales;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;

where broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of such methods of sale; and

any other method permitted pursuant to applicable law.

Any shares covered by this prospectus may be sold in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(1) under the Securities Act, if available, rather than pursuant to this prospectus, provided that the selling stockholders meet the criteria and conform to the requirements of those provisions. In addition, the selling stockholders may transfer the shares by other means not described in this prospectus.

In connection with distributions of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of our common stock in the course of hedging the positions they assume with the selling stockholders. The selling stockholders may also sell the common stock short and if such short sale shall take place after the date that the registration statement of which this prospectus is a part is declared effective by the SEC, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such

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short sales. The selling stockholders may also enter into options or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders may also pledge shares to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Any broker-dealer participating in such transactions as underwriter or agent may receive commissions from a selling stockholder and may receive compensation in the form of discounts, concessions or commissions from the selling stockholders or from purchasers of the offered shares for whom they may act as agents. In addition, underwriters may sell the shares to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents. Broker-dealers may agree with a selling stockholder to sell a specified number of shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for the selling stockholder, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to the selling stockholder. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) on the NASDAQ Global Market, on the over-the-counter market, in privately-negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above. To the extent required under the Securities Act, an amendment to this prospectus, or a supplemental prospectus will be filed, disclosing:

- the name of any such broker-dealers;
- the number of shares involved;
- the price at which such shares are to be sold;
- the commission paid or discounts or concessions allowed to such broker-dealers, where applicable;
- that such broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and
- other facts material to the transaction.

In order to comply with the securities laws of some states, if applicable, the shares must be sold in those states only through registered or licensed brokers or dealers. In addition, some states may restrict the selling stockholders from selling their shares unless the shares have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Underwriters and purchasers that are deemed underwriters under the Securities Act may engage in transactions that stabilize, maintain or otherwise affect the price of the securities, including the entry of stabilizing bids or syndicate covering transactions, short sales or the imposition of penalty bids. The selling stockholders and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases and sales of any of the shares of common stock set forth in this prospectus by the selling stockholders or other persons or entities. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. In addition, the anti-manipulation rules under the Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

The selling stockholders may transfer the shares of common stock in certain circumstances, in which case the transferees or other successors in interest will be the selling stockholders for purposes of this prospectus. We will file a prospectus supplement naming the new selling

stockholders if the shares are transferred.

We will make copies of this prospectus available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. We have agreed to pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees, as well as certain fees of counsel for the selling stockholders incurred in the preparation of the registration statement, of which this prospectus is a part. The selling stockholders will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, if any.

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Under the terms of the registration rights agreement, we have agreed to indemnify the selling stockholders and certain other persons against certain liabilities in connection with the offering of the shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute toward amounts required to be paid in respect of such liabilities.

At any time a particular offer of the shares of common stock is made, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC, to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock.

We have agreed with the selling stockholders to cause the registration statement of which this prospectus is a part to remain effective until the earlier of (i) the date on which all of the shares covered by this prospectus have been sold pursuant to the registration statement of which this prospectus is a part or (ii) March 17, 2013.

Once sold under the shelf registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon by Carol A. Gamble, our Senior Vice President, General Counsel and Corporate Secretary. As of the date of this prospectus, Ms. Gamble beneficially owns 33,408 shares of our common stock, including 104,420 shares of common stock issuable upon the exercise of outstanding options that are exercisable within 60 days of June 11, 2008.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2007, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

This prospectus is part of a registration statement we filed with the Securities and Exchange Commission. You should rely only on the information contained in this prospectus or incorporated by reference. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of common stock.

We file reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any reports, proxy statements or other information filed by us at the Securities and Exchange Commission s Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at (800) SEC-0330. The Securities and Exchange Commission maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the Securities and Exchange Commission, including Jazz Pharmaceuticals. The address of the Securities and Exchange Commission website is http://www.sec.gov.

Important Information Incorporated By Reference

The Securities and Exchange Commission allows us to incorporate by reference information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the Securities and Exchange Commission. The SEC file number for the documents incorporated by reference in this prospectus is 001-33500. The documents incorporated by reference into this prospectus contain important information that you should read about us.

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The following documents are incorporated by reference into this document:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and filed with the SEC on March 31, 2008;
- The information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 from our definitive proxy statement on Schedule 14A filed with the SEC on April 28, 2008;
- Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 and filed with the SEC on May 15, 2008;
- Our Current Reports on Form 8-K, filed on January 8, 2008, January 31, 2008, February 29, 2008, March 18, 2008, April 8, 2008, May 9, 2008 and June 11, 2008; and
- The description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed with the SEC on May 25, 2007, including any amendments or reports filed for the purpose of updating such description.

We also incorporate by reference into this prospectus all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the Securities and Exchange Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial registration statement and prior to effectiveness of the registration statement, or (ii) from the date of this prospectus but prior to the termination of the offering . These documents include periodic reports, such as Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. Requests should be directed to: Jazz Pharmaceuticals, Inc., Attn: Investor Relations, 3180 Porter Drive, Palo Alto, CA 94304, telephone: (650) 496-3777.

Any statement contained herein or in a document incorporated or deemed to be incorporated by reference into this document will be deemed to be modified or superseded for purposes of the document to the extent that a statement contained in this document or any other subsequently filed document that is deemed to be incorporated by reference into this document modifies or supersedes the statement.

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PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses payable by the registrant in connection with the common stock being registered. The selling stockholders will not bear any portion of such expenses. All the amounts shown are estimates, except for the SEC registration fee.

SEC registration fee	$ 983
Accounting fees and expenses	15,000
Legal fees and expenses	25,000
Printing and miscellaneous expenses	10,000
Total	$ 50,983

Item 15. Indemnification of Directors and Officers.

The registrant s amended and restated certificate of incorporation contains provisions permitted under Delaware law relating to the liability of directors. These provisions eliminate a director s personal liability for monetary damages resulting from a breach of fiduciary duty, except in circumstances involving wrongful acts, such as:

any breach of the director s duty of loyalty to the registrant or its stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of the law;

any act related to unlawful stock repurchases, redemptions or other distribution or payments of dividends; or

any transaction from which the director derived an improper personal benefit.

These provisions do not limit or eliminate the registrant s rights or any stockholder s rights to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of a director s fiduciary duty. These provisions will not alter a director s liability under federal securities laws.

As permitted by Section 145 of the Delaware General Corporation Law, or DGCL, the registrant s amended and restated bylaws require the registrant to indemnify its directors and officers to the fullest extent not prohibited by the DGCL or any other applicable law. The registrant may modify the extent of such indemnification by individual contracts with the registrant s directors and officers. Further, the registrant may decline to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person, unless such indemnification is expressly required to be made by law, the proceeding was authorized by the registrant s board of directors, such indemnification is provided by the registrant, in its sole discretion, pursuant to the powers vested in the registrant under the DGCL or any other applicable law, or otherwise required under the registrant s amended and restated bylaws.

The registrant has entered into indemnity agreements with each of its directors, executive officers and vice presidents that require it to indemnify such persons against any and all expenses (including attorneys fees), witness fees, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding or alternative dispute resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of the registrant or any of its affiliated enterprises, provided that such person s conduct

did not constitute a breach of his or her duty of loyalty to the registrant or its stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnity agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. At present, there is no pending litigation or proceeding involving any of the registrant s directors, officers or employees for which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification by the registrant.

The registrant has the power to indemnify its other employees and other agents, as permitted by the DGCL or any other applicable law, but the registrant is not required to do so.

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The registrant maintains directors and officers liability insurance. The policy insures the registrant s directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses the registrant for those losses for which the registrant has lawfully indemnified the directors and officers. The policy contains various exclusions, none of which apply to any offerings pursuant to this registration statement.

The amended and restated investors rights agreement between the registrant and certain investors provides for cross-indemnification in connection with registration of the registrant s common stock on behalf of such investors. In connection with the expansion of our senior debt on March 17, 2008, we also entered into a registration rights agreement with the purchasers of the $40.0 million of additional secured indebtedness that provides for cross-indemnification in connection with registration of the registrant s common stock on behalf of such purchasers. In addition, the common stock purchase agreement and the registration rights agreement entered into on May 7, 2008 between the registrant and Kingsbridge provides for cross-indemnification in connection with the registration of the registrant s common stock on behalf of Kingsbridge and the entering into of the transactions contemplated by the common stock purchase agreement and the registration rights agreement.

Item 16. Exhibits.

Exhibit Number	Description of the Document
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.(5)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(6)
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.(5)
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.(5)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(5)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(5)
4.5D	Form of Common Stock Warrant of the Registrant.(5)
4.5E#	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(5)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(6)
4.6B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated May 7, 2008.(6)
5.1	Opinion of Registrant s General Counsel.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Registrant s General Counsel (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).

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

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

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

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

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

(5) Incorporated herein by reference to the same numbered exhibit to the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.

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

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

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

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(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on June 11, 2008.

Jazz Pharmaceuticals, Inc.

(Registrant)

/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 **Bruce C. Cozadd, Samuel R. Saks, M.D., Matthew K. Fust** and **Carol A. Gamble**, and each or any one of them, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement and to sign any and all additional registration statements relating to the Registration Statement and filed pursuant to Rule 462(b) of the Securities Act of 1933, as amended, and to file the same, with all 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 in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Samuel R. Saks, M.D. **Samuel R. Saks, M.D.**	Chief Executive Officer and Director (*Principal Executive Officer*)	June 11, 2008
/s/ Matthew K. Fust **Matthew K. Fust**	Executive Vice President and Chief Financial Officer (*Principal Accounting and Financial Officer*)	June 11, 2008
/s/ Samuel D. Colella **Samuel D. Colella**	Director	June 11, 2008
/s/ Bruce C. Cozadd **Bruce C. Cozadd**	Director	June 11, 2008
/s/ Bryan C. Cressey **Bryan C. Cressey**	Director	June 11, 2008
/s/ Michael W. Michelson **Michael W. Michelson**	Director	June 11, 2008
/s/ James C. Momtazee **James C. Momtazee**	Director	June 11, 2008
/s/ Kenneth W. O keefe **Kenneth W. O Keefe**	Director	June 11, 2008
/s/ Jaimin R. Patel **Jaimin R. Patel**	Director	June 11, 2008
/s/ Alan M. Sebulsky **Alan M. Sebulsky**	Director	June 11, 2008
/s/ James B. Tananbaum, M.D. **James B. Tananbaum, M.D.**	Director	June 11, 2008
/s/ Nathaniel M. Zilkha **Nathaniel M. Zilkha**	Director	June 11, 2008

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4.5E#	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(5)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(6)
4.6B	Registration Rights Agreement, by and between Kingsbridge Capital Limited and the Registrant, dated May 7, 2008.(6)
5.1	Opinion of Registrant s General Counsel.
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Registrant s General Counsel (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).

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

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

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

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

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

(5) Incorporated herein by reference to the same numbered exhibit to the Registrant s annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.

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

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