

JAZZ PHARMACEUTICALS INC

Form S-1/A

November 10, 2009

Table of Contents

As filed with the Securities and Exchange Commission on November 10, 2009

Registration No. 333 -161350

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**AMENDMENT NO. 1**  
**TO**  
**FORM S-1**  
**REGISTRATION STATEMENT**  
*UNDER*  
*THE SECURITIES ACT OF 1933*

**JAZZ PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>2834</b> (Primary Standard Industrial Classification Code Number) <b>3180 Porter Drive</b>  <b>Palo Alto, CA 94304</b>  <b>(650) 496-3777</b>	<b>05-0563787</b> (I.R.S. Employer Identification Number)
--	---	---

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

**Bruce C. Cozadd**  
  
**Chief Executive Officer**  
  
**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.**  
  
**Philip J. Honerkamp, Esq.**  
  
**Jazz Pharmaceuticals, Inc.**  
  
**3180 Porter Drive**  
  
**Palo Alto, CA 94304**  
  
**(650) 496-3777**

**Suzanne Sawochka Hooper, Esq.**  
  
**Chadwick L. Mills, 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 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 check the following box:

**Table of Contents**

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 post-effective amendment filed pursuant to Rule 462(d) 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. "

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   
(Do not check if a smaller reporting company)

Smaller reporting company "

**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 that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**Table of Contents**

**The information in this prospectus is not complete and may be changed. The selling stockholders 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 November 10, 2009**

**PROSPECTUS**

**2,843,601 Shares**

**Common Stock**

This prospectus relates to the disposition from time to time of up to 2,843,601 shares of our common stock, which includes 947,867 shares of our common stock issuable upon the exercise of outstanding warrants, which are held by the selling stockholders named in this prospectus. We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders.

The selling stockholders identified in this prospectus, or their permitted transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices. We provide more information about how the selling stockholders may sell their shares of common stock in the section entitled **Plan of Distribution** beginning on page 44 of this prospectus. We will not be paying any underwriting discounts or commissions in connection with any offering of common stock under this prospectus.

Our common stock is listed on The NASDAQ Global Market under the symbol **JAZZ**. On November 9, 2009, the last reported sale price of our common stock on The NASDAQ Global Market was \$6.73.

*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, and under similar headings in any amendments or supplements to 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\_\_ .

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>About this Prospectus</u>	i
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	3
<u>Disclosure Regarding Forward-Looking Statements</u>	27
<u>Use of Proceeds</u>	28
<u>Price Range of our Common Stock</u>	28
<u>Dividend Policy</u>	28
<u>Description of Capital Stock</u>	29
<u>Management</u>	34
<u>Certain Relationships and Related Party Transactions</u>	37
<u>Selling Stockholders</u>	42
<u>Plan of Distribution</u>	44
<u>Validity of Common Stock</u>	46
<u>Experts</u>	46
<u>Where You Can Find More Information</u>	46

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission, or SEC, using the shelf registration process. Under this process, selling stockholders may from time to time, in one or more offerings, sell the common stock described in this prospectus.

You should rely only on the information contained in or incorporated by reference into this prospectus (as supplemented and amended). We have not authorized anyone to provide you with different information. This document may only be used where it is legal to sell these securities. You should not assume that the information contained in this prospectus is accurate as of any date other than its date regardless of the time of delivery of the prospectus or any sale of our common stock.

We urge you to read carefully this prospectus (as supplemented and amended), together with the information incorporated herein by reference as described under the heading Where You Can Find More Information, before deciding whether to invest in any of the common stock being offered.

---

**Table of Contents**

**PROSPECTUS SUMMARY**

*This summary may not contain all of the information that may be important to you. You should read the entire prospectus (as supplemented and amended), including the financial data and related notes, risk factors and other information incorporated by reference in this prospectus, before making an investment decision.*

**Jazz Pharmaceuticals, Inc.**

**Overview**

We are a specialty pharmaceutical company focused on developing and commercializing innovative products to meet unmet medical needs in neurology and psychiatry. Our goal is to build a broad portfolio of products through a combination of internal development, acquisition and in-licensing activities, and to utilize our specialty sales force to promote our products in our target markets. We apply novel formulations and drug delivery technologies to known drug compounds, and to compounds with the same mechanism of action or similar chemical structure as marketed products, to improve patient care by, among other things, improving efficacy, reducing adverse side effects or increasing patient compliance relative to existing therapies. Since our inception in 2003, we have built a commercial operation and assembled a portfolio of products and product candidates that currently includes two marketed products, one product candidate in late Phase III clinical development and several product candidates in various stages of clinical development.

Our marketed products and late-stage product candidate are:

*Xyrem (sodium oxybate) oral solution.* Xyrem is the only product approved by the U.S. Food and Drug Administration, or FDA, for the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. Narcolepsy is a chronic neurologic disorder caused by the brain's inability to regulate sleep-wake cycles. We promote Xyrem in the U.S. for its FDA-approved indications to sleep specialists, neurologists, pulmonologists and psychiatrists through our specialty sales force. We have significantly increased U.S. sales of Xyrem since acquiring the rights to Xyrem in June 2005. We have licensed the rights to commercialize Xyrem in 54 countries outside of the U.S. to UCB Pharma Limited, or UCB, and in Canada to Valeant Canada Limited, or Valeant. UCB currently markets Xyrem in 14 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 began promoting Luvox CR through our specialty sales force in April 2008. Luvox CR is a once-daily extended-release formulation of fluvoxamine, a selective serotonin reuptake inhibitor, or SSRI. Luvox CR was developed by Solvay Pharmaceuticals, Inc., or Solvay, in collaboration with Elan Pharma International Limited, or Elan. We obtained the exclusive rights to market and distribute Luvox CR in the U.S. from Solvay in January 2007. Solvay retained the rights to market and distribute Luvox CR outside of the U.S.

*JZP-6 (sodium oxybate).* We are developing sodium oxybate, the active pharmaceutical ingredient in Xyrem, for the treatment of fibromyalgia. The program includes two Phase III pivotal clinical trials and a long term safety trial. In November 2008 and June 2009, we announced positive top-line results from our first and second Phase III pivotal clinical trials, respectively. The two randomized, double-blind, placebo-controlled studies demonstrated that sodium oxybate significantly decreased pain and fatigue and improved daily function and patient global impression of change, in patients with fibromyalgia. We plan to submit a new drug application, or NDA, for JZP-6 by the end of 2009. If our NDA is approved by the FDA, we expect to market JZP-6 in the U.S. to specialists who treat fibromyalgia patients, through an expanded specialty sales force and/or in partnerships with third parties. We have granted UCB the commercialization rights to JZP-6 in 54 countries outside of the U.S.

Our other product candidates in clinical development are JZP-8 (intranasal clonazepam), being developed for the treatment of recurrent acute repetitive seizures in epilepsy patients who continue to have seizures while on stable



## **Table of Contents**

anti-epileptic regimens, JZP-4 (elpetrigine), being developed for the treatment of epilepsy and bipolar disorder, and JZP-7 (ropinirole gel), being developed for the treatment of restless legs syndrome. We do not anticipate significant additional development progress on JZP-8, JZP-4 or JZP-7 unless or until we partner a program or otherwise obtain additional funding that we believe is sufficient to continue a program's development.

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

## **Corporate Information**

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](http://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®, Luvox®, Luvox CR® and the Jazz Pharmaceuticals logo as trademarks in the United States and other countries. We have licensed the right to use the registered trademark Luvox® and Luvox CR® from Solvay Pharmaceuticals, Inc. All other trademarks or trade names referred to in this prospectus are the property of their respective owners.

## **The Offering**

The selling stockholders named in this prospectus may offer and sell up to 2,843,601 shares of our common stock, which include 947,867 shares of our common stock issuable upon the exercise of outstanding warrants. The shares issuable upon exercise of the warrants will become eligible for sale by the selling stockholders under this prospectus only as the warrants are exercised. Our common stock currently is listed on The NASDAQ Global Market under the symbol JAZZ. Shares of common stock that may be offered in this offering, when issued and paid for in the case of shares issuable upon exercise of the outstanding warrants, will be fully paid and non-assessable. We will not receive any of the proceeds of sales by the selling stockholders of any of the common stock covered by this prospectus. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders, we are referring to the shares and the shares underlying the warrants issued to the selling stockholders pursuant to the securities purchase agreement we entered into with the selling stockholders on June 6, 2009, and when we refer to the selling stockholders in this prospectus, we are referring to the purchasers under the securities purchase agreement and, as applicable, 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.

---

**Table of Contents**

**RISK 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 (as supplemented and amended), 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 Relating to Our Business**

***We are dependent on sales of Xyrem and Luvox CR to generate the cash necessary to operate our business, and, if we are not able to maintain or increase revenue from the sales of our products, it would have a material adverse effect on our business, financial condition, results of operation and growth prospects.***

We are dependent on sales of Xyrem and Luvox CR to generate the cash necessary to operate our business and our future plans assume revenue from sales of our products will remain constant or increase. Sales and prescriptions of Xyrem increased in 2008 and during the first three quarters of 2009; however, cataplexy and excessive daytime sleepiness associated with narcolepsy are orphan conditions, which means that a relatively limited number of people suffer from those conditions. We significantly increased the price of Xyrem during the past year, including an approximately 20% increase in October 2009. While increased pricing does not appear to have negatively affected sales of the product, we cannot assure you that this or future price increases will not negatively affect sales of Xyrem. In July 2009, our orphan drug exclusivity for Xyrem for cataplexy in patients with narcolepsy expired and we cannot assure you that a generic equivalent will not be introduced for that indication in the future. If sales of Luvox CR do not increase as expected, they may not cover the payments due to Solvay under our license agreement for Luvox CR plus the cost to manufacture, market and sell the product and to fulfill our Phase IV clinical trial commitment to the U.S. Food and Drug Administration, or FDA. If revenue from sales of Xyrem and Luvox CR do not maintain current levels or increase as expected, we may be required to further reduce our operating expenses, decrease our efforts in support of Luvox CR or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operation and growth prospects.

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

We are currently developing JZP-6 for the treatment of fibromyalgia. Our Phase III clinical program for JZP-6 includes two Phase III pivotal clinical trials. Although we received statistically significant positive results from both of our Phase III pivotal clinical trials and believe our results show JZP-6 to be safe and effective for the treatment of fibromyalgia, we do not know if the FDA will agree with our interpretation of the results or whether the FDA and other regulatory authorities will approve JZP-6 for the treatment of fibromyalgia. Even if the FDA or other regulatory authorities approve JZP-6 for the treatment of fibromyalgia, we cannot assure you that the approval will not include additional restrictions on the label that 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. Further, although JZP-6 has the same active pharmaceutical ingredient as Xyrem, which has been approved by the FDA for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy, this does not assure approval by the FDA, or any other regulatory authorities, of this active pharmaceutical ingredient for the treatment of fibromyalgia. A failure to obtain FDA or other regulatory approval of JZP-6 for fibromyalgia patients could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Lyrica (pregabalin), marketed by Pfizer, Cymbalta (duloxetine), marketed by Eli Lilly, and Savella (milnacipran), marketed by Forest Laboratories, were approved by the FDA in June 2007, June 2008, and January 2009, respectively, for the treatment of fibromyalgia. With treatments for fibromyalgia already approved, the FDA may be less willing to approve JZP-6 for the treatment of fibromyalgia.

---

**Table of Contents**

Even if the FDA approves JZP-6 for the treatment of fibromyalgia, the FDA will likely require us to have a Risk Evaluation and Mitigation Strategy program, or REMS, which may be similar to the one we use for Xyrem. Under the Xyrem REMS, Xyrem must be distributed through a single central pharmacy. The central pharmacy must maintain physician and patient registries, and the product may not be stocked in retail pharmacies. Each physician and patient must be educated about the risks and benefits of the product before the physician can prescribe, or a patient can receive, Xyrem. Whenever a prescription is received by the central pharmacy, the central pharmacy must verify the prescription and obtain additional information by contacting the patient's insurance company. The central pharmacy must also speak with the patient before it can ship any Xyrem to the patient. The central pharmacy must ship the product directly to the patient by a courier service, and the patient or his/her designee must sign for the package. The initial shipment may only be for a one month supply, and physicians may only prescribe up to six months of supply of Xyrem.

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

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

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

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

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

As a condition of approval of Xyrem, the FDA mandated that we maintain a risk management program for Xyrem under which all Xyrem that we sell in the U.S. must be shipped directly to patients through a central pharmacy. The process under which patients receive Xyrem under our Xyrem REMS is cumbersome. While we have an agreement with the central pharmacy for Xyrem, Express Scripts, if the central pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, shipments of Xyrem, and our sales, would be adversely affected. Changing central pharmacy distributors could take a significant amount of time. In addition, sodium oxybate, the active pharmaceutical ingredient in Xyrem, is regulated by the U.S. Drug Enforcement Administration, or DEA, as a controlled substance. The new central pharmacy would need to be registered with the DEA and would also need to develop the particular processes, procedures and activities necessary to distribute Xyrem, including the REMS approved by the FDA. If we change central pharmacies, new contracts might also be required with government and other insurers who pay for Xyrem. Transitioning to a new central pharmacy could result in product shortages, which would adversely affect sales of Xyrem in the U.S.

---

**Table of Contents**

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

The DEA limits the quantity of certain Schedule I controlled substances that may be produced in the U.S. in any given calendar year through a quota system. Because the active pharmaceutical ingredient of Xyrem and JZP-6, sodium oxybate, is a Schedule I controlled substance, our supplier of the active pharmaceutical ingredient and our product manufacturers must obtain DEA quotas in order to supply us with sodium oxybate, Xyrem and JZP-6. Since the DEA typically grants quotas on an annual basis and requires a detailed submission and justification for each request, obtaining a DEA quota is a difficult and time consuming process. If our commercial or clinical requirements for sodium oxybate, Xyrem or JZP-6 exceed our supplier's and contract manufacturer's DEA quotas, our supplier and contract manufacturer would need quota increases from the DEA, which could be difficult and time consuming to obtain and might not ultimately be obtained on a timely basis, or at all. We believe, although we cannot assure you, that our quota for 2009 will be sufficient to meet our commercial, clinical and development needs. The DEA has issued a preliminary quota for 2010 that is the same as that issued for 2009 but that is substantially less than the quota we believe we will need both to provide commercial supplies of Xyrem and to prepare for the commercial launch of JZP-6. We are in discussion with the DEA concerning the 2010 quota; however, if we are not successful in changing the quota before it becomes final we would have to petition for a change to the quota which could delay the potential commercial launch of JZP-6. 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, JZP-6 or sodium oxybate for the marketplace or for use in our clinical studies, or both.

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

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

The availability of our products for commercial sale is dependent upon our ability to procure the ingredients, packaging materials and finished products we need. If one of our suppliers or product manufacturers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to qualify a new supplier or manufacturer. The loss of one of our suppliers or product manufacturers could require us to obtain regulatory clearance in the form of a prior approval supplement and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredient or product manufacturing process. We believe that it could take as long as two years to qualify a new supplier or manufacturer, and we may not be able to obtain active pharmaceutical ingredients, packaging materials or finished products from new suppliers or manufacturers on acceptable terms and at reasonable prices, or at all. Should we lose either an active pharmaceutical ingredient supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we wait for FDA approval of a new active pharmaceutical ingredient supplier or product manufacturer.

## **Table of Contents**

For Xyrem, JZP-6 or sodium oxybate, the new supplier or manufacturer would also need to be registered with the DEA and obtain a DEA quota. In addition, the FDA must approve suppliers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products, as well as suppliers of finished products. The qualification of new suppliers and manufacturers could potentially delay the manufacture of our products and product candidates and result in shortages in the marketplace or for our clinical trials, or both, particularly since we do not have secondary sources of supply of the active pharmaceutical ingredient or backup manufacturers for our products and product candidates. If there are delays in qualifying the new manufacturer or the new manufacturer is unable to obtain a sufficient quota from the DEA, there could be a shortage of Xyrem for the marketplace.

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

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

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

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

Any delay in supplying, or failure to supply, products by any of our suppliers could result in our inability to meet the commercial demand for our products or our needs for use in clinical trials, and could adversely affect our business, financial condition, results of operations and growth prospects. For example, if Lonza is unable to timely provide fluvoxamine maleate in the quantities we need there could be an interruption in the supply of Luvox CR to the market. In addition, under our agreement with UCB, we are responsible for the supply of Xyrem and, if approved, JZP-6 to UCB. Our failure to meet our contractual obligations to supply UCB with adequate quantities of Xyrem and JZP-6 would result in lost revenues to us and, if material, could result in termination of our agreements by UCB.

## **Table of Contents**

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

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

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

prevalence of the disease or condition for which the product is approved and the severity of side effects;

acceptance by physicians and patients of each product as a safe and effective treatment;

perceived advantages over alternative treatments;

relative convenience and ease of administration;

the cost of treatment in relation to alternative treatments, including generic products;

the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations; and

the availability of adequate reimbursement by third parties.

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

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

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

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

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

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;

## **Table of Contents**

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

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

insufficient funds to complete the trials.

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

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

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

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

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

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

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

From time to time, there is negative publicity about illicit GHB and its effects, including with respect to illegal use, overdoses, serious injury and death and because sodium oxybate, the active pharmaceutical ingredient in Xyrem, is a derivative of GHB, Xyrem sometimes also receives negative mention in publicity relating to GHB. Because sodium oxybate is a derivative of GHB, patients, physicians and regulators may view Xyrem as the same as or similar to illicit GHB. In addition, there are regulators and some law enforcement agencies that oppose the prescription and use of Xyrem generally because of the connection to GHB. Xyrem's label includes information





## **Table of Contents**

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

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

In April 2006, we and our subsidiary Orphan Medical received subpoenas from the U.S. Department of Justice, acting through the U.S. Attorney for the Eastern District of New York, in connection with the sale and marketing of Xyrem. We and Orphan Medical have settled this matter with the U.S., acting through the Department of Justice, the U.S. Attorney's Office for the Eastern District of New York and other federal agencies, including the Office of Inspector General, U.S. Department of Health and Human Services. Orphan Medical pled guilty to one felony count of introducing a misbranded drug into interstate commerce. A total of approximately \$20.0 million in civil and criminal payments is required to be paid in connection with this matter, of which \$1.0 million was paid in July 2007, \$2.0 million was paid in January 2008, and \$2.5 million was paid in October 2009; the remaining amount will be due over the next three years.

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

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

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

The FDA has required that Xyrem's label include a box warning regarding the risk of abuse. A box warning is the strongest type of warning that the FDA can require for a drug product and warns prescribers that the drug carries a significant risk of serious or even life-threatening adverse effects. A box warning also means, among other things, that the product cannot be advertised through reminder ads, ads which mention the pharmaceutical brand name but not the indication or medical condition it treats. Provigil and Nuvigil, the only other products approved by the FDA specifically for the treatment of excessive daytime sleepiness in patients with narcolepsy, do not have a box warning and can be advertised with reminder ads. In addition, Xyrem's FDA approval under the FDA's Subpart H regulations requires that all of the promotional materials for Xyrem be provided to the FDA for review at least 30 days prior to the intended time of first use. Unlike Xyrem, Provigil and Nuvigil were not approved under the FDA's Subpart H regulations and are not subject to the pre-review requirements. Accordingly, promotional materials for Provigil and Nuvigil are not subject to the same delays that we experience with respect to new promotional materials for Xyrem.

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

## Table of Contents

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

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

We are marketing Luvox CR in the U.S. for the treatment of obsessive compulsive disorder and social anxiety disorder. Selective serotonin reuptake inhibitors are the standard treatment for anxiety disorders, including obsessive compulsive disorder and social anxiety disorder. Six other branded products are currently approved by the FDA for the treatment of obsessive compulsive disorder, including five selective serotonin reuptake inhibitors: Paxil, which is marketed by GlaxoSmithKline, Zoloft, which is marketed by Pfizer, Prozac, which is marketed by Eli Lilly, Pexeva, which is a branded generic marketed by Noven Therapeutics and Luvox, which is not currently marketed. Anafranil, the sixth other branded product approved by the FDA for the treatment of obsessive compulsive disorder, is a tricyclic antidepressant marketed by Mallinckrodt in the U.S. Each of these products currently has generic equivalents. Generic products are generally sold at significantly lower prices than non-generic branded products, tending to both take market share away from branded products and put downward pricing pressure on branded products. Four other products are currently approved by the FDA for the treatment of social anxiety disorder, including three selective serotonin reuptake inhibitors: Zoloft, Paxil and Paxil CR, an extended-release version of Paxil, and one serotonin-norepinephrine reuptake inhibitor, Effexor XR. Each of these products has generic competitors.

We are developing JZP-6 for the treatment of fibromyalgia. In June 2007, the FDA approved Lyrica, an anticonvulsant marketed by Pfizer for the treatment of partial seizures, post herpetic neuralgia and diabetic peripheral neuropathy, for the treatment of fibromyalgia. In June 2008, the FDA approved Cymbalta, a selective serotonin and norepinephrine reuptake inhibitor marketed by Eli Lilly for the treatment of major depressive disorder and generalized anxiety disorder, and diabetic peripheral neuropathic pain, for the treatment of fibromyalgia. In January 2009, the FDA approved Savella, a selective serotonin and norepinephrine reuptake inhibitor marketed by Forest Laboratories for the treatment of fibromyalgia. There are currently no other products approved by the FDA for the treatment of fibromyalgia. In clinical practice, a variety of drugs are often prescribed to address individual symptoms of fibromyalgia, including antidepressants, pain medications, muscle relaxants, hypnotics and anticonvulsants.

Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with other large, established companies. Our commercial opportunities may be reduced or eliminated if our competitors develop and commercialize generic or branded products that are safer or more effective, have fewer side effects or are less expensive than our products. In addition, we have undertaken several cost-cutting measures that may affect our ability to compete with other companies and due to our financial condition we may be required to take additional cost-cutting measures in the future.

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

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.

---

**Table of Contents**

*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 had previously granted orphan drug exclusivity in the U.S. for cataplexy in patients with narcolepsy, but this exclusivity expired in July 2009 and other companies could possibly introduce generic equivalents of Xyrem for the cataplexy indication if they do not infringe our existing patents covering Xyrem. Although the FDA has granted orphan drug exclusivity for Xyrem until November 2012 for excessive daytime sleepiness in patients with narcolepsy, prescriptions for Xyrem for the excessive daytime sleepiness in patients with narcolepsy indication, or if approved by the FDA, JZP-6, could possibly be filled with generic equivalents that are granted approval for the treatment of cataplexy in patients with narcolepsy, even if the patient is diagnosed with excessive daytime sleepiness or fibromyalgia.

Patent protection is not available for the active pharmaceutical ingredient in most of our products and product candidates, including Xyrem, Luvox CR and JZP-6. Although Xyrem is covered by patents expiring in 2019 and 2020 with claims covering the formula and process for manufacturing our commercial formulation of Xyrem, JZP-6 is covered by a patent expiring in 2017 with claims covering the use of JZP-6 in patients with fibromyalgia, and Luvox CR is covered by a patent covering the orally administered formulation of extended-release fluvoxamine, it is possible that other companies could manufacture generic equivalents of Xyrem, JZP-6 and Luvox CR in ways that are not covered by the claims of these patents.

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

Luvox CR is covered by a patent owned by Elan with claims covering the orally administered extended-release formulation of fluvoxamine. It is possible that other companies could manufacture similar or therapeutically equivalent products in ways that are not covered by the claims of the patent. In August 2009, we received a Paragraph IV Patent Certification notice from Actavis Elizabeth, LLC, or Actavis, advising that Actavis has filed an abbreviated New Drug Application, or ANDA, with the FDA for a generic version of Luvox CR. In September 2009, we received an additional Paragraph IV Patent Certification notice from Anchen Pharmaceuticals, Inc., or Anchen, advising that Anchen has filed an ANDA with the FDA for a generic version of Luvox CR. We have not been informed as to the timing or status of the FDA's review of either party's filing, or whether either filer has complied with FDA requirements for proving bioequivalence. Actavis' Paragraph IV Certification alleges that Elan's U.S. Patent No. 7,465,462, listed in the Orange Book, is invalid on the basis that the inventions claimed therein were obvious. Anchen's Paragraph IV Certification alleges that Elan's U.S. Patent No. 7,465,462, listed in the Orange Book, will not be infringed by Anchen's manufacture, use or sale of the generic product for which the ANDA was submitted. The expiration date for the patent at issue is May 10, 2020. We and Elan have filed lawsuits in response to the Paragraph IV certifications. We cannot assure you that these lawsuits will prevent introduction of generics for any particular length of time, or at all.

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

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

In order to grow our business, we will need to acquire or in-license additional products and product candidates that we believe have significant commercial potential. We do not believe we will be able to acquire or in-license additional products and product candidates until our financial condition improves. Any growth through acquisitions or in-licensing will be dependent upon the continued availability of suitable acquisition or in-license products and product candidates at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify products or product candidates suitable for potential acquisition or in-licensing, or we may not have the financial resources necessary to pursue such opportunities. Other companies, many of which may have substantially greater financial, marketing and sales resources, compete with us for the right to acquire and in-license such products or product candidates.



## **Table of Contents**

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

In November 2008, we reduced the size of our sales force as a result of the lower than expected demand for Luvox CR. Each of our remaining sales representatives is now responsible for a larger territory than he or she was responsible for prior to the reduction in force. Our potential future commercial products, including JZP-6, may require expansion of our sales force and sales support organization, and we will need to commit significant additional funds, management and other resources to the growth of our sales organization before the commercial launch of those product candidates. We may not be able to achieve the necessary growth in a cost-effective manner or realize a positive return on our investment, and we may not have the financial resources to achieve the necessary growth in a timely manner or at all. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel which our recent reduction in force of our sales force may make more difficult. Turnover in our sales force could negatively affect sales of our products. If we elect to rely on third parties to sell our products in the U.S., we may receive less revenue or incur more expense than if we sold our products directly. In addition, we may have little or no control over the sales efforts of those third parties. If we are unable to appropriately size our sales force or collaborate with third parties to sell our products, our ability to generate revenues would be adversely affected.

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

Our success depends in part on our continued ability to retain and motivate highly qualified personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our executive management team. The loss of services of any one or more members of our executive management team or other key personnel could delay or prevent the successful completion of some of our key activities. We do not carry key person insurance. Any member of our executive management team and any other key employees may terminate his or her employment at any time without notice and without cause or good reason. In the last year, two of our senior executives have left the company.

In June 2008, we reduced the number of non-sales employees in our company in connection with efforts to focus, in the near term, on our commercial products and later-stage product candidates. In November 2008, we significantly reduced the number of sales representatives. In December 2008, we further reduced the number of non-sales employees in our company. These reductions in force may negatively affect our ability to retain or attract talented employees. Competition for qualified personnel in the life sciences industry has historically been intense. If we need to hire additional personnel to expand our development, clinical and commercial activities, or to support those activities, we may not be able to attract and retain quality personnel on acceptable terms.

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

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

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

---

**Table of Contents**

**Risks Related to Our Intellectual Property**

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

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

The patent position of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, invalidated, held unenforceable or circumvented. In the case of Luvox CR, for example, Actavis Paragraph IV Certification alleges that Elan's U.S. Patent No. 7,465,462, listed in the Orange Book, is invalid on the basis that the inventions claimed therein were obvious; Anchen's Paragraph IV Certification alleges that Elan's U.S. Patent No. 7,465,462, listed in the Orange Book, will not be infringed by Anchen's manufacture, use or sale of the generic product for which the ANDA was submitted. 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

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

trade secrets and other unpatented proprietary information, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions or trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.



---

## Table of Contents

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

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

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

If we choose to go to court to stop someone else from pursuing the inventions claimed in our patents or in or our licensed patents or those of our partners, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that the other party's activities do not infringe our rights to these patents or that it is in the public interest to permit the infringing activity. In October 2009, we and Elan filed lawsuits in response to the Paragraph IV certifications that we received from Actavis and Anchen. We cannot assure you that these lawsuits will be successful in stopping the infringement of our related patents, that the litigation will be cost effective, or that the litigation will have a satisfactory result for us.

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

pay damages, including up to treble damages and the other party's attorneys' fees, which may be substantial;

cease the development, manufacture, use and sale of our products that infringe the patent rights of others through a court-imposed sanction such as an injunction;

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

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

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents in the U.S.

## **Table of Contents**

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

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

### **Risks Related to Our Industry**

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

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

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

***We are 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. We are 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, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products are, and any of our product candidates that may be approved by the FDA will be, subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with any of our products in the U.S. or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers' facilities, or withdraw

---

**Table of Contents**

the product from the market. In addition, we may experience a significant drop in the sales of the affected products and our product revenues and reputation in the marketplace may suffer, and we could become the target of lawsuits, including class action suits. The FDA and other governmental authorities also actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

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

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid.

Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. Pharmaceutical and other health care companies have also been prosecuted on other legal theories of Medicare fraud. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply 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.

---

**Table of Contents**

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

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

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The Medicaid rebate amount is computed each quarter based on our submission to the Centers for Medicare & Medicaid Services at the U.S. Department of Health and Human Services of our current average manufacturing price and best prices for the quarter. If we become aware that our reporting for prior quarters was incorrect, or changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected average manufacturing price or best price for that quarter. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. In addition to retroactive rebates (and interest, if any), if we are found to have knowingly submitted false information to the government, we may be liable for civil monetary penalties in the amount of \$100,000 per item of false information. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid.

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

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

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

---

**Table of Contents**

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

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

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

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

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

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

## **Table of Contents**

### ***Product liability and product recalls could harm our business.***

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

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

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

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation.

### **Risks Relating to Our Financial Condition**

**Table of Contents**

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

We have incurred significant net losses since our inception in 2003, and we may continue to incur net losses in the future. Our independent registered public accounting firm issued an opinion on our audited consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2008 that states that our recurring losses from operations and net capital deficiency raises substantial doubt about our ability to continue as a going concern.

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

the amount of sales and other revenues from our commercial products, including selling prices for products that we may begin selling and price increases for our current products;

market acceptance of and the number of prescriptions written for our products;

selling and marketing costs associated with Xyrem and Luvox CR in the U.S.;

revenues from current and potential future development and/or commercial collaboration partners, in particular our current partnership with UCB;

our ability to properly prepare and timely file our New Drug Application for JZP-6;

the scope, rate of progress, results and costs of our preclinical studies, clinical trials, including our Phase IV clinical trial commitment to the FDA for Luvox CR, and other research and development activities;

the number and characteristics of product candidates that we pursue;

the cost and timing of establishing clinical and commercial supplies of our product candidates;

the cost and timing of obtaining regulatory approval;

payments of milestones to third parties;

increased expenses associated with our current employees and new employees hired to support our continued growth;

the cost of investigations, litigation and/or settlements related to regulatory activities;



## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and

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

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

---

**Table of Contents**

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

While we believe we will be able to fund our operations and meet all of our ongoing current financial obligations for at least the next 12 months, we have based this estimate on assumptions that may prove to be wrong, including assumptions with respect to the level of revenues from product sales, and we could exhaust our available financial resources. The sufficiency of our current cash resources, and our potential need for additional capital and the timing thereof, will depend on many factors, including primarily the amount of revenues that we receive from sales of Xyrem and Luvox CR and our ability to use our net operating loss carryforwards to offset taxable income that would otherwise be due. If we are unable to raise sufficient additional funds when or if needed, we would be required to further reduce operating expenses. Furthermore, any additional funds we may raise could be on terms that are not favorable to us and may be dilutive to existing stockholders.

We have reduced the net cash used in our operations by implementing three reductions in force in 2008 and focusing our efforts on our commercial products and JZP-6. We cannot predict with certainty the level of our product sales. If product sales do not meet our expectations and/or we do not raise additional funds, we will need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we have taken and may take in the future may not be sufficient to enable us to meet our cash requirements or for us to reach profitability, and they may negatively affect our business and prospects.

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

There is currently outstanding \$119.5 million principal amount of our senior secured notes, or the Senior Notes. Our substantial debt combined with our other financial obligations and contractual commitments could have important consequences. For example, it could:

make us more vulnerable to adverse changes in general United States and worldwide economic, industry and competitive conditions and adverse changes in government regulation;

require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, capital expenditures and acquisitions;

limit our flexibility in planning for, or reacting to, changes in our business and our industry;

place us at a competitive disadvantage compared to our competitors who have less debt; and

limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

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

We did not timely make the quarterly interest payments on the Senior Notes due on December 31, 2008, March 31, 2009 and June 30, 2009. In addition, we failed to comply with a covenant to establish and maintain a minimum cash balance in an account pledged to the collateral agent for the Senior Notes, which became applicable in May 2009 because our annualized aggregate net product sales did not exceed \$100.0 million for the three months ended March 31, 2009. The failure to make the quarterly interest payments when due and the failure to establish the required restricted cash balance account in May 2009 constituted events of default under the Senior Note Agreement, which then permitted the holders of more than 50% in principal amount of the Senior Notes to accelerate payment of the Senior Notes.

We recently amended the Senior Note Agreement to provide, among other things, for amortization of a portion of the principal amount of the Senior Notes. In connection with that amendment, the holders of the Senior Notes have waived the prior events of default described above.

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

However, our failure to comply with the terms of the Senior Note Agreement on an ongoing basis could result in the holders of our Senior Notes attempting to accelerate our indebtedness under the Senior Notes. If we do not have sufficient funds to pay the quarterly interest or required amortization of principal, or to restrict cash if required under the Senior Note Agreement, we may be required to refinance all or part of our existing debt, sell assets, borrow more money or sell securities, none of which we can assure you that we would be able to do in a timely manner or at all. In addition, our ability to refinance any amounts that may become accelerated or to secure future waivers from the holders of the Senior Notes with respect to compliance with the Senior Note Agreement covenants may be adversely affected by our prior defaults under the Senior Notes. The holders of the Senior Notes have a first priority security interest in all of our assets other than inventory and accounts receivable.

---

## **Table of Contents**

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

The terms of our Senior Notes currently contain, and any future indebtedness may contain, a number of restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests. The terms of the Senior Notes include covenants, 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 an additional portion of the debt early under certain circumstances; and

maintain restricted cash balances under certain circumstances.

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

We have significant net operating loss carryforwards, or NOLs. Our ability to use our net operating losses to offset taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty when, if ever, we will be able to generate future taxable income. In addition, even if we generate taxable income, realization of our NOLs to offset taxes that would otherwise be due could be restricted by annual limitations on use of NOLs triggered by an ownership change under Section 382 of the Internal Revenue Code and similar state provisions. An ownership change may occur when there is a 50% or greater change in total ownership of our company by one or more 5% shareholders within a three-year period. If we generate taxable income, the loss of some or all of our NOLs could materially and adversely affect our business, financial condition, results of operations and growth prospects.

As described under the caption "Description of Capital Stock - NOL Preservation Lock-Up Agreement," effective July 7, 2009, we entered into a NOL preservation lock-up agreement with the selling stockholders and most of our other significant stockholders that restricts transferability of shares of our common stock by the stockholders who entered into the agreement until June 2011, unless terminated earlier under certain circumstances, in order to minimize the risk that we will undergo an ownership change within the meaning of Section 382(g) of the Internal Revenue Code prior to that time. Section 382 of the Internal Revenue Code is an extremely complex provision with respect to which there are many uncertainties. Although the NOL preservation lock-up agreement is intended to minimize the risk of such an ownership change we cannot assure you that such an ownership change will not occur. In addition, we have not requested a ruling from the Internal Revenue Service, or IRS, regarding whether we have effectively preserved our NOLs, and we cannot ensure that the IRS will agree that our NOLs have been effectively preserved for purposes of Section 382.

### **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. Although recently the trading price and average volume of our common stock has increased, historically our common stock has had a very low average trading volume and our stockholders may not be able to sell any or all of their holdings quickly or at all. The price of our stock has also fluctuated significantly since the beginning of 2009 and we cannot predict if it will continue to do so. In addition, the stock market in general and the market for life sciences companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been

instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

**Table of Contents**

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

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

conditions or trends in the pharmaceutical industry, the credit and financial markets or the U.S. and worldwide economy in general;

our financial situation, including our ability or inability to raise additional capital if needed and the terms on which we raise it;

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

the success of our development efforts and clinical trials;

our ability to properly prepare and timely file our New Drug Application for JZP-6;

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 ability of Elan to provide us with sufficient commercial supply of Luvox CR;

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;

the filing of, and thereafter the possible FDA approval of, ANDAs for generic forms of Xyrem and Luvox CR;

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

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

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

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

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

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

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

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

changes in the market valuation of similar companies;

trading volume of our common stock; and

sales of our common stock by us or our stockholders.

---

**Table of Contents**

*Our common stock was recently at risk for delisting from The NASDAQ Global Market and may be again in the future. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease.*

Our common stock is currently listed on The NASDAQ Global Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Global Market. These requirements include maintaining a minimum closing bid price of \$1.00 per share. Although the trading price of our common stock is currently above \$1.00 per share, the closing bid price of our common stock earlier in 2009 was well below \$1.00. These requirements also include maintaining a minimum market value of publicly held shares, and, although as of October 30, 2009 we met this requirement, earlier in 2009 we did not. There can be no assurance that we will continue to meet these requirements in the future, and, if we do not, it is possible that NASDAQ may notify us that we have failed to meet the minimum listing requirements and initiate the delisting process. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of October 30, 2009, we had 30,992,088 shares of common stock outstanding, all of which shares were eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements under Rule 144 and the restrictions under our NOL preservation lock-up agreement.

As of October 30, 2009, the holders of up to approximately 18,312,159 shares of common stock, based on shares outstanding as of that date, including 785,728 shares underlying outstanding warrants, were entitled to certain rights with respect to the registration of such shares under the Securities Act of 1933, as amended, under an amended and restated investor rights agreement that we entered into with these holders. In addition, upon exercise of outstanding options by our executive officers, our executive officers will be entitled to rights under the amended and restated investor rights agreement with respect to registration of the shares of common stock acquired on exercise. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement and include shares held by these holders pursuant to the exercise of their registration rights, these sales may impair our ability to raise capital. We also entered into a registration rights agreement pursuant to which we agreed to file a registration statement covering the resale of the 562,192 shares underlying the warrants that we issued in connection with the issuance of the Senior Notes. In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, to register the shares of our common stock reserved for issuance under our stock option and employee stock purchase plans, and intend to file additional registration statements on Form S-8 to register the shares automatically added each year to the share reserves under these plans.

We entered into a committed equity financing facility, or CEFF, on May 7, 2008 with Kingsbridge Capital Limited, or Kingsbridge. The perceived risk of dilution from sales of our common stock to or by Kingsbridge in connection with the CEFF may cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. The registration rights agreement entered into in connection with the CEFF requires that we use commercially reasonable efforts to ensure that the registration statement in connection with the CEFF remains effective for the term of such agreement. We have not drawn down funds and have not issued shares of our common stock under our committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, or Kingsbridge. Our ability to draw down funds and sell shares under the CEFF requires the continued effectiveness of and the ability to use the registration statement that we filed registering the resale of any shares issuable to Kingsbridge under the CEFF; however, we believe that the use of such registration statement may not be permitted under applicable SEC rules and guidance. Even if we are successful in taking the necessary steps to cause the resumption of the permitted use of such registration statement (as may be amended) in a timely manner, we are not able to sell shares under the CEFF if the average price of our common stock is lower than \$4.50 per share.

Pursuant to the terms of an investor rights agreement dated July 7, 2009 we entered into with the selling stockholders, we have filed a registration statement under the Securities Act, of which this prospectus is a part, registering the resale of the 1,895,734 shares of common stock we issued to the selling stockholders pursuant to the securities purchase agreement we entered into with the selling stockholders on July 6, 2009, as well as the 947,867 shares of common stock underlying the warrants we issued to the selling stockholders pursuant to the securities purchase agreement. In the event that a registration statement registering the resale of all of the 2,843,601 shares held by or issuable to the selling stockholders has not been declared effective by the SEC on or prior to November 15, 2009, we may be subject to the payment of liquidated damages to the selling stockholders. In addition, if we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the selling stockholders are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration.





## **Table of Contents**

***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 October 30, 2009, our executive officers and directors, together with their respective affiliates, beneficially owned approximately 65.7% of our capital stock, of which approximately 4.2% was beneficially owned by our executive officers. Accordingly, our executive officers and directors together with their respective affiliates are able to determine the composition of our board of directors, retain the voting power to approve all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on the market value of our common stock, and may prevent attempts by our stockholders to replace or remove our board of directors or management.

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

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

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

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.

## **Table of Contents**

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

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

authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

dividing our board of directors into three classes;

limiting the removal of directors by the stockholders;

eliminating cumulative voting rights and therefore allowing the holders of a majority of the shares of our common stock to elect all of the directors standing for election, if they should so choose;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

eliminating the ability of stockholders to call a special meeting of stockholders; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

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

Our business requires significant funding, and we currently invest more in product development than we earn from sales of our products. In addition, the agreements governing our debt restrict our ability to pay dividends on our common stock. Therefore, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently plan to invest all available funds and future earnings in the development and growth of our business and in the payment of our obligations. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

**Table of Contents**

**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

future performance from Xyrem and Luvox CR sales efforts;

our ability to comply with the agreement governing our senior secured notes on an ongoing basis;

submission and timing of applications for regulatory approval of JZP-6;

our expectations with respect to the potential commercialization of any of our product candidates, including JZP-6;

development progress and expectations with respect to our JZP-8, JZP-4 and JZP-7 product candidates; and

our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional funding.

In some cases, you can identify forward-looking statements by terms such as anticipate, believe, could, estimate, expect, intend, may, potential, predict, project, should, will, would and similar expressions intended to identify forward-looking statements. While we believe we have a reasonable basis for each forward-looking statement, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. We discuss many of these risks, uncertainties and other factors in greater detail under the heading **Risk Factors** contained in this prospectus and under similar headings in any amendments or supplements to this prospectus. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should read carefully this prospectus and the information incorporated herein by reference as described under the heading **Where You Can Find More Information** in this prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify all of our forward-looking statements by these cautionary statements.

Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

**Table of Contents****USE OF PROCEEDS**

The selling stockholders will receive all of the net proceeds from sales of the common stock sold pursuant to this prospectus. However, in the case of warrants issued to the selling stockholders on July 7, 2009, upon exercise of the warrants for cash, the selling stockholders would pay us an exercise price of \$4.00 per share of common stock, or an aggregate of \$3.8 million if the warrants are exercised in full for cash. The proceeds to us of such warrant exercises, if any, are expected to be used for working capital and general corporate purposes. The warrants are also exercisable on a cashless basis, and if the warrants are exercised on a cashless basis, we would not receive any cash payment from the selling stockholders upon any such exercise of the warrants.

**PRICE RANGE OF OUR COMMON STOCK**

Since June 1, 2007, our common stock has been listed on The NASDAQ Global Market under the symbol **JAZZ**. The following table sets forth, for the periods indicated, the reported high and low sales prices of our common stock on The NASDAQ Global Market:

<b>Fiscal Year ended December 31, 2007</b>	<b>High</b>	<b>Low</b>
Second Quarter (beginning June 1, 2007)	\$ 18.00	\$ 15.50
Third Quarter	17.11	11.20
Fourth Quarter	17.14	11.30
<b>Fiscal Year ended December 31, 2008</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 15.58	\$ 8.82
Second Quarter	9.87	5.13
Third Quarter	8.85	3.26
Fourth Quarter	5.52	0.91
<b>Fiscal Year ending December 31, 2009</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 2.00	\$ 0.58
Second Quarter	4.56	0.55
Third Quarter	10.37	3.63
Fourth Quarter (through November 9, 2009)	8.78	6.03

The reported last sale price of our common stock on The NASDAQ Global Market on November 9, 2009 was \$6.73 per share. As of November 9, 2009, there were 40 holders of record of our common stock.

**DIVIDEND POLICY**

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

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

**General**

Our authorized capital stock consists of 150,000,000 shares of common stock, \$0.0001 par value per share, and 20,000,000 shares of preferred stock, \$0.0001 par value per share. As of October 30, 2009, there were 30,992,088 shares of our common stock outstanding and no shares of preferred stock outstanding.

The following summary description of our capital stock is based on the provisions of our certificate of incorporation and bylaws, the applicable provisions of the Delaware General Corporation Law and the agreements with certain of our security holders described below. This information is qualified entirely by reference to the applicable provisions of our certificate of incorporation, bylaws, the Delaware General Corporation Law and such agreements. For information on how to obtain copies of such agreements and our certificate of incorporation and bylaws, which are exhibits to the registration statement of which this prospectus is a part, see [Where You Can Find More Information](#).

**Common Stock**

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders. The holders of our common stock do not have cumulative voting rights in the election of directors. Subject to preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends as may be declared by our Board of Directors out of legally available funds. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock. Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock.

The rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any preferred stock that we may designate and issue in the future.

**Preferred Stock**

Pursuant to our certificate of incorporation, our Board of Directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or NASDAQ rules), to designate and issue up to 20,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, voting powers, preferences and rights of the shares of each wholly unissued series, and any qualifications, limitations or restrictions thereof, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

We will fix the rights, preferences, privileges and restrictions of the preferred stock of each series that we may issue in the certificate of designation relating to that series. The General Corporation Law of the State of Delaware, the state of our incorporation, provides that the holders of preferred stock will have the right to vote separately as a class (or, in some cases, as a series) on an amendment to our certificate of incorporation if the amendment would change the par value or, unless the certificate of incorporation provides otherwise, the number of authorized shares of the class or change the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Our Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

---

**Table of Contents****Registration Rights**

*Third Amended and Restated Investor Rights Agreement.* Pursuant to the terms of a third amended and restated investor rights agreement dated June 6, 2007, as amended, by and between us and certain holders of our common stock and warrants to purchase our common stock, as of October 30, 2009, the holders of up to approximately 18,312,159 shares of our common stock, and warrants to purchase 785,728 shares of our common stock, or their transferees, are entitled to certain rights with respect to the registration of such shares under the Securities Act. In addition, upon exercise of outstanding options by our executive officers, certain of our executive officers will be entitled to rights with respect to registration of the shares of common stock acquired upon exercise. If we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the holders of these shares are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration. These holders have waived these registration rights in connection with the filing of, and any offerings that might be made pursuant to, the registration statement of which this prospectus is a part. In addition, the holders of these shares may require us, at our expense and subject to certain limitations, to file a registration statement under the Securities Act with respect to their shares of our common stock.

*Registration rights with respect to senior debtholder warrants issued in May 2008.* We and JPIC entered into a senior secured note and warrant purchase agreement dated March 14, 2008, as amended, with the purchasers named therein, as well as certain related agreements. Under the terms of the senior secured note and warrant purchase agreement, JPIC issued and sold \$120 million in aggregate principal amount of senior secured notes, and we issued warrants to purchase 562,192 shares of our common stock to certain of the purchasers of \$40 million in aggregate principal amount of such notes. In connection with the transaction, we also entered into a registration rights agreement with the purchasers holding these warrants. Under the terms of the registration rights agreement, as amended, we agreed to file, on or before January 9, 2010, and thereafter keep effective, a registration statement under the Securities Act registering the resale of the 562,192 shares of our common stock underlying these warrants.

*Registration rights with respect to the Committed Equity Financing Facility, or CEFF, with Kingsbridge Capital Limited.* We have entered into a registration rights agreement with Kingsbridge Capital Limited, or Kingsbridge, in connection with the CEFF that we entered into with Kingsbridge on May 7, 2008 pursuant to which we agreed to file and keep effective a registration statement under the Securities Act registering the resale of up to 4,922,064 shares of common stock issuable under the CEFF as well as 220,000 shares of common stock issuable upon exercise of a warrant issued to Kingsbridge in connection with the CEFF. To date, we have not drawn down funds under and have not issued any shares of common stock under the CEFF. Our ability to draw down funds and sell shares under the CEFF requires the continued effectiveness of and ability to use the registration statement that we filed registering the resale of the shares issuable under the CEFF and upon exercise of the warrant we issued to Kingsbridge; however, we believe that the use of such registration statement may not be permitted under applicable SEC rules and guidance. Even if we are successful in taking the necessary steps to cause the resumption of the permitted use of such registration statement (as may be amended) in a timely manner, we are not able to sell shares under the CEFF if the average price of our common stock is lower than \$4.50 per share.

*Registration rights with respect to July 2009 private placement.* Pursuant to the terms of an investor rights agreement dated July 7, 2009 we entered into with the selling stockholders, we have filed a registration statement under the Securities Act, of which this prospectus is a part, registering the resale of the 1,895,734 shares of common stock we issued to the selling stockholders pursuant to a securities purchase agreement we entered into with the selling stockholders on July 6, 2009, as well as the 947,867 shares of common stock underlying the warrants we issued to the selling stockholders pursuant to the securities purchase agreement, and to keep such registration statement effective. In the event that a registration statement registering the resale of all of the 2,843,601 shares held by or issuable to the selling stockholders has not been declared effective by the SEC on or prior to November 15, 2009, we may be subject to the payment of liquidated damages to the selling stockholders. In addition, if we propose to register any of our securities under the Securities Act, either for our own

---

## **Table of Contents**

account or for the account of others, the selling stockholders are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration.

### **NOL Preservation Lock-Up Agreement**

Effective July 7, 2009, we entered into a NOL preservation lock-up agreement with the selling stockholders and most of our other significant stockholders holding in the aggregate approximately 18,767,567 shares of our common stock, or 60.6% of our outstanding common stock as of October 30, 2009, and warrants to purchase up to an aggregate of 2,064,656 shares of our common stock. The NOL preservation lock-up agreement restricts these stockholders from, among other things, acquiring additional shares of our capital stock or certain other equity securities, or transferring shares of our capital stock or certain other equity securities, in each case until the earlier of (a) June 24, 2011, (b) immediately prior to certain change in control transactions, (c) such date as all of the stockholders that are a party to the agreement agree in writing to terminate the agreement or (d) such date on which we determine that the restrictions contained in the agreement are no longer needed. These restrictions are intended to minimize the risk that any ownership change (as defined in Section 382(g) of the Internal Revenue Code) with respect to us may limit our ability to utilize certain tax benefits, including net operating loss carryovers. Under the agreement, we may, in our discretion, authorize a proposed acquisition or transfer by any of these stockholders if we determine that the proposed acquisition or transfer, as the case may be, would not be likely to result in an ownership change within the meaning of Section 382(g) of the Internal Revenue Code that would be likely to limit our ability to utilize such tax benefits. Although the NOL preservation lock-up agreement is intended to minimize the risk of such an ownership change, we cannot assure you that such an ownership change will not occur. Because some corporate takeovers occur through an acquirer's purchase, in the public market or otherwise, of sufficient stock to give it control of a company, an agreement with certain of our significant stockholders that restricts the transferability of our securities could have the effect of delaying or discouraging such a takeover of us. Accordingly, the NOL preservation lock-up agreement could have an anti-takeover effect.

### **Anti-Takeover Effects of Provisions of Delaware Law and Our Charter Documents**

*Delaware Takeover Statute.* We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation such as us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction which resulted in the stockholder becoming an interest stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, lease, exchange, mortgage, pledge, transfer or other disposition (in one transaction or a series of transactions) involving the interested stockholder of 10% or more of the assets of the corporation;



Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

**Table of Contents**

any transaction involving the corporation that has the effect, directly or indirectly, of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and

the receipt by the interested stockholder of the benefit, directly or indirectly (except proportionately as a stockholder of such corporation), of any loans, advances, guarantees, pledges or other financial benefits, other than certain benefits set forth in Section 203, provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

*Charter Documents.* Provisions of our fourth amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our fourth amended and restated certificate of incorporation and amended and restated bylaws:

permit our Board of Directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;

provide that the authorized number of directors may be changed only by resolutions adopted by a majority of the authorized number of directors constituting the Board of Directors;

provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide our Board of Directors into three classes;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;

do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and

provide that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least 66-2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

The amendment of any of these provisions would require approval by the holders of at least 66-2/3% of our then outstanding common stock, voting as a single class.

These and other provisions contained in our fourth amended and restated certificate of incorporation and amended and restated bylaws could delay or discourage some types of transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

**Table of Contents**

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. Its address is 250 Royall Street, Canton, MA 02021.

**NASDAQ Global Market Listing**

Our common stock is listed on The NASDAQ Global Market under the trading symbol JAZZ.

**Table of Contents****MANAGEMENT**

The following table sets forth certain information concerning our directors and executive officers as of October 30, 2009:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Bruce C. Cozadd	46	Chairman and Chief Executive Officer
Robert M. Myers	46	President and Director
Carol A. Gamble	57	Senior Vice President, General Counsel and Corporate Secretary
Janne L.T. Wissel	53	Senior Vice President, Chief Regulatory and Compliance Officer
Joan E. Colligan	58	Controller and Acting Principal Financial Officer
Bryan C. Cressey	60	Director
Samuel D. Colella	69	Director
Patrick G. Enright	47	Director
Michael W. Michelson	58	Director
James C. Momtazee	37	Director
Kenneth W. O Keefe	42	Director
Alan M. Sebulsky	50	Director
James B. Tananbaum, M.D.	46	Director
Nathaniel M. Zilkha	34	Director

**Executive Officers**

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

*Robert M. Myers* is a co-founder and was appointed as our President in March 2007 and has served as a member of our Board of Directors since April 2009. From 2003 until 2007, he served as our Executive Vice President and Chief Business Officer. From 2002 until 2003, he served as Executive Vice President, Pharmaceuticals at Exelixis, Inc., a biotechnology company. He previously held various positions with ALZA Corporation from 1992 to 2001, most recently as its Senior Vice President, Commercial Development. In this role, he was responsible for ALZA Corporation's corporate development, mergers and acquisitions, new product planning and corporate planning. He received B.S. and M.S. degrees from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

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

*Janne L. T. Wissel* has served as Senior Vice President and Chief Regulatory Officer since October 2007. Prior to that she served as our Senior Vice President of Development from 2004 to 2007, and previously she served as our Vice President of Development. From 1981 to 2003, she held various positions at ALZA Corporation, most recently

## **Table of Contents**

as its Senior Vice President, Operations, with responsibility for ALZA Corporation's global regulatory, quality, general operations and manufacturing activities. She has led the development, registration and launch of more than 20 pharmaceutical products in the neurology, pediatric psychiatry, endocrinology, urology and oncology areas. She received a B.S. from the University of California, Davis and an M.B.A. from the University of Phoenix.

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

## **Directors**

*Bryan C. Cressey* has served as a member of our Board of Directors since 2006. Since 2007, he has been a Partner of Cressey and Company, LLC, and since 1998, he has been a Partner of Thoma Cressey Bravo, Inc., both private equity firms of which he is a founder. He serves on the boards of Belden, Inc., a networking cable technology company, Select Medical Corporation, a healthcare services company, and several privately-held healthcare services companies. He received a B.A. from the University of Washington, a J.D. from Harvard Law School and an M.B.A. from Harvard Business School.

*Samuel D. Colella* has served as a member of our Board of Directors since 2004. Since 1999, he has served as Managing Member of Versant Ventures, a venture capital firm, which he co-founded. He serves on the boards of Alexza Pharmaceuticals, Inc., a drug delivery company, Genomic Health Inc., a molecular diagnostics company, and several privately-held companies. He received a B.S. from the University of Pittsburgh and an M.B.A. from the Stanford Graduate School of Business.

*Patrick G. Enright* has served as a member of our Board of Directors since July 2009, and his appointment to our Board of Directors was a condition to the closing of the transactions contemplated by the securities purchase agreement with the selling stockholders. Since 2006, he has served as a Managing Member of Longitude Capital, a venture capital firm, of which he is a founder. From 2002 through 2006, Mr. Enright was a Managing Director of Pequot Ventures where he co-led the life sciences investment practice. Mr. Enright also has significant life sciences operations experience, beginning his career more than 25 years ago at Sandoz (now Novartis). He currently serves on the boards of Corcept Therapeutics Incorporated, a pharmaceutical company and several privately-held companies. Mr. Enright received a B.S. from Stanford University and an M.B.A. from the Wharton School at the University of Pennsylvania.

*Michael W. Michelson* has served as a member of our Board of Directors since 2004. Since 1981, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is a Member and also serves on KKR's Investment and Other Business committees. He serves on the boards of HCA Inc., a healthcare services company, and Biomet, Inc., a healthcare manufacturing company. He received an A.B. from Harvard College and a J.D. from Harvard Law School.

*James C. Momtazee* has served as a member of our Board of Directors since 2004. Since 1996, he has been employed by Kohlberg Kravis Roberts & Co. L.P., where he is a Member. He serves on the boards of HCA Inc., a healthcare services company, and Accellent Inc., a manufacturing and engineering services company. He received an A.B. from Stanford University and an M.B.A. from the Stanford Graduate School of Business.

*Kenneth W. O'Keefe* has served as a member of our Board of Directors since 2004. Since 1997, he has been Managing Director of Beecken Petty O'Keefe & Company, a private equity firm, which he co-founded. He serves on the boards of several privately-held healthcare companies. He received a B.A. from Northwestern University and an M.B.A. from the University of Chicago.

## **Table of Contents**

*Alan M. Sebulsky* has served as a member of our Board of Directors since 2004. Since 2003, he has served as a Managing Partner of Apothecary Capital LLC, an investment advisory firm. From 2002 to 2003, he was an independent investor. From 1994 to 2002, he held various positions, most recently as a Managing Director, at Lincoln Capital Management, a private investment management firm, where he was responsible for investments in the health care industry. He received a B.B.A. and an M.S. from the University of Wisconsin, Madison.

*James B. Tananbaum, M.D.* has served as a member of our Board of Directors since 2003. Since 2000, Dr. Tananbaum has been a Managing Member of Prospect Venture Partners, a venture capital firm he co-founded. He serves on the boards of Critical Therapeutics, Inc., Infinity Pharmaceuticals, Inc., Novavax, Inc., and several privately-held companies. Dr. Tananbaum was also the founder of GelTex, Inc. and Theravance, Inc. He received a B.S.E.E. from Yale University, and an M.D. and an M.B.A. from Harvard University.

*Nathaniel M. Zilkha* has served as a member of our Board of Directors since October 2007. Since August 2007, he has been employed at Kohlberg Kravis Roberts & Co., L.P., where he is a Director. From July 1999 to May 2007, Mr. Zilkha was a vice president at Goldman Sachs, where he led the healthcare investing efforts for the Goldman Sachs Capital Partners funds. He currently serves on the board of Oriental Brewery Co. Ltd. Mr. Zilkha graduated cum laude from Princeton University in 1999.

### **Independence of Jazz Pharmaceuticals Board of Directors**

As required under the NASDAQ Stock Market LLC, or NASDAQ, listing standards, a majority of the members of a listed company's board of directors must qualify as independent, as affirmatively determined by the board of directors. Our Board of Directors consults with internal counsel to ensure that our Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of independent, including those set forth in pertinent listing standards of NASDAQ, as in effect time to time. Consistent with these considerations, after review of all relevant transactions or relationships between each director, or any of his or her family members, and Jazz Pharmaceuticals, its senior management and its independent registered public accounting firm, the Board has affirmatively determined that all of our directors are independent directors within the meaning of the applicable NASDAQ listing standards, except that Mr. Cozadd, our Chairman and Chief Executive Officer, and Mr. Myers, our President, are not independent directors by virtue of their employment with Jazz Pharmaceuticals. Our Board of Directors also determined that Samuel R. Saks, M.D., our former Chief Executive Officer, was not an independent director by virtue of his former employment with Jazz Pharmaceuticals.

---

**Table of Contents**

**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

**Policy and Procedures for Review of Related Party Transactions**

In 2007, we adopted a Related Party Transaction Policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related-person transactions. For purposes of our policy only, a related-person transaction is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related-person transaction (including any transaction that was not a related-person transaction when originally consummated or any transaction that was not initially identified as a related-person transaction prior to consummation), our management must present information regarding the related-person transaction to our Audit Committee (or, if Audit Committee approval would be inappropriate, to another independent body of our Board of Directors) for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will, on an annual basis, collect information that our General Counsel deems reasonably necessary from each director, executive officer and (to the extent feasible) significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest to our General Counsel, or, if the employee is an executive officer, to our Board of Directors. In considering related-person transactions, our Audit Committee (or other independent body of our Board of Directors) will take into account the relevant available facts and circumstances including, but not limited to, the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products and, if applicable the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated.

The policy requires that, in determining whether to approve, ratify or reject a related-person transaction, our Audit Committee (or other independent body of our Board of Directors) must consider, in light of known circumstances, whether the transaction is, or is not inconsistent with, our best interests and those of our stockholders, as our Audit Committee (or other independent body of our Board of Directors) determines in the good faith exercise of its discretion.

**Certain Transactions With or Involving Related Persons**

Below is a description of certain transactions with or involving related persons since January 1, 2006 to the date of this prospectus. Where applicable, the share numbers and per share prices listed below have been adjusted to reflect a 1-for-11.06701 reverse stock split of our common stock and preferred stock effected on May 15, 2007. All of our preferred stock listed below was converted into common stock on a 1-for-1 basis (after giving effect to above reverse stock split) immediately prior to the closing of our initial public offering on June 6, 2007.

***Sales of Securities***

*Preferred Stock Private Placements.* During the period from January 1, 2006 through December 2006, we issued and sold an aggregate of 3,180,707 shares of our Series B preferred stock at a per share price of \$15.09 for aggregate consideration of approximately \$48 million, and we also issued and sold an aggregate of 3,445,768 shares of Series B Prime preferred stock at a per share price of \$15.09 for aggregate consideration of \$52 million. We refer to these issuances below as the Preferred Stock Financings. The Preferred Stock Financings were effected prior to the adoption of our Related Party Transaction Policy and were approved by our Board of Directors.



**Table of Contents**

*Registered Direct Offering.* In July 2008, we sold an aggregate of 3,848,289 immediately separable units in a registered direct offering to select investors, with each unit consisting of one share of our common stock and a warrant to purchase 0.45 of a share of common stock at a price per unit of \$6.75625 for aggregate consideration of approximately \$26.0 million. In the aggregate, we issued and sold 3,848,289 shares of our common stock and warrants to purchase up to an aggregate of 1,731,724 shares of our common stock pursuant to the terms of a placement agent agreement and the related subscription agreements. Each warrant has an exercise price of \$7.37 per share. The investors in the registered direct public offering included certain of our existing stockholders as set forth in the table below, and other select institutional investors. We refer to these issuances below as the Registered Direct. As a result of the participation of related persons in the Registered Direct, such participation was reviewed and pre-approved in accordance with our Related Party Transaction Policy by a special committee of our Board of Directors comprised solely of independent directors who were not affiliated or associated with the investors in the Registered Direct.

*July 2009 Private Placement.* In July 2009, we sold an aggregate of 1,895,734 immediately separable units in a private placement to the selling stockholders, with each unit consisting of one share of our common stock and a warrant to purchase 0.5 of a share of common stock at a price per unit of \$3.6925 for aggregate consideration of approximately \$7.0 million. In the aggregate, we issued and sold 1,895,734 shares of common stock and warrants to purchase up to an aggregate of 947,867 additional shares of common stock to the selling stockholders pursuant to a securities purchase agreement. Each warrant has an exercise price of \$4.00 per share. We refer to these issuances below as the July 2009 Private Placement. Although the July 2009 Private Placement occurred after the adoption of our Related Party Transaction Policy, our Related Party Transaction Policy did not require that we obtain prior approval of this transaction by our Audit Committee (or other independent body of our Board of Directors) since at the time we entered into the securities purchase agreement pursuant to which the July 2009 Private Placement was effected, neither Mr. Enright nor the selling stockholders were related persons within the meaning of our Related Party Transaction Policy. However, in accordance with our Related Party Transaction Policy, we submitted the July 2009 Private Placement to the Audit Committee for review and ratification at their first regularly-scheduled meeting following the transaction and the Audit Committee ratified the transaction in accordance with our Related Party Transaction Policy.

Set forth in the table below is certain information regarding related person participation in the Preferred Stock Financings, the Registered Direct and the 2009 Private Placement:

<b>Purchaser</b>	<b>Common Stock</b>	<b>Common Stock Warrants</b>	<b>Series B Preferred Stock</b>	<b>Series B Prime Preferred Stock</b>
<b>Executive Officers and Directors</b>				
Bruce C. Cozadd			26,505	
Samuel R. Saks, M.D.(1)			26,505	
Robert M. Myers			18,554	
Matthew K. Fust(2)			7,951	
Janne L.T. Wissel			26,505	
<b>Principal Stockholders(3)</b>				
Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.(4)	1,328,527	597,837		3,445,768
Entities affiliated with Thoma Cressey Bravo, Inc.(5)	306,583	137,962	795,177	
Entity affiliated with Beecken Petty O Keefe & Company, LLC(6)	204,389	91,975	530,118	
Entities affiliated with Prospect Venture Partners(7)	190,334	85,650	225,300	
Entities affiliated with Versant Ventures(8)	296,022	133,209	225,300	
Entities affiliated with Longitude Capital Partners, LLC(9)	1,895,734	947,867		

(1) Dr. Saks resigned as our Chief Executive Officer (and as a director) effective April 3, 2009.

(2) Mr. Fust resigned as our Chief Financial Officer effective December 31, 2008.

**Table of Contents**

- (3) Certain of our directors are affiliated and/or associated with our principal stockholders as indicated in the table below:

<b>Director</b>	<b>Principal Stockholder</b>
Bryan C. Cressey	Entities affiliated with Thoma Cressey Bravo, Inc.
Samuel D. Colella	Entities affiliated with Versant Ventures
Patrick G. Enright	Entities affiliated with Longitude Capital Partners, LLC
Michael W. Michelson	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
James C. Momtazee	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.
Kenneth W. O Keefe	Entity affiliated with Beecken Petty O Keefe & Company, LLC
James B. Tananbaum, M.D.	Entities affiliated with Prospect Venture Partners
Nathaniel M. Zilkha	Entities affiliated with Kohlberg Kravis Roberts & Co. L.P.

- (4) Consists of 3,431,190 shares of Series B Prime preferred stock acquired by KKR JP LLC and 14,578 shares of Series B Prime preferred stock acquired by KKR JP III LLC in the Preferred Stock Financings, and 1,328,527 shares of common stock acquired by KKR JP LLC in the Registered Direct. Also consists of a warrant to purchase 597,837 shares of common stock acquired by KKR JP LLC in the Registered Direct.
- (5) Consists of 782,959 shares of Series B preferred stock acquired by Thoma Cressey Fund VII, LP and 12,218 shares of Series B preferred stock acquired by Thoma Cressey Friends Fund VII, LP in the Preferred Stock Financings, and 301,870 shares of common stock acquired by Thoma Cressey Fund VII, LP and 4,713 shares of common stock acquired by Thoma Cressey Friends Fund VII, LP in the Registered Direct. Also consists of a warrant to purchase 135,841 shares of common stock acquired by Thoma Cressey Fund VII, LP and a warrant to purchase 2,121 shares of common stock acquired by Thoma Cressey Friends Fund VII, LP in the Registered Direct.
- (6) Consists of 530,118 shares of Series B preferred stock acquired by Jazz Investors LLC in the Preferred Stock Financings, 204,389 shares of common stock acquired by Jazz Investors LLC in the Registered Direct, and a warrant to purchase 91,975 shares of common stock acquired by Jazz Investors LLC in the Registered Direct.
- (7) Consists of 221,921 shares of Series B preferred stock acquired by Prospect Venture Partners II, L.P. and 3,379 shares of Series B preferred stock acquired by Prospect Associates II, L.P. in the Preferred Stock Financings, and 187,479 shares of common stock acquired by Prospect Venture Partners II, L.P. and 2,855 shares of common stock acquired by Prospect Associates II, L.P. in the Registered Direct. Also consists of a warrant to purchase 84,365 shares of common stock acquired by Prospect Venture Partners II, L.P. and a warrant to purchase 1,285 shares of common stock acquired by Prospect Associates II, L.P. in the Registered Direct.
- (8) Consists of 219,182 shares of Series B preferred stock acquired by Versant Venture Capital II, L.P., 4,159 shares of Series B preferred stock acquired by Versant Affiliates Fund II-A, L.P. and 1,959 shares of Series B preferred stock acquired by Versant Side Fund II, L.P. in the Preferred Stock Financings, and 288,029 shares of common stock acquired by Versant Venture Capital II, L.P., 5,476 shares of common stock acquired by Versant Affiliates Fund II-A, L.P. and 2,517 shares of common stock acquired by Versant Side Fund II, L.P. in the Registered Direct. Also consists of a warrant to purchase 129,613 shares of common stock acquired by Versant Venture Capital II, L.P., a warrant to purchase 2,464 shares of common stock acquired by Versant Affiliates Fund II-A, L.P. and a warrant to purchase 1,132 shares of common stock acquired by Versant Side Fund II, L.P. in the Registered Direct.
- (9) Consists of 1,858,486 shares of common stock acquired by Longitude Venture Partners, L.P. and 37,248 shares of common stock acquired by Longitude Capital Associates, L.P. in the 2009 Private Placement. Also consists of a warrant to purchase 929,243 shares of common stock acquired by Longitude Venture Partners, L.P. and a warrant to purchase 18,624 shares of common stock acquired by Longitude Capital Associates, L.P. in the 2009 Private Placement.

---

**Table of Contents***Senior Secured Notes and Related Warrants*

In June 2005, Orphan Medical, Inc., or Orphan Medical, a wholly-owned subsidiary of Jazz Pharmaceuticals, issued senior secured notes in the aggregate principal amount of \$80.0 million, or the Orphan Notes, with interest payable on the Orphan Notes at the rate of 15% per year, payable quarterly in arrears. We guaranteed the obligations of Orphan Medical to repay the Orphan Notes pursuant to a senior secured note and warrant purchase agreement we entered into with the purchasers of the Orphan Notes, and also issued warrants to purchase an aggregate of 785,728 shares of Series BB Preferred Stock having an exercise price of \$20.36 per share. KKR Financial Holdings III, LLC, or KFN, an entity affiliated with Kohlberg Kravis Roberts & Co. L.P., and LB I Group, Inc., an entity affiliated with Lehman Brothers Holdings Inc., both of which were significant stockholders during 2006, 2007 and 2008, purchased \$25.0 million and \$31.0 million principal amount of Orphan Notes, respectively, and warrants to purchase 245,540 and 304,469 shares of our common stock, respectively. With respect to KFN, the \$25.0 million principal amount represented the largest aggregate amount of principal balance outstanding on the Orphan Notes to date. In March 2008, KFN sold \$17.9 million in principal amount of notes and warrants to purchase 175,384 shares of common stock to LB I Group. With respect to LB I Group, \$56.0 million principal amount represented the largest aggregate amount of principal balance outstanding on the Orphan Notes to date. For the period from January 1, 2006 to March 17, 2008, total interest payments under the Orphan Notes were \$26.6 million, of which \$7.7 million and \$11.1 million was paid to KFN and LB I Group, respectively. The issuance of the Orphan Notes and related warrants were effected prior to the adoption of our Related Party Transaction Policy and were approved by our Board of Directors.

In March 2008, JPIC issued senior secured notes in the aggregate principal amount of \$120.0 million, or the JPIC Notes, with interest payable on the JPIC Notes at the rate of 15% per year, payable quarterly in arrears commencing June 30, 2008. With respect to defaults, interest is payable at an annual default rate of 17%. We guaranteed the obligations of JPIC to repay the JPIC Notes pursuant to a senior secured note and warrant purchase agreement we entered into with the purchasers of the JPIC Notes. Of the \$120.0 million in principal amount of JPIC Notes issued in March 2008, \$80.0 million in principal amount of JPIC Notes were issued in exchange for the same principal amount of Orphan Notes and in connection therewith, the Orphan Notes were retired. With respect to KFN, KFN was issued \$7.1 million in principal amount of JPIC Notes in exchanges for its Orphan Notes. LB I Group was issued \$56.0 million in principal amount of JPIC Notes in exchanges for its Orphan Notes, and also purchased \$33.5 million in principal amount of additional JPIC Notes. In connection with the purchase of additional JPIC Notes, LB I Group was issued a warrant to purchase 470,836 shares of our common stock having an exercise price of \$14.23 per share. Together, the \$89.5 million in aggregate principal amount of JPIC Notes issued to LB I Group represented the largest aggregate amount of principal balance outstanding to date held by LB I Group. In August 2008, JPIC paid certain holders of the senior secured notes \$504,000 aggregate principal amount plus accrued interest as their pro rata share of the proceeds from the JPIC's sale of its rights to Antizol and Antizol-Vet and the principal amount was reduced accordingly. Under the terms of the agreement with the senior secured note holders, JPIC is obligated to pay the holders of the senior secured notes the proceeds from any future sale of the JPIC's rights to Xyrem, Luvox CR and JZP-6, if the holders so elect. Other than with respect to the August 2008 payment and the retiring of the Orphan Notes in March 2008, no principal payments have been made on either the Orphan Notes or the JPIC Notes. For the period from January 1, 2008 to October 1, 2009, total interest payments under the JPIC Notes were \$28.9 million, of which \$1.7 million and \$21.6 million was paid to KFN and LB I Group, respectively. Although the issuance of the JPIC Notes and our entry into a senior secured note and warrant purchase agreement, or the Senior Note Agreement, in connection therewith (and the issuance of warrants to purchase our common stock pursuant thereto) occurred after the adoption of our Related Party Transaction Policy, our Related Party Transaction Policy did not require that we obtain approval or ratification of this transaction by our Audit Committee (or other independent body of our Board of Directors) since at the time we entered into the transaction, LB I Group and each other of the purchasers of the new JPIC Notes were not related persons within the meaning of our Related Party Transaction Policy. Although KFN is affiliated with Kohlberg Kravis Roberts & Co. L.P., which is a related person within the meaning of our Related Party Transaction, KFN did not purchase any additional notes or warrants in the transaction, and KFN's participation in the transaction was limited to exchanging its Orphan Note for the same principal amount of JPIC Notes. Our Board of Directors was, however, aware of KFN's participation in the transaction when it approved the transaction.

## **Table of Contents**

In November 2009, we entered into an amendment and waiver agreement pursuant to which the holders of the JPIC Notes waived our prior events of default under the Senior Note Agreement and the other agreements related thereto, and pursuant to which the Senior Note Agreement was amended to, among other things, (i) require us to make certain scheduled principal payments on the JPIC Notes totaling \$40.0 million commencing on March 31, 2010 and ending on March 31, 2011, (ii) allow us, prior to February 15, 2010 and subject to certain restrictions, to voluntarily prepay up to \$40.0 million principal amount of the JPIC Notes without any prepayment penalty or make-whole amount, and (iii) reduce the minimum cash balance required to be maintained by us under certain circumstances. Pursuant to the amendment and waiver agreement, the warrants to purchase our common stock that we issued in connection with the issuance of the Orphan Notes and the JPIC Notes were each amended to reduce the respective exercise prices of such warrants, such that the exercise price of the warrants we issued in connection with the issuance of the Orphan Notes, or the Orphan Warrants, was reduced from \$20.36 to \$9.34 per share, and the exercise price of the warrants that we issued in connection with the issuance of the JPIC Notes, or the JPIC Warrants, was reduced from \$14.23 to \$9.34 per share. As of the date of the amendment and waiver agreement, KFN and LB I Group held Orphan Warrants exercisable for 70,156 shares and 550,010 shares, respectively, and LB I Group held a JPIC Warrant exercisable for 470,836 shares. The amendment and waiver agreement also provides for certain amendments to our registration obligations with respect to the JPIC Warrants, which registration obligations are generally described under Description of Capital Stock Registration Rights Registration rights with respect to senior debtholder warrants issued in May 2008. In addition, we agreed to pay to the holders of the JPIC Notes a restructuring fee totaling \$500,000, payable on the maturity date of the JPIC Notes (or upon earlier repayment in full of the JPIC Notes), of which \$28,500 and \$374,500 is payable to KFN and LB I Group, respectively. The amendment and waiver agreement was reviewed and pre-approved in accordance with our Related Party Transaction Policy.

### **Registration Rights**

We have entered into investor rights and registration rights agreements with certain holders of our common stock and warrants to purchase our common stock, including our principal stockholders with which certain of our directors are affiliated. For a description of these registration rights, see Description of Capital Stock Registration Rights.

### **Indemnification Agreements**

We have entered into indemnity agreements with each of our directors, executive officers and vice presidents that require us 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 us or any of our affiliated enterprises, provided that such person's conduct did not constitute a breach of his or her duty of loyalty to us or our 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. The indemnity agreements with certain of our directors further provide that, with respect to a director that is serving on our Board of Directors at the direction of a venture or other investment fund or entity, or fund, with respect to such indemnitee's service as a director, officer, employee, agent and/or fiduciary of Jazz Pharmaceuticals, our obligations under the indemnity agreement are the primary source of indemnification and advancement, we are required to make all expense advances, and we are liable for all of such indemnitee's expenses, to the extent required by the indemnity agreement, our amended and restated certificate of incorporation and amended and restated bylaws, without regard to any rights the indemnitee may have against the fund, and we irrevocably waive, relinquishes and releases any and all claims against the fund for contribution, subrogation or any other recovery of any kind in connection with our obligations under the indemnity agreement. We believe that these agreements are necessary to attract and retain qualified persons as officers and directors of Jazz Pharmaceuticals. We also maintain directors' and officers' liability insurance.

### **Compensation Committee Interlocks and Insider Participation**

In 2008, our Compensation Committee was composed of three directors: Messrs. Colella and Michelson and Dr. Tananbaum. None of the members of our Compensation Committee has at any time been an officer or employee of Jazz Pharmaceuticals. None of our executive officers serves, or in the past fiscal year has served, as a member of the board of directors or the compensation committee of any entity that has one or more of its executive officers serving on our Board of Directors or Compensation Committee. Please see the disclosure above under Certain Transactions With or Involving Related Persons Sales of Securities Registered Direct Offering and the related disclosure in the table that follows regarding the Registered Direct and the participation therein of the entities with which Messrs. Colella and Michelson and Dr. Tananbaum are affiliated.

**Table of Contents****SELLING STOCKHOLDERS**

On July 6, 2009, we entered into a securities purchase agreement with the selling stockholders, pursuant to which we sold an aggregate of 1,895,734 immediately separable units in a private placement, with each unit consisting of one share of our common stock and a warrant to purchase 0.5 of a share of common stock at a price per unit of \$3.6925. In the aggregate, we issued and sold 1,895,734 shares of common stock and warrants to purchase up to an aggregate of 947,867 additional shares of common stock to the selling stockholders at the closing of the private placement on July 7, 2009. We also entered into an investor rights agreement with the purchasers dated July 7, 2009 as described under

**Description of Capital Stock** **Registration Rights** Registration rights with respect to July 2009 private placement pursuant to which we agreed to file the registration statement, of which this prospectus is a part, to cover the resale of the shares and the shares underlying the warrants issued to the selling stockholders pursuant to the securities purchase agreement and to keep such registration statement effective. The warrants were issued to the selling stockholders in the private placement on July 7, 2009 and are immediately exercisable by their terms at an exercise price of \$4.00 per share, and will expire seven years from the date of issuance. The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including subdivisions and stock splits, stock dividends, reorganizations, reclassifications, consolidations, mergers or sales of assets and upon the issuance of certain assets or securities to holders of our common stock, as applicable. 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 equal to the aggregate exercise price of the shares with respect to which the warrant is being exercised.

We are registering the above-referenced shares to permit each of the selling stockholders and their donees, pledges, transferees or other successors-in-interest that receive their shares after the date of this prospectus to resell or otherwise dispose of the shares in the manner contemplated under **Plan of Distribution** in this prospectus (as supplemented and amended). This prospectus covers the sale or other disposition by the selling stockholders or their transferees of up to the total number of shares of common stock issued to the selling stockholders pursuant to the securities purchase agreement, plus the total number of shares of common stock issuable upon exercise of the warrants issued to the selling stockholders pursuant to the securities purchase agreement. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders, we are referring to the shares and the shares underlying the warrants issued to the selling stockholders pursuant to the securities purchase agreement, and when we refer to the selling stockholders in this prospectus, we are referring to the purchasers under the securities purchase agreement and, as applicable, 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.

On July 6, 2009, our Board of Directors approved an increase to the total number of authorized directors to twelve directors and, upon the recommendation of the Nominating and Corporate Governance Committee of the Board, elected Patrick G. Enright to the Board, effective as of the closing of the private placement. Mr. Enright is a managing member of Longitude Capital Partners, LLC, the sole general partner of each of the selling stockholders, and his election to our Board of Directors was a condition to the closing of the private placement. Except with respect to the foregoing, none of the selling stockholders has, or within the past three years has had, any position, office or other material relationship with us. In September 2009, our Board of Directors approved a decrease to the total number of authorized directors from twelve to eleven directors in connection with E. Alexander Albert's resignation from our Board of Directors.

The following table sets forth the name of each selling stockholder, the number of shares held by the selling stockholders and issuable to the selling stockholders upon a cash exercise of the warrants, the number of shares that may be offered under this prospectus and the number of shares of our common stock owned by the selling stockholders assuming all of the shares covered hereby are sold. The number of shares in the column **Number of Shares of Common Stock Being Offered** represents all of the shares that a selling stockholder may offer under this prospectus. The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them; however, the selling stockholders are subject to certain restrictions on the transfer of our capital stock and certain of our other equity securities (including restrictions on the exercise of warrants) pursuant to the NOL preservation lock-up agreement described under **Description of Capital Stock** **NOL Preservation Lock-Up Agreement**. Other than the NOL preservation lock-up agreement, we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale or other disposition of any of the shares. The shares covered hereby may be offered from time to time by the selling stockholders, subject to the restrictions set forth in the NOL preservation lock-up agreement.

**Table of Contents**

The information set forth below is based upon information obtained from the selling stockholders and upon information in our possession regarding the issuance of shares of common stock and warrants to the selling stockholders in connection with the private placement. For purposes of the table below, we have assumed that the selling stockholders exercised the warrants in full pursuant to a cash exercise. The information regarding shares to be beneficially owned after the offering assumes the sale of all shares offered by the selling stockholders under this prospectus. The percentage of shares owned prior to and after the offering is based both on 30,992,088 shares of our common stock outstanding as of October 30, 2009, and on the assumption that all shares of common stock issuable upon exercise of the warrants held by a particular selling stockholder are outstanding as of that date.

Name of Selling Stockholder(2)	Shares of Common Stock Beneficially Owned Prior to Offering(1)		Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After Offering(1)	
	Number	Percent		Number	Percent
Longitude Venture Partners, L.P.	2,934,782(3)	9.19%	2,787,729(3)	147,053	0.47%
Longitude Capital Associates, L.P.	58,819(4)	0.19%	55,872(4)	2,947	0.01%

- (1) Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares indicated in the table.
- (2) The business address of each of Longitude Venture Partners, L.P. ( LVP ) and Longitude Capital Associates, L.P. ( LCA ) is 800 El Camino Real, Suite 220, Menlo Park, California 94025. Longitude Capital Partners, LLC ( Longitude Capital ) is the sole general partner of each of LVP and LCA. Longitude Capital and each of Patrick G. Enright and Juliet Tammenoms Bakker, managing members of Longitude Capital, may be deemed to have shared voting and dispositive power with respect to the shares held by or issuable to LVP and LCA, and each disclaims beneficial ownership of all such shares except to the extent of such person's proportionate pecuniary interest therein. Patrick G. Enright is a member of our Board of Directors.
- (3) Includes 929,243 shares of common stock subject to a warrant issued pursuant to the securities purchase agreement.
- (4) Includes 18,624 shares of common stock subject to a warrant issued pursuant to the securities purchase agreement.

**Table of Contents**

**PLAN OF DISTRIBUTION**

We are registering the shares of common stock issued to the selling stockholders and issuable upon exercise of the warrants issued to the selling stockholders to permit the resale of these shares of common stock by the holders of the shares of common stock 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.

Each selling stockholder of the common stock and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock covered hereby on The NASDAQ Global Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or negotiated prices. A selling stockholder may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440-1.

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

In connection with the sale of the common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions or to return borrowed shares in connection with such short sales, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities 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). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered on this registration statement to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the Commission.



## **Table of Contents**

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling stockholders who are underwriters within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Each selling stockholder has informed us that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act, and the selling stockholders may be entitled to contribution. We may be indemnified by the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, or we may be entitled to contribution.

The selling stockholders will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder unless an exemption therefrom is available.

The selling stockholders have advised us that there is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to use our commercially reasonable best efforts keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume restrictions under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares of common stock covered hereby may not be sold unless they 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.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement of which this prospectus forms a part.

Once sold under the 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.

**Table of Contents**

**VALIDITY OF COMMON STOCK**

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 30,596 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 October 30, 2009.

**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, 2008, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 2 to the consolidated financial statements), 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 MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock that may be sold by the selling stockholders may from time to time in one or more offerings. The registration statement, including the exhibits and schedules thereto, contains additional relevant information about us and our capital stock. The rules and regulations of the SEC allow us to omit from this prospectus certain information included in the registration statement. For further information about us and our common stock, you should refer to the registration statement and the exhibits and schedules to the registration statement. With respect to the statements contained in this prospectus regarding the contents of any agreement or any other document, in each instance, the statement is qualified in all respects by the complete text of the agreement or document, a copy of which has been filed or incorporated by reference as an exhibit to the registration statement.

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Jazz Pharmaceuticals. The SEC's Internet site can be found at [www.sec.gov](http://www.sec.gov).

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus. We incorporate by reference the following information or documents that we have filed with the SEC (Commission File No. 0-50549):

our Current Report on Form 8-K filed with the SEC on January 12, 2009 (with respect to Item 8.01);

our Current Report on Form 8-K filed with the SEC on February 10, 2009;

our Current Report on Form 8-K filed with the SEC on February 20, 2009, as amended by Amendment No. 1 to our Current Report on Form 8-K/A filed with the SEC on February 23, 2009;

our Annual Report on Form 10-K for the year ended December 31, 2008 filed with the SEC on March 26, 2009, as amended by Amendment No. 1 to our Annual Report on Form 10-K/A filed with the SEC on April 29, 2009;

our Current Report on Form 8-K filed with the SEC on April 3, 2009;



**Table of Contents**

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 filed with the SEC on May 7, 2009;

our Current Report on Form 8-K filed with the SEC on June 4, 2009;

our Current Report on Form 8-K filed with the SEC on June 25, 2009;

our Current Report on Form 8-K filed with the SEC on July 7, 2009 (except for the information furnished under Item 2.02 or any related exhibit);

our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 filed with the SEC on August 14, 2009;

our Current Report on Form 8-K filed with the SEC on October 5, 2009;

our definitive proxy statement on Schedule 14A filed with the SEC on October 23, 2009 (other than the portions thereof specifically not to be incorporated by reference in any filing made by us under the Securities Act or the Exchange Act);

our Quarterly Report on Form 10-Q for the quarter ended September 30, 2009 filed with the SEC on November 6, 2009; and

our Current Report on Form 8-K filed with the SEC on November 10, 2009.

Any information in any of the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus or in an amendment or supplement to this prospectus modifies or replaces such information.

We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to: Jazz Pharmaceuticals, Inc., Attn: Investor Relations, 3180 Porter Drive, Palo Alto, CA 94304. Our telephone number is (650) 496-3777. In addition, all of the documents incorporated by reference into this prospectus may be accessed via the Internet at our website: <http://www.jazzpharmaceuticals.com>.

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated costs and expenses, other than any underwriting discounts and commissions, payable by the registrant in connection with the offering of the common stock being registered. All the amounts shown are estimates, except for the SEC registration fee.

	<b>Amount to be Paid</b>
SEC registration fee	\$ 974
Legal fees and expenses	80,000
Accounting fees and expenses	40,000
Printing and miscellaneous expenses	14,026
<b>Total</b>	<b>\$ 135,000</b>

**Item 14. 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

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

(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. The indemnity agreements with certain of the registrant's directors further provide that, with respect to a director that is serving on the registrant's Board of Directors at the direction of a venture or other investment fund or entity, with respect to such indemnitee's service as a director, officer, employee, agent and/or fiduciary of the registrant, the registrant's obligations under the indemnity agreement are the primary source of indemnification and advancement, the registrant is required to make all expense advances, and the registrant is liable for all of such indemnitee's expenses, to the extent required by the indemnity agreement, the registrant's amended and restated certificate of

II-1

---

**Table of Contents**

incorporation and amended and restated bylaws, without regard to any rights the indemnitee may have against the applicable venture or other investment fund or entity, and the registrant irrevocably waives, relinquishes and releases any and all claims against the applicable venture or other investment fund or entity for contribution, subrogation or any other recovery of any kind in connection with the registrant's obligations under the indemnity agreement. 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.

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 investor 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 the registrant's senior debt in March 2008, the registrant also entered into a registration rights agreement with the purchasers of \$40.0 million of additional secured indebtedness that provides for cross-indemnification in connection with registration of the registrant's common stock underlying warrants on behalf of such purchasers. The common stock purchase agreement and the registration rights agreement the registrant entered into with Kingsbridge Capital Limited in May 2008 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. In addition, the investor rights agreement the registrant entered into with certain investors affiliated with Longitude Capital Partners, LLC in July 2009 provides for cross-indemnification in connection with registration of the registrant's common stock on behalf of such investors.

**Item 15. Recent Sales of Unregistered Securities.**

From January 1, 2006 through the date hereof, the registrant has issued and sold the following unregistered securities. The following share numbers and per share prices have been adjusted, where applicable, to reflect a 1-for-11.06701 reverse stock split of the registrant's common stock and preferred stock effected on May 15, 2007. All of the registrant's preferred stock listed below was converted into common stock on a 1-for-1 basis (after giving effect to above reverse stock split) immediately prior to the closing of the registrant's initial public offering on June 6, 2007.

- (1) The registrant granted stock options to employees and directors under its 2003 Equity Incentive Plan and 2007 Equity Incentive Plan covering an aggregate of 542,506 shares of common stock, with exercise prices ranging from \$16.60 to \$19.37 per share. Of these, options covering an aggregate of 275,624 were cancelled without being exercised.
- (2) The registrant sold an aggregate of 11,029 shares of common stock to employees and directors for cash consideration in the aggregate amount of \$85,780 upon the exercise of stock options granted under its 2003 Equity Incentive Plan.
- (3) On January 26, 2006, the registrant issued and sold an aggregate of 1,113,245 shares of Series B preferred stock to a total of thirty-two accredited investors for aggregate consideration of \$16,799,996.53.
- (4) On January 26, 2006, the registrant issued and sold an aggregate of 1,206,019 shares of Series B Prime preferred stock to a total of two accredited investors for aggregate consideration of \$18,200,000.56.
- (5) On December 14, 2006, the registrant issued and sold an aggregate of 2,067,462 shares of Series B preferred stock to a total of thirty-two institutional and accredited investors for aggregate consideration of \$31,199,983.44.
- (6) On December 14, 2006, the registrant issued and sold an aggregate of 2,239,749 shares of Series B Prime preferred stock to a total of two institutional and accredited investors for aggregate consideration of \$33,799,997.74.

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

(7) On March 14, 2008, JPI Commercial, LLC, a wholly-owned subsidiary of the registrant ( JPIC ), issued and sold senior secured notes in the aggregate principal amount of \$120,000,000, of which senior secured notes in the aggregate principal amount of

II-2



**Table of Contents**

\$40,000,000 were issued and sold to a total of three accredited investors (the Purchased Notes), and senior secured notes in the aggregate principal amount of \$80 million were issued to a total of twelve accredited investors in exchange for the same principal amount of senior secured notes previously issued by Orphan Medical, LLC, a wholly-owned subsidiary of the registrant (Orphan Medical). In connection with the purchase and sale of the Purchased Notes, the registrant issued and sold warrants to purchase up to an aggregate of 562,192 shares of the registrant's common stock to the purchasers of the Purchased Notes, with each warrant originally having an exercise price of \$14.23 per share (the 2008 Debtholder Warrants). Pursuant to the agreement governing the issuance of the JPIC senior secured notes and warrants to purchase the registrant's common stock, the aggregate consideration allocated to the 2008 Debtholder Warrants was \$1,976,000.

(8) On May 7, 2008, the registrant entered into a Committed Equity Financing Facility (the CEFF) with Kingsbridge Capital Limited (Kingsbridge), pursuant to which Kingsbridge committed to purchase, subject to certain conditions (including those described below), up to \$75,000,000 of common stock over a three year period. Under the terms of the CEFF, the maximum number of shares that the registrant may sell to Kingsbridge is 4,922,064 shares (exclusive of the shares underlying the warrant issued to Kingsbridge as discussed below), less any shares that the registrant may be required to issue to Kingsbridge as liquidated damages under certain circumstances. In connection with entering into the CEFF, the registrant issued a warrant to Kingsbridge to purchase up to 220,000 shares of common stock with an exercise price of \$11.20 per share (the Kingsbridge Warrant). To date, the registrant has not drawn down funds under and has not issued any shares of common stock under the CEFF. The registrant's ability to draw down funds and sell shares under the CEFF requires the continued effectiveness of and ability to use the registration statement that the registrant filed registering the resale of the shares issuable under the CEFF and upon exercise of the Kingsbridge Warrant; however, the registrant believes that the use of such registration statement may not be permitted under applicable SEC rules and guidance. Even if the registrant is successful in taking the necessary steps to cause the resumption of the permitted use of such registration statement (as may be amended) in a timely manner, the registrant will not be able to sell shares under the CEFF if the average price of the registrant's common stock is lower than \$4.50 per share.

(9) On July 7, 2009, the registrant issued and sold an aggregate of 1,895,734 units comprised of an aggregate of 1,895,734 shares of common stock and warrants to purchase up to an aggregate of 947,867 additional shares of common stock to a total of two accredited investors, for aggregate consideration of \$6,999,997.80. Each warrant has an exercise price of \$4.00 per share.

(10) Pursuant to an Amendment and Waiver Agreement, dated as of November 10, 2009, by and among the registrant, JPIC, LB I Group Inc. and the other parties named therein (the Debtholder Amendment Agreement), the registrant and the holders of the 2008 Debtholder Warrants agreed to amend the 2008 Debtholder Warrants to reduce the exercise price of the 2008 Debtholder Warrants from \$14.23 to \$9.34 per share in consideration of the holders of the 2008 Debtholder Warrants entering into the Debtholder Amendment Agreement. In addition, pursuant to the Debtholder Amendment Agreement, the registrant and the twelve accredited investor holders of warrants to purchase up to an aggregate of 785,728 shares of the registrant's common stock (as adjusted in connection with the registrant's initial public offering) issued in June 2005 to such holders in connection with the sale and issuance of senior secured notes in the aggregate principal amount of \$80,000,000 by Orphan Medical (the 2005 Debtholder Warrants), agreed to amend the 2005 Debtholder Warrants to reduce the exercise price of the 2005 Debtholder Warrants from \$20.36 to \$9.34 per share in consideration of the holders of the 2005 Debtholder Warrants entering into the Debtholder Amendment Agreement.

The offers, sales and issuances of the securities described in Items 15(1) and 15(2) were exempt from registration under the Securities Act under either (a) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (b) Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were our employees or directors and received the securities under our 2003 Equity Incentive Plan or our 2007 Equity Incentive Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment or business relationships, to information about us.

The offers, sales, and issuances of the securities described in Items 15(3) through 15(10) were exempt from registration under the Securities Act under Section 4(2) of the Securities Act and Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

**Table of Contents****Item 16. Exhibits and Financial Statement Schedules.***(a) Exhibits***Exhibit**

<b>Number</b>	<b>Description of Document</b>
2.1	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.(6)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(3)
4.3A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between the Registrant and the other parties named therein.(4)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(12)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(13)
4.3D	Waiver and Amendment Agreement, dated as of July 6, 2009 by and between the Registrant and the other parties named therein.(25)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(5)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(12)
4.5A	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein.(12)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(12)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(12)
4.5D	Form of Common Stock Warrant of the Registrant.(12)
4.5E	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(12)
4.5F	Amendment and Waiver Agreement, dated as of November 10, 2009, by and among the Registrant, JPI Commercial, LLC and the other parties named therein.(27)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(13)
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
4.7	Form of Registered Direct Common Warrant.(15)
4.8	NOL Preservation Lock-Up Agreement, effective as of July 7, 2009, by and between the Registrant and the other parties named therein.(23)
4.9A	Form of Common Stock Warrant of the Registrant issued on July 7, 2009.(23)
4.9B	Investor Rights Agreement, dated July 7, 2009 by and between the Registrant and the other parties named therein.(26)
5.1	Opinion of Registrant's General Counsel.(28)
10.1+	Form of Indemnification Agreement between the Registrant and its officers and directors.(3)
10.2+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce C. Cozadd.(6)

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

- 10.3+ Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel R. Saks.(6)
- 10.4+ Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert M. Myers.(6)

II-4

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew K. Fust.(6)
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol A. Gamble.(6)
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne L.T. Wissel.(6)
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.(6)
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert M. Myers.(6)
10.17+	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert M. Myers.(6)
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert M. Myers.(6)
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew K. Fust.(6)
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol A. Gamble.(6)
10.21+	2003 Equity Incentive Plan, as amended.(3)
10.22+	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.(3)
10.23+	2007 Equity Incentive Plan.(3)
10.24+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.(7)
10.25+	2007 Non-Employee Directors Stock Option Plan.(3)
10.26+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.(3)
10.27+	2007 Employee Stock Purchase Plan.(3)
10.28+	Form of 2007 Employee Stock Purchase Plan Offering Document.(3)
10.29+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(6)
10.30	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.(8)
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(7)
10.32	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.(7)

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.33	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.(9)
10.34	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.35	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.36	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.41	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.(8)
10.42	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(8)
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.45	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc. and Elan Pharma International Limited.(9)
10.46	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(8)
10.47	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(9)
10.48	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(9)
10.49	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.(8)
10.50	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(8)
10.51	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(9)
10.52	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.(9)
10.54	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.(7)
10.55+	Directors Deferred Compensation Plan.(3)
10.56+	Non-Employee Director Compensation Arrangements, as modified on August 14, 2008.(18)
10.57A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(10)
10.57B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and the Registrant.(10)
10.57C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.(10)
10.57D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and the Registrant.(10)
10.58+	Amended Executive Change in Control and Severance Benefit Plan.(1)
10.59+	Form of Amendment to Employment Agreement, by and between the Registrant and each of Bruce Cozadd, Samuel Saks, M.D., Robert Myers, Matthew Fust, Carol Gamble and Janne Wissel.(1)



**Table of Contents****Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.60+	Form of Letter, amending outstanding options granted under the Registrant's 2003 Equity Incentive Plan.(1)
10.62+	Amendment No. 2 to Employment Agreement, effective on September 1, 2007, by and between the Registrant and Bruce C. Cozadd.(11)
10.63	Addendum No. 4 to Amended and Restated Master Services Agreement, dated as of July 6, 2007, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(11)
10.64+	Form of Restricted Stock Unit Award under the Registrant's 2007 Equity Incentive Plan.(11)
10.65+	Non-Employee Director Compensation Arrangements, as modified on December 18, 2007.(12)
10.66	Amendment Number 4 to Development, License and Supply Agreement, dated as of October 26, 2007, by and between the Registrant and Elan Pharma International, Inc.(12)
10.67	Addendum No. 5 to Amended and Restated Master Services Agreement, dated as of October 5, 2007, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and Orphan Medical, Inc.(12)
10.68	Amendment No. 1 to Amended and Restated Xyrem License and Distribution Agreement, dated as of December 21, 2007, by and between the Registrant and UCB Pharma Limited.(12)
10.69	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.(12)
10.70	Common Stock Purchase Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
10.71+	Amended Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(14)
10.72+	2008 Executive Officer Compensation Arrangements.(14)
10.73+	Form of Stock Award Grant Notice and Stock Award Agreement under the Registrant's 2007 Equity Incentive Plan.(14)
10.74	Master Services Agreement dated May 6, 2008, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and CuraScript, Inc.(14)
10.75	Amendment No. 2 to Amended and Restated Xyrem License and Distribution Agreement, dated July 23, 2008, by and between the Registrant and UCB Pharma Limited.(16)
10.76	Antizol® Product Rights Acquisition Agreement, dated as of August 1, 2008, by and among the Registrant, JPI Commercial, LLC, Paladin Labs (Barbados) Inc., and Paladin Labs (USA) Inc.(17)
10.77	Amendment No. 2 to License Agreement, dated as of October 17, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(18)
10.78	Amendment No. 3 to License Agreement, dated as of December 19, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(20)
10.79	Amendment No. 4 to License Agreement, dated as of February 5, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(20)
10.80+	Directors Deferred Compensation Plan, as amended.(20)
10.81+	Amended and Restated Executive Change in Control and Severance Benefit Plan.(20)
10.82	Revision of Payment Terms of the Plea Agreement dated as of July 17, 2007 between the U.S. Attorney for the Eastern District of New York and Orphan Medical, Inc.(20)
10.83	Amendment to Settlement Agreement, signed by the Company on February 6, 2009, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(20)
10.84	Form of Registered Direct Subscription Agreement.(19)
10.85	Consulting Agreement dated April 3, 2009 by and between the Registrant and Samuel R. Saks, MD(21)
10.86	First Amendment of Lease, dated June 1, 2009, by and between the Registrant and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University.(22)





**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.87	Securities Purchase Agreement, dated July 6, 2009, by and between the Registrant and the purchasers listed on the signature pages thereto.(23)
10.88	2009 Executive Officer Compensation Arrangements.(24)
10.89	Form of Indemnification Agreement.(23)
10.90	Amendment No. 5 to License Agreement, dated as of June 23, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(25)
10.91	Amendment No. 5 to License Agreement, dated as of October 23, 2009, by and between the Registrant and Elan Pharma International Limited.(29)
21.1	Subsidiaries of the Registrant.(20)
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 page II-11 to the Registration Statement on Form S-1 (File No. 333-161350) filed with the SEC on August 14, 2009).

+ Indicates management contract or compensatory plan.

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

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

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

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

- (8) Incorporated herein by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
- (9) Incorporated herein by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
- (10) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
- (11) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
- (12) Incorporated herein by reference to the same numbered exhibit to the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.

**Table of Contents**

- (13) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
- (14) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.
- (15) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
- (16) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 24, 2008.
- (17) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 6, 2008.
- (18) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2008, as filed with the SEC on November 14, 2008.
- (19) Incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
- (20) 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, 2008, as filed with the SEC on March 26, 2009.
- (21) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
- (22) 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 June 4, 2009.
- (23) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
- (24) Incorporated herein by reference to that exhibit numbered 10.84 to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
- (25) 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, 2009, as filed with the SEC on August 14, 2009.

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

- (26) Incorporated herein by reference to Exhibit 10.88 to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
- (27) Incorporated 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 November 10, 2009.
- (28) Incorporated by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1 (File No. 333-161350), as filed with the SEC on August 14, 2009.
- (29) Incorporated by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2009, as filed with the SEC on November 6, 2009.  
*(b) Financial Statement Schedules.*

No financial statement schedules are provided because they are inapplicable or the requested information is shown in the consolidated financial statements of the registrant or related notes thereto included in the registrant's Annual Report on Form 10-K filed with the SEC on March 26, 2009.

**Table of Contents**

**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% 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.

(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.

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.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on the 10<sup>th</sup> day of November, 2009.

**JAZZ PHARMACEUTICALS, INC.**

By: /s/ BRUCE C. COZADD  
Bruce C. Cozadd  
*Chairman and Chief Executive Officer*

II-11

**Table of Contents**

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ BRUCE C. COZADD Bruce C. Cozadd	Chairman and Chief Executive Officer ( <i>Principal Executive Officer</i> )	November 10, 2009
/s/ JOAN E. COLLIGAN Joan E. Colligan	Controller and Acting Principal Financial Officer ( <i>Principal Accounting and Financial Officer</i> )	November 10, 2009
*	Director	November 10, 2009
Samuel D. Colella		
*	Director	November 10, 2009
Bryan C. Cressey		
*	Director	November 10, 2009
Patrick G. Enright		
*	Director	November 10, 2009
Michael W. Michelson		
*	Director	November 10, 2009
James C. Momtazee		
*	Director	November 10, 2009
Robert M. Myers		
*	Director	November 10, 2009
Kenneth W. O Keefe		
*	Director	November 10, 2009
Alan M. Sebulsky		
*	Director	November 10, 2009
James B. Tananbaum, M.D.		
*	Director	November 10, 2009
Nathaniel M. Zilkha		

**\*By:** /s/ BRUCE C. COZADD  
**Bruce C. Cozadd**

*Attorney-in-Fact*

II-12



**Table of Contents****EXHIBIT INDEX****Exhibit**

<b>Number</b>	<b>Description of Document</b>
2.1	Agreement and Plan of Merger dated as of April 18, 2005, by and among the Registrant, Twist Merger Sub, Inc. and Orphan Medical, Inc.(6)
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws.(2)
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock Certificate.(3)
4.3A	Third Amended and Restated Investor Rights Agreement, made effective as of June 6, 2007, by and between the Registrant and the other parties named therein.(4)
4.3B	Waiver and Amendment Agreement, dated as of March 12, 2008, by and between the Registrant and the other parties named therein.(12)
4.3C	Waiver and Amendment Agreement, dated as of May 7, 2008, by and between the Registrant and the other parties named therein.(13)
4.3D	Waiver and Amendment Agreement, dated as of July 6, 2009 by and between the Registrant and the other parties named therein.(25)
4.4A	Form of Series BB Preferred Stock Warrant of the Registrant.(5)
4.4B	Form of Series BB Preferred Stock Warrant of the Registrant, as amended.(12)
4.5A	Senior Secured Note and Warrant Purchase Agreement, dated as of March 14, 2008, by and among the Registrant, JPI Commercial, LLC and the Purchasers named therein.(12)
4.5B	Form of Senior Secured Tranche A Note of JPI Commercial, LLC.(12)
4.5C	Form of Senior Secured Tranche B Note of JPI Commercial, LLC.(12)
4.5D	Form of Common Stock Warrant of the Registrant.(12)
4.5E	Registration Rights Agreement, dated as of March 17, 2008, by and between the Registrant and the other parties named therein.(12)
4.5F	Amendment and Waiver Agreement, dated as of November 10, 2009, by and among the Registrant, JPI Commercial, LLC and the other parties named therein.(27)
4.6A	Warrant issued to Kingsbridge Capital Limited, dated May 7, 2008.(13)
4.6B	Registration Rights Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
4.7	Form of Registered Direct Common Warrant.(15)
4.8	NOL Preservation Lock-Up Agreement, effective as of July 7, 2009, by and between the Registrant and the other parties named therein.(23)
4.9A	Form of Common Stock Warrant of the Registrant issued on July 7, 2009.(23)
4.9B	Investor Rights Agreement, dated July 7, 2009 by and between the Registrant and the other parties named therein.(26)
5.1	Opinion of Registrant's General Counsel.(28)
10.1+	Form of Indemnification Agreement between the Registrant and its officers and directors.(3)
10.2+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Bruce C. Cozadd.(6)
10.3+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Samuel R. Saks.(6)

10.4+ Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Robert M. Myers.(6)

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.5+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Matthew K. Fust.(6)
10.6+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Carol A. Gamble.(6)
10.7+	Employment Agreement, dated as of February 18, 2004, by and between the Registrant and Janne L.T. Wissel.(6)
10.8+	Stock Purchase Agreement, dated as of September 24, 2004, by and between the Registrant and Alan Sebulsky.(6)
10.9+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.10+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.11+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.12+	Common Stock Purchase Agreement, dated as of October 30, 2003, by and between the Registrant and Bruce C. Cozadd.(6)
10.13+	Common Stock Purchase Agreement, dated as of March 20, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.14+	Stock Restriction Agreement, dated as of April 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.15+	Amendment to Stock Restriction Agreement, dated as of October 30, 2003, by and between the Registrant and Samuel R. Saks.(6)
10.16+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Robert M. Myers.(6)
10.17+	Amendment No. 1 to Amended and Restated Stock Purchase Agreement, dated as of December 18, 2003, by and between the Registrant and Robert M. Myers.(6)
10.18+	Common Stock Purchase Agreement, dated as of January 9, 2004, by and between the Registrant and Robert M. Myers.(6)
10.19+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Matthew K. Fust.(6)
10.20+	Amended and Restated Stock Purchase Agreement, dated as of April 30, 2003, by and between the Registrant and Carol A. Gamble.(6)
10.21+	2003 Equity Incentive Plan, as amended.(3)
10.22+	Form of Option Exercise and Stock Purchase Agreement and Forms of Grant Notices under the 2003 Equity Incentive Plan.(3)
10.23+	2007 Equity Incentive Plan.(3)
10.24+	Form of Option Agreement and Form of Option Grant Notice under the 2007 Equity Incentive Plan.(7)
10.25+	2007 Non-Employee Directors Stock Option Plan.(3)
10.26+	Form of Stock Option Agreement and Form of Option Grant Notice under the 2007 Non-Employee Directors Stock Option Plan.(3)
10.27+	2007 Employee Stock Purchase Plan.(3)
10.28+	Form of 2007 Employee Stock Purchase Plan Offering Document.(3)
10.29+	Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(6)
10.30	Asset Purchase Agreement, dated as of October 4, 2004, by and among the Registrant, Glaxo Group Limited and SmithKline Beecham Corporation dba GlaxoSmithKline.(8)
10.31	Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of November 6, 1996, by and between Orphan Medical, Inc. and Lonza, Inc.(7)
10.32	Amendment No. 1 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of February 7, 2005, by and between Orphan Medical, Inc. and Lonza, Inc.(7)

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.33	Amended and Restated Services Agreement, dated as of May 31, 2005, by and between Orphan Medical, Inc. and Express Scripts Specialty Distribution Services, Inc.(9)
10.34	Consent and Addendum to Amended and Restated Master Services Agreement, dated as of June 1, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.35	Addendum No. 2 to Amended and Restated Master Services Agreement, dated as of June 22, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.36	Addendum No. 3 to Amended and Restated Master Services Agreement, dated as of August 17, 2006, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(9)
10.41	Amended and Restated Xyrem License and Distribution Agreement, dated as of June 30, 2006, by and between the Registrant and UCB Pharma Limited.(8)
10.42	License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(8)
10.43	Supply Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.44	Trademark License Agreement, dated as of January 31, 2007, by and between the Registrant and Solvay Pharmaceuticals, Inc.(7)
10.45	Assignment, Assumption and Consent, dated as of January 31, 2007, by and among the Registrant, Solvay Pharmaceuticals, Inc. and Elan Pharma International Limited.(9)
10.46	License Agreement, dated as of December 22, 1997, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(8)
10.47	Amendment to License Agreement, dated as of March 1, 1999, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation, plc.(9)
10.48	Letter Amendment No. 2 to License Agreement, dated April 13, 2000, by and between Solvay Pharmaceuticals, Inc and Elan Pharmaceutical Technologies.(9)
10.49	Amendment Agreement No. 3 to License Agreement, dated as of November 7, 2006, by and between Solvay Pharmaceuticals, Inc. and Elan Corporation plc.(8)
10.50	Xyrem Manufacturing Services and Supply Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(8)
10.51	Quality Agreement, dated as of March 13, 2007, by and between the Registrant and Patheon Pharmaceuticals, Inc.(9)
10.52	Commercial Lease, dated as of June 2, 2004, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.(9)
10.54	Amendment No. 2 to Sodium Gamma Hydroxybutyrate Development and Supply Agreement, dated as of March 30, 2007, by and between Registrant and Lonza, Inc.(7)
10.55+	Directors Deferred Compensation Plan.(3)
10.56+	Non-Employee Director Compensation Arrangements, as modified on August 14, 2008.(18)
10.57A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(10)
10.57B	Non-Prosecution Agreement, dated July 13, 2007, between the United States Attorney s Office for the Eastern District of New York and the Registrant.(10)
10.57C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.(10)
10.57D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and the Registrant.(10)
10.58+	Amended Executive Change in Control and Severance Benefit Plan.(1)
10.59+	Form of Amendment to Employment Agreement, by and between the Registrant and each of Bruce Cozadd, Samuel Saks, M.D., Robert Myers, Matthew Fust, Carol Gamble and Janne Wissel.(1)

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.60+	Form of Letter, amending outstanding options granted under the Registrant's 2003 Equity Incentive Plan.(1)
10.62+	Amendment No. 2 to Employment Agreement, effective on September 1, 2007, by and between the Registrant and Bruce C. Cozadd.(11)
10.63	Addendum No. 4 to Amended and Restated Master Services Agreement, dated as of July 6, 2007, by and between the Registrant and Express Scripts Specialty Distribution Services, Inc.(11)
10.64+	Form of Restricted Stock Unit Award under the Registrant's 2007 Equity Incentive Plan.(11)
10.65+	Non-Employee Director Compensation Arrangements, as modified on December 18, 2007.(12)
10.66	Amendment Number 4 to Development, License and Supply Agreement, dated as of October 26, 2007, by and between the Registrant and Elan Pharma International, Inc.(12)
10.67	Addendum No. 5 to Amended and Restated Master Services Agreement, dated as of October 5, 2007, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and Orphan Medical, Inc.(12)
10.68	Amendment No. 1 to Amended and Restated Xyrem License and Distribution Agreement, dated as of December 21, 2007, by and between the Registrant and UCB Pharma Limited.(12)
10.69	Amendment No. 1 to License Agreement, dated as of March 12, 2008, by and between the Registrant and Solvay Pharmaceuticals, Inc.(12)
10.70	Common Stock Purchase Agreement, dated as of May 7, 2008, by and between the Registrant and Kingsbridge Capital Limited.(13)
10.71+	Amended Jazz Pharmaceuticals, Inc. Cash Bonus Plan.(14)
10.72+	2008 Executive Officer Compensation Arrangements.(14)
10.73+	Form of Stock Award Grant Notice and Stock Award Agreement under the Registrant's 2007 Equity Incentive Plan.(14)
10.74	Master Services Agreement dated May 6, 2008, by and among the Registrant, Express Scripts Specialty Distribution Services, Inc. and CuraScript, Inc.(14)
10.75	Amendment No. 2 to Amended and Restated Xyrem License and Distribution Agreement, dated July 23, 2008, by and between the Registrant and UCB Pharma Limited.(16)
10.76	Antizol® Product Rights Acquisition Agreement, dated as of August 1, 2008, by and among the Registrant, JPI Commercial, LLC, Paladin Labs (Barbados) Inc., and Paladin Labs (USA) Inc.(17)
10.77	Amendment No. 2 to License Agreement, dated as of October 17, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(18)
10.78	Amendment No. 3 to License Agreement, dated as of December 19, 2008, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(20)
10.79	Amendment No. 4 to License Agreement, dated as of February 5, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(20)
10.80+	Directors Deferred Compensation Plan, as amended.(20)
10.81+	Amended and Restated Executive Change in Control and Severance Benefit Plan.(20)
10.82	Revision of Payment Terms of the Plea Agreement dated as of July 17, 2007 between the U.S. Attorney for the Eastern District of New York and Orphan Medical, Inc.(20)
10.83	Amendment to Settlement Agreement, signed by the Company on February 6, 2009, among the United States of America acting through the entities named therein, the Registrant and Orphan Medical, Inc.(20)
10.84	Form of Registered Direct Subscription Agreement.(19)
10.85	Consulting Agreement dated April 3, 2009 by and between the Registrant and Samuel R. Saks, MD(21)
10.86	First Amendment of Lease, dated June 1, 2009, by and between the Registrant and Wheatley-Fields, LLC, successor in interest to the Board of Trustees of the Leland Stanford Junior University.(22)

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description of Document</b>
10.87	Securities Purchase Agreement, dated July 6, 2009, by and between the Registrant and the purchasers listed on the signature pages thereto.(23)
10.88	2009 Executive Officer Compensation Arrangements.(24)
10.89	Form of Indemnification Agreement.(23)
10.90	Amendment No. 5 to License Agreement, dated as of June 23, 2009, by and between JPI Commercial, LLC and Solvay Pharmaceuticals, Inc.(25)
10.91	Amendment No. 5 to License Agreement, dated as of October 23, 2009, by and between the Registrant and Elan Pharma International Limited.(29)
21.1	Subsidiaries of the Registrant.(20)
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 page II-11 to the Registration Statement on Form S-1 (File No. 333-161350) filed with the SEC on August 14, 2009).

+ Indicates management contract or compensatory plan.

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

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

(7)

## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

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

- (8) Incorporated herein by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on May 31, 2007.
- (9) Incorporated herein by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1, as amended (File No. 333-141164), as filed with the SEC on March 27, 2007.
- (10) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 18, 2007.
- (11) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2007, as filed with the SEC on November 9, 2007.
- (12) Incorporated herein by reference to the same numbered exhibit to the Registrant's annual report on Form 10-K (File No. 001-33500) for the period ended December 31, 2007, as filed with the SEC on March 31, 2008.

**Table of Contents**

- (13) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on May 9, 2008.
- (14) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2008, as filed with the SEC on May 15, 2008.
- (15) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
- (16) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 24, 2008.
- (17) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on August 6, 2008.
- (18) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2008, as filed with the SEC on November 14, 2008.
- (19) Incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 16, 2008.
- (20) 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, 2008, as filed with the SEC on March 26, 2009.
- (21) Incorporated herein by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
- (22) 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 June 4, 2009.
- (23) Incorporated herein by reference to the same numbered exhibit to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
- (24) Incorporated herein by reference to that exhibit numbered 10.84 to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2009, as filed with the SEC on May 7, 2009.
- (25) 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, 2009, as filed with the SEC on August 14, 2009.



## Edgar Filing: JAZZ PHARMACEUTICALS INC - Form S-1/A

- (26) Incorporated herein by reference to Exhibit 10.88 to the Registrant's current report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009.
- (27) Incorporated 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 November 10, 2009.
- (28) Incorporated by reference to the same numbered exhibit to the Registrant's registration statement on Form S-1 (File No. 333-161350), as filed with the SEC on August 14, 2009.
- (29) Incorporated by reference to the same numbered exhibit to the Registrant's quarterly report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2009, as filed with the SEC on November 6, 2009.